

United States International Trade Commission

**Advice Concerning the  
Addition of Certain  
Pharmaceutical Products  
and Chemical Intermediates  
to the Pharmaceutical  
Appendix to the Harmonized  
Tariff Schedule of the  
United States**

Investigation No. 332-476  
USITC Publication 3883  
September 2006



# U.S. International Trade Commission

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# **U.S. International Trade Commission**

Washington, DC 20436

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## **Advice Concerning the Addition of Certain Pharmaceutical Products and Chemical Intermediates to the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States**

**Investigation No. 332-476**



**Publication 3883**

**September 2006**

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# **ABSTRACT**

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Under the Pharmaceutical Zero-for-Zero Initiative, which entered into force in 1995, the United States and its major trading partners eliminated tariffs on many pharmaceuticals, their derivatives, and certain chemical intermediates used to make pharmaceuticals. The U.S. list of pharmaceutical products and chemical intermediates eligible for duty-free treatment under the agreement is given in the Pharmaceutical Appendix to the *Harmonized Tariff Schedule of the United States*. The Pharmaceutical Appendix is periodically updated to provide duty relief for additional such products, including newly developed pharmaceuticals. This report provides advice on the third update to the agreement, in which approximately 1,300 products are proposed to receive duty-free treatment. In 2005, U.S. imports of products currently included in the pharmaceutical agreement totaled over \$58 billion; U.S. exports of such products exceeded \$25 billion. U.S. imports of items proposed for addition to the agreement are estimated to be valued at \$619 million in 2007 versus about \$6 million for exports. However, these values for the products likely underestimate eventual trade because estimates were not available for many of the products.



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# **EXECUTIVE SUMMARY**

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In 1995, the United States and 21 other countries agreed to eliminate tariffs on pharmaceutical products, their derivatives, and certain chemical intermediates used to manufacture pharmaceuticals. This agreement is known as the Pharmaceutical Zero-for-Zero Initiative. Since the original agreement entered into force, it has been updated twice, in 1997 and 1999, to expand the list of products that can be imported free of duty. This report provides advice to the United States Trade Representative (USTR) concerning the products proposed for the third update.

As a result of the first update, 496 items were added to the Pharmaceutical Appendix to the *Harmonized Tariff Schedule of the United States* (HTS). The second update included an additional 642 items. In this update, 823 pharmaceutical products, identified by their International Nonproprietary Names (INNs), and 475 chemical intermediates are proposed for addition. Eighty prefixes and suffixes used to identify derivatives of INNs are also included in the current update. These new products, prefixes, and suffixes were provided to the USTR by U.S. pharmaceutical firms or submitted by signatory countries.

Pharmaceutical products covered in the Pharmaceutical Zero-for-Zero Initiative can be imported either as bulk active ingredients or in dosage forms that can be packaged for retail sale. Products in dosage form are generally classified under chapter 30 of the HTS, where most of the subheadings are duty-free. Many of the bulk pharmaceutical active ingredients and chemical intermediates are classified under HTS subheadings that also contain non-pharmaceutical products and have rates of duty ranging from 0 to 6.5 percent ad valorem. In order for pharmaceutical products classified under these HTS subheadings to be imported free of duty, they must be listed in the Pharmaceutical Appendix.

The Pharmaceutical Appendix to the HTS consists of three tables. The first table lists the INNs of pharmaceutical active ingredients that are eligible for duty-free treatment. The second table consists of chemical prefixes and suffixes that may be combined with the INNs to specify pharmaceutical derivatives that are also included in the agreement. The third table specifies the chemical intermediates for which duties have been eliminated.

In 2005, U.S. imports of products included in the Pharmaceutical Zero-for-Zero Initiative totaled over \$58 billion; U.S. exports of these products exceeded \$25 billion. For the products proposed for the current update, an estimate, which is limited to only about 10 percent of the proposed items, shows imports of \$619 million and exports of \$6 million in 2007. A more precise estimate of imports and exports of items in this update is not possible for many reasons, including the level of proprietary data in this industry.



# **CHAPTER 1**

## **Purpose and Scope of Study**

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During the Uruguay Round trade negotiations, the United States and 21<sup>1</sup> other nations agreed to eliminate tariffs on pharmaceutical products, certain derivatives, and certain chemical intermediates used in the production of pharmaceuticals. This agreement is known as the Pharmaceutical Zero-for-Zero Initiative (“pharmaceuticals agreement”). The agreement, effective January 1, 1995, eliminated tariffs in signatory countries on approximately 7,000 pharmaceutical products and chemical intermediates for all World Trade Organization members on a Most Favored Nation (MFN) basis.<sup>2</sup> In the Uruguay Round Agreements Act (URAA), Congress authorized the President to grant duty-free treatment to new pharmaceutical products and chemical intermediates through periodic updates to the Pharmaceutical Zero-for-Zero Initiative. One of the requirements in the URAA is that the President get advice from the U.S. International Trade Commission (“the Commission”) about the proposed additions. This report provides information about pharmaceutical products proposed for the third update to the Pharmaceutical Zero-for-Zero Initiative.<sup>3</sup> As requested by the USTR, the report contains the following information: (1) a summary description of the products contained in the Pharmaceutical Appendix and the modifications to be made to that Appendix; (2) an explanation of the relationship between the various elements in the Appendix and the Harmonized Tariff Schedule of the United States; and (3) an estimate of the current U.S. imports and, where possible, current U.S. exports of the products included in the existing Pharmaceutical Appendix and the proposed additions to the Appendix.<sup>4</sup>

## **Description of Products Covered**

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Pharmaceuticals (NAICS 3254, “Pharmaceutical and Medicine Manufacturing”)<sup>5</sup> are used to prevent, diagnose, treat, or cure diseases in humans and animals.<sup>6</sup> Products included in the pharmaceuticals agreement include dosage-form pharmaceuticals, bulk pharmaceuticals, and certain chemical intermediates used in the production of pharmaceuticals. Dosage-form pharmaceuticals are formulated products in dosage forms, such as tablets or vials, that may be packaged for retail sale. Pharmaceuticals in dosage form are generally sold to the final

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<sup>1</sup> The 21 countries were the EU-15 (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom), Canada, the Czech Republic, Japan, Norway, the Slovak Republic, and Switzerland.

<sup>2</sup> In the United States, MFN countries are called Normal Trade Relations (NTR) countries.

<sup>3</sup> On August 12, 2004, the United States Trade Representative (USTR) published a *Federal Register* notice (69 FR 49940) requesting public submissions of products to be included in the current update. Appropriate products from these public submissions were combined with products proposed by other signatory countries to produce the final list of products being considered for the current update.

<sup>4</sup> A copy of the request letter from the USTR, dated May 25, 2006, is included in Appendix A of this report. The *Federal Register* notice of the U.S. International Trade Commission’s initiation of this investigation, dated June 15, 2006, is included in Appendix B.

<sup>5</sup> The North American Industry Classification System (NAICS) is the industry classification system used by the U.S. Census Bureau and other statistical agencies. The NAICS replaced the Standard Industrial Classification (SIC) system in 1997. See U.S. Department of Commerce, Census Bureau, *North American Industry Classification System (NAICS)*.

<sup>6</sup> The Pharmaceutical Zero-for-Zero Initiative applies only to pharmaceuticals for human use.

customer as generic or brand name products, either by prescription or over-the-counter. Bulk pharmaceuticals are active ingredients that are produced or purchased by pharmaceutical firms and further processed into dosage-form products. The chemical intermediates covered, generally organic chemicals, are inputs in the production of pharmaceutical active ingredients. Chemical intermediates are produced by either pharmaceutical firms or specialty chemicals firms (NAICS 325199, “All Other Basic Organic Chemical Manufacturing”)<sup>7</sup> and usually used by pharmaceutical firms for producing bulk pharmaceutical products.

Most pharmaceuticals and chemical intermediates covered in the Pharmaceutical Zero-for-Zero Initiative are classified in chapters 29 and 30 of the HTS. Dosage-form pharmaceuticals are classified in chapter 30 of the HTS, “Pharmaceutical Products.” The majority of bulk pharmaceutical and chemical intermediates included in the initiative are organic chemicals and are thus classified in chapter 29 of the HTS. Many bulk pharmaceuticals are classified under the following headings in chapter 29:

HTS heading 2936 .....	Provitamins and vitamins
HTS heading 2937 .....	Hormones
HTS heading 2939 .....	Alkaloids
HTS heading 2941 .....	Antibiotics

In general, the remaining bulk pharmaceuticals are classified in chapter 29 according to their chemical structure, occasionally under 8-digit HTS subheadings specifically applicable to drugs.

## Overview of the U.S. Chemical and Pharmaceutical Industries

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Most finished pharmaceutical products and bulk active ingredients are manufactured by pharmaceutical companies. Chemical intermediates included in the Pharmaceutical Appendix may be produced by either pharmaceutical companies or by specialty chemicals firms. The closer an intermediate is to the final pharmaceutical product, the more likely it is to be produced by a pharmaceutical firm. Pharmaceutical companies may produce final and intermediate products by either fermentation or traditional chemical synthesis.<sup>8</sup> Specialty chemical companies that supply intermediates to drug companies generally use traditional chemical synthesis, but future advances in biotechnology may allow more specialty chemicals to be produced via fermentation or enzymatic processes. Both the pharmaceutical and chemical industries include large, multinational firms that often have manufacturing facilities throughout North America, Europe, and Asia. In the United States, pharmaceutical production facilities are concentrated in California, New Jersey, New York, and Pennsylvania, while chemical firms have manufacturing plants throughout the country.

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<sup>7</sup> NAICS 325199 comprises firms primarily engaged in manufacturing basic organic chemical products, excluding aromatic petrochemicals, industrial gases, synthetic organic dyes and pigments, gum and wood chemicals, cyclic crudes and intermediates, and ethyl alcohol. See U.S. Department of Commerce, Census Bureau, *North American Industry Classification System (NAICS)*.

<sup>8</sup> Fermentation is the cultivation of microorganisms for the enzymatically controlled production of compounds by cellular metabolism. Chemical synthesis is the formation of compounds from simpler compounds by chemical reaction.

Both the U.S. chemical industry and the U.S. pharmaceutical industry spend large amounts of money on research and development (R&D). According to the Pharmaceutical Research and Manufacturers Association (PhRMA), the pharmaceutical industry spent \$39.4 billion on R&D in 2005.<sup>9</sup> Much of that spending went to the development of new drugs. The average cost of developing one new drug is estimated to be \$800 million over 10 to 15 years.<sup>10</sup> The largest portion of the money and time is spent in clinical trials, which the U.S. Food and Drug Administration (FDA) requires to ensure the safety and efficacy of the new drug.<sup>11</sup> Since other chemical sectors typically do not face as stringent a regulatory system as pharmaceutical companies, product development in these sectors is generally faster and less expensive.

Patent protection is also important to the pharmaceutical industry. In the United States, firms receive exclusive rights to sell a pharmaceutical product for 20 years. However, depending on the length of the product approval process, the period of time during which the patent holder has the exclusive right to commercially market the product may be significantly less than 20 years. The U.S. patent law allows pharmaceutical patents to be extended to offset approval delays when certain conditions are met.<sup>12</sup> After the patent expires, the product may quickly face competition from generic copies. Generic drugs are increasingly being produced in developing countries, such as China and India, for internal consumption and export.

Data for the chemical industry (NAICS 325), pharmaceutical industry (NAICS 3254), and All Other Basic Organic Chemical Manufacturing (NAICS 325199)<sup>13</sup> are given in table 1-1. In 2002, shipments for the chemical and allied products industry totaled approximately \$454 billion; the pharmaceutical industry accounted for 31 percent of this amount. The pharmaceutical industry also accounted for 47 percent of U.S. chemical imports and 24 percent of U.S. chemical exports in 2002. Employment in the pharmaceutical industry accounts for 30 percent of total employment in the chemical industry and 24 percent of its production workers.

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<sup>9</sup> This value includes only research and development (R&D) spending by members of PhRMA. If the R&D spending of biotechnology firms, which are often supported by pharmaceutical companies through business ventures and funding, had been included, the total amount would have been \$51.3 billion. See PhRMA, *Pharmaceutical Industry Profile*, 2. R&D spending by the U.S. chemical industry, excluding pharmaceuticals, was valued at \$6.7 billion in 2004. See American Chemistry Council, *Guide to the Business of Chemistry 2005*, 87.

<sup>10</sup> PhRMA, *Pharmaceutical Industry Profile*, 2.

<sup>11</sup> Out of 5,000 drugs discovered, approximately five will be deemed safe and effective enough in preclinical trials to continue to clinical trials. Only one of these five drugs is likely to receive FDA approval. The low success rate of new drugs adds to average costs and time of development. See PhRMA, *Pharmaceutical Industry Profile*, 4.

<sup>12</sup> 35 U.S.C. § 156.

<sup>13</sup> While this category will include most firms that produce chemical intermediates for the pharmaceutical industry, it also includes many firms not connected with producing intermediates for pharmaceuticals.

**Table 1-1** U.S. chemical and pharmaceutical industries: Statistics for 2002

Industry	Total shipments <sup>a</sup>	U.S. imports <sup>b</sup>	U.S. exports <sup>b</sup>	Trade balance	apparent consumption	Total employment <sup>a,c</sup>	Production workers <sup>a,c</sup>
	Billion dollars					1,000 persons	
NAICS 325:							
Chemical manufacturing . . .	453.9	87.3	78.0	-9.3	463.2	846	476
NAICS 3254							
Pharmaceutical and medicine manufacturing . .	140.7	40.6	18.7	-21.9	162.6	252	115
NAICS 325199							
All other basic organic chemical manufacturing . .	48.2	12.9	15.0	2.1	46.1	77	46

Source: Official statistics of the U.S. Department of Commerce.

<sup>a</sup>U.S. Department of Commerce, Census Bureau, *2002 Economic Census*.

<sup>b</sup>USITC, *Dataweb*.

<sup>c</sup>Another source gives slightly higher 2002 numbers for total employment (930,000 for the chemical industry and 293,000 for the pharmaceutical industry) and production workers (532,000 for the chemical industry and 129,000 for the pharmaceutical industry). See *Chemical & Engineering News*, "Chemical Employment Falls."

# **CHAPTER 2**

## **Description of the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States**

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The duty-free treatment of pharmaceutical products, their derivatives, and certain chemical intermediates used to make pharmaceuticals is reflected in the Harmonized Tariff Schedule of the United States in two different ways. First, the normal-trade-relations (NTR) tariff rates for subheadings in chapter 30 of the HTS (“Pharmaceutical Products”) and HTS headings 2936, 2937, 2939, and 2941 (bulk vitamins, hormones, alkaloids, and antibiotics, respectively)<sup>14</sup> were reduced to zero when the Pharmaceutical Zero-for -Zero Initiative went into effect on January 1, 1995. Second, bulk pharmaceutical active ingredients and chemical intermediates used in their manufacture that are not classified in chapter 30 or the headings listed above receive duty-free treatment by being listed in the Pharmaceutical Appendix.

As described in general note 13 of the HTS, a pharmaceutical product or chemical intermediate imported under an 8-digit HTS subheading that has the symbol “K” in the special-rate-of-duty column<sup>15</sup> is eligible for duty-free treatment provided that the product is listed in the Pharmaceutical Appendix. Eight-digit HTS subheadings that have the “K” symbol generally cover a large range of products, many of which may not be pharmaceuticals or otherwise included in the Pharmaceutical Zero-for-Zero Initiative. Therefore, the Pharmaceutical Appendix is necessary to identify the products imported under the 8-digit subheading that will receive duty-free treatment. The special duty rates are available for imports from all NTR countries.

When a new pharmaceutical is available for human use, it is immediately eligible for duty-free treatment if it is classified in chapter 30, defined in part as imported in dosage form and/or packaged for sale, or if it is imported as a bulk pharmaceutical under one of the four HTS headings in chapter 29 mentioned above. However, if this new pharmaceutical is imported in bulk under another HTS heading and is not already included in the Pharmaceutical Appendix, it may be added to the duty-free list in the appendix only after a periodic update. Most chemical intermediates used to make new pharmaceuticals that are not yet covered by the agreement would fall outside Chapter 30 and HTS headings 2936, 2937, 2939, and 2941 and would have to be added to the Pharmaceutical Appendix to receive duty-free treatment.

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<sup>14</sup> Chapter 30 of the HTS contains pharmaceutical products such as medicaments for human and veterinary use as well as other medical items, such as bandages and surgical equipment. One subheading in this chapter, 3006.70.00 (“Gel preparations designed to be used in human and veterinary medicine as a lubricant for parts of the body for surgical operations or physical examinations”), is not duty-free but has an ad valorem tariff rate of 5.0 percent in the 2006 HTS. One item in heading 2941 is not free of duty. Subheading 2941.20.10 (“Dihydrostreptomycin and its derivatives”) has an ad valorem tariff rate of 3.5 percent in the 2006 HTS.

<sup>15</sup> Special rates of duty are the rates applied under one or more special tariff treatment programs, such as the Pharmaceutical Zero-for-Zero Initiative or various free trade agreements. See general note 3 of the HTS.

The Pharmaceutical Appendix to the HTS comprises three tables. Table 1 lists pharmaceuticals by their International Nonproprietary Names (INNs). The Chemical Abstract Service (CAS) number for the product is also given for most items in this table.<sup>16</sup> When the Pharmaceutical Zero-for-Zero Initiative originally took effect, table 1 contained the pharmaceuticals listed in the World Health Organization (WHO) Proposed INN Lists 1-69.<sup>17</sup> In the first update of the Pharmaceutical Appendix, INNs from WHO lists 70-73 were added. WHO Proposed INN Lists 74-78 were added in the second update. The current update includes 823 products from WHO Proposed INN Lists 79-93.

Table 2 of the Pharmaceutical Appendix contains prefixes and suffixes that can be combined with the INNs of table 1 to specify derivative products, such as salts, esters, and hydrates, which are also eligible for duty-free treatment. As stated in general note 13 of the HTS, the derivative product formed from a combination of items in tables 1 and 2 must be classifiable in the same 6-digit tariff provision as the original product listed in table 1 in order for it to receive duty-free treatment. Since items in table 1 can be combined with multiple items in table 2 to form derivative products, it is very difficult to enumerate the total number of products that are eligible for duty-free treatment under the Pharmaceutical Zero-for-Zero Initiative. Under the original agreement, 310 prefixes and suffixes were listed in table 2. The first and second updates added 81 and 5 items to this table, respectively. The current update would add 90 prefixes and suffixes to table 2.

Table 3 lists chemical intermediates used in the production of pharmaceutical products. Most of these chemicals are classified either in chapters 29 or 39 of the HTS; a few are found in chapters 28, 32, 34, and 38. Over 300 chemical intermediates were included in the original table 3, with 232 and 365 intermediates added in the first and second updates, respectively. In the third update, 475 chemical intermediates are proposed for addition.

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<sup>16</sup> The Chemical Abstract Service (CAS), a division of the American Chemical Society, manages CAS numbers, which are unique identifiers of chemical substances. Inclusion of CAS numbers for items in the Pharmaceutical Appendix eases the burden of Customs officials examining import documentation by providing an unambiguous way of identifying a chemical product that may have many systematic, generic, proprietary, or common names.

<sup>17</sup> WHO Proposed INN Lists can be found at <http://www.who.int/druginformation/general/innlists.shtml> (accessed June 6, 2006).

# **CHAPTER 3**

## **Estimates of Current U.S. Trade in the Products Included in the Existing Pharmaceutical Appendix and the Proposed Additions to the Appendix**

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Trade data from 2004-05 for the products currently included in the Pharmaceutical Zero-for-Zero Initiative are presented in tables 3-1 and 3-2. Table 3-1 provides U.S. imports for consumption, domestic exports, and the trade balance for HTS chapter 30 and HTS headings 2936, 2937, 2939, and 2941.<sup>18</sup> Total trade in products classified under these subheadings was valued at more than \$64 billion in 2005. U.S. imports of products currently listed in the Pharmaceutical Appendix and tracked using the “K” special-rate-of-duty code are listed in table 3-2 by 6-digit HTS subheadings. Imports of these items were valued at approximately \$19.2 billion in 2004 and \$18.8 billion in 2005.<sup>19</sup> Bulk pharmaceutical active ingredients and chemical intermediates listed in the appendix are classified under various HTS subheadings; the tariff rates for the products range from 0 to 6.5 percent ad valorem. Based on 2005 import data, the ad valorem equivalent tariff rate for the products currently in the Pharmaceutical Appendix would have been 6.0 percent if they had not received duty-free treatment.<sup>20</sup>

For the proposed additions to the Pharmaceutical Appendix, the Commission is unable to provide official trade statistics because the 8-digit classifications of goods included in this study cover multiple products, many of which are not included in the pharmaceutical agreement. In the *Federal Register* notice for this study,<sup>21</sup> the Commission requested written submissions containing estimates of levels of trade for the proposed items. Two submissions were received.<sup>22</sup>

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<sup>18</sup> As noted in chapter 2 of this report, the subheadings in HTS Chapter 30 and headings 2936, 2937, 2939, and 2941 are duty-free except for subheadings 3006.70.00 and 2941.20.10. Imports and exports for items in these two subheadings are included in the values in table 3-1. In 2005, U.S. imports for consumption were \$2.9 million for 3006.70.00 and \$0.4 million for 2941.20.10. Domestic exports for subheading 3006.70.00 were \$14.7 million in 2005. The exact value of domestic exports for subheading 2941.20.10 in 2005 is not known, but it did not exceed \$12.7 million, which is the value of all domestic exports under the 6-digit HTS subheading 2941.20.

<sup>19</sup> Equivalent export data are not available because export data are generally aggregated at a higher level than import data and because the preference program only applies to imports inasmuch as no duties are collected on exports.

<sup>20</sup> The ad valorem equivalent tariff rate for products in the Pharmaceutical Appendix was calculated by dividing the sum of duties that would have been collected in 2005 if the products had not received duty-free treatment by the total value of imports for the products in that year.

<sup>21</sup> See Appendix B.

<sup>22</sup> Commission staff was able to obtain estimates for two additional products through telephone interviews with industry officials. These interviews took place on June 15 and June 19, 2006. The public versions of the submissions from PhRMA and Novus International are included in Appendix C.

Table 3-3 contains aggregate trade data estimates, provided by industry representatives, for items proposed for inclusion in the Pharmaceutical Appendix.<sup>23</sup> These data, which may underestimate trade in these products, may not adequately reflect the possible magnitude of trade that might occur when the duties are eliminated. These data represent only a small percentage of the products proposed for addition to the Pharmaceutical Appendix because data on many individual products are proprietary and not publicly available. Moreover, the proposed items may not be traded in the near future or at any time, e.g., some may still be awaiting regulatory approval. Finally, estimates are not available for the multitude of possible drug derivatives that may be imported free of duty by combining the prefixes or suffixes from table 2 of the Pharmaceutical Appendix with the INNs listed in table 1.

**Table 3-1** Pharmaceutical products covered under chapter 30 and headings 2936, 2937, 2939, and 2941 of the HTS: U.S. imports, exports, and trade balance, 2004–2005 (million dollars)

Product grouping	2004	2005
U.S. imports for consumption		
2936 .....	644	620
2937 .....	1,720	1,697
2939 .....	644	336
2941 .....	1,197	1,380
Chapter 30 .....	<u>32,245</u>	<u>35,574</u>
Total .....	36,451	39,607
U.S. domestic exports		
2936 .....	424	425
2937 .....	2,405	1,879
2939 .....	17	135
2941 .....	1,149	1,348
Chapter 30 .....	<u>18,934</u>	<u>21,059</u>
Total .....	22,929	24,846
U.S. trade balance		
2936 .....	-221	-195
2937 .....	685	181
2939 .....	-627	-201
2941 .....	-48	-32
Chapter 30 .....	<u>-13,312</u>	<u>-14,515</u>
Total .....	-13,522	-14,761

Source: Official statistics of the U.S. Department of Commerce.

<sup>23</sup> The data in table 3-3 have been aggregated to prevent disclosure of business proprietary information.

**Table 3-2** Products imported at the pharmaceutical special rate of duty: U.S. imports for consumption, by six-digit HTS subheadings, 2004-2005<sup>a</sup> (actual dollars)

Six-digit HTS subheading	U.S. imports	
	2004	2005
283329 .....	294,954	125,025
284110 .....	18,000	20,578
284210 .....	0	160,319
284290 .....	252,631	228,706
284330 .....	350,665	177,710
284390 .....	18,981,027	8,646,277
284690 .....	49,933	225,094
290322 .....	0	0
290330 .....	0	551,121
290345 .....	0	0
290347 .....	0	33,150
290349 .....	0	4,750
290351 .....	0	0
290359 .....	84,074	299,627
290362 .....	0	0
290369 .....	776,375	58,089
290410 .....	4,819	13,489
290490 .....	85,636	106,610
290519 .....	37,246	56,474
290522 .....	0	60,730
290529 .....	11,878	150,804
290539 .....	11,502	36,120
290549 .....	47,643	78,817
290559 .....	1,253,629	2,519,245
290611 .....	371,963	453,882
290619 .....	1,830,480	769,654
290621 .....	2,527	0
290629 .....	3,931	0
290719 .....	1,637,799	2,586,408
290729 .....	56,816	74,500
290810 .....	2,927,526	4,417,440
290820 .....	0	0
290890 .....	0	159,300
290919 .....	76,306,714	86,632,476
290920 .....	0	0
290930 .....	3,435,094	1,524,195
290949 .....	370,293	373,444
290950 .....	29,206,559	24,291,665
291030 .....	7,319	61,377
291090 .....	406,466	70,396
291100 .....	72,650	1,561,998
291219 .....	2,927,106	3,879,633
291229 .....	157,938	512,921
291249 .....	0	0
291419 .....	259,335	9,522
291429 .....	106,111	162,547
291439 .....	686,838	1,067,119
291440 .....	173,153	200,015
291450 .....	35,470,674	36,313,127
291469 .....	105,004,975	165,765,531
291470 .....	2,828,373	1,619,690
291529 .....	49,621	70,596

See footnote at end of table.

**Table 3-2** Products imported at the pharmaceutical special rate of duty: U.S. imports for consumption, by six-digit HTS subheadings, 2004-2005<sup>a</sup> (actual dollars)—Continued

Six-digit HTS subheading	U.S. imports	
	2004	2005
291539 .....	3,869,529	2,995,193
291540 .....	37,665	0
291550 .....	245,849	24,550
291590 .....	26,482,946	25,463,101
291619 .....	92,727	57,914
291620 .....	11,273,365	10,884,427
291631 .....	20,333	3,650
291639 .....	237,829	500,660
291713 .....	103,307	755,139
291719 .....	1,464,715	464,993
291720 .....	36,505	0
291734 .....	139,966	18,686
291739 .....	74,100	0
291811 .....	8,564	0
291813 .....	216,872	3,024,148
291816 .....	2,817,213	2,754,920
291819 .....	465,991,977	353,791,010
291822 .....	4,660	0
291823 .....	714,942	1,099,055
291829 .....	1,327,978	459,286
291830 .....	29,816,618	6,733,285
291890 .....	91,448,877	63,771,442
291900 .....	849,302	977,148
292090 .....	392,365	361,690
292112 .....	24,544	0
292119 .....	4,975,613	15,620,008
292129 .....	145,441	39,628
292130 .....	4,723,630	2,061,158
292142 .....	1,850,429	583,531
292143 .....	0	0
292145 .....	15,340	14,500
292149 .....	44,915,325	61,572,284
292159 .....	310,596	127,538
292211 .....	0	0
292212 .....	3,875	0
292219 .....	698,255,138	223,184,026
292229 .....	3,770,899	2,755,759
292239 .....	48,351,372	17,684,881
292241 .....	6,297,232	1,593,487
292242 .....	467,204	540,343
292243 .....	0	0
292249 .....	296,976,642	350,643,652
292250 .....	133,166,553	98,669,938
292310 .....	692,457	792,991
292320 .....	117,358	645,054
292390 .....	28,745,767	23,527,571
292419 .....	24,351,865	29,862,974
292421 .....	2,937,469	1,689,259
292423 .....	64,152	249,541
292429 .....	252,228,588	270,043,334
292519 .....	2,652,731	3,549,669

See footnote at end of table.

**Table 3-2** Products imported at the pharmaceutical special rate of duty: U.S. imports for consumption, by six-digit HTS subheadings, 2004-2005<sup>a</sup> (actual dollars)—Continued

Six-digit HTS subheading	U.S. imports	
	2004	2005
292520 .....	90,867,254	62,382,046
292690 .....	29,742,772	29,812,346
292700 .....	13,727,916	10,128,295
292800 .....	33,170,624	39,639,930
292990 .....	24,892	1,404,700
293010 .....	0	0
293020 .....	620,157	748,060
293030 .....	541,753	2,046,945
293090 .....	45,641,836	48,222,301
293100 .....	986,927,198	1,009,803,101
293219 .....	17,665,067	17,867,722
293221 .....	277,430	481,708
293229 .....	255,308,777	253,322,622
293299 .....	349,173,313	358,585,861
293311 .....	17,682	26,487
293319 .....	3,234,269	8,366,813
293321 .....	3,354,933	3,401,813
293329 .....	281,941,605	407,267,122
293339 .....	809,566,825	761,011,530
293349 .....	1,196,419,236	1,450,441,727
293354 .....	0	0
293359 .....	505,586,750	439,525,054
293369 .....	58,698,197	67,656,549
293379 .....	172,313,044	274,052,669
293399 .....	4,919,775,686	5,583,254,430
293410 .....	167,746,910	211,254,048
293420 .....	70,266,178	77,952,834
293430 .....	11,971,209	8,462,555
293499 .....	6,325,356,142	5,171,349,691
293500 .....	248,441,009	401,312,244
293810 .....	651,449	484,747
293890 .....	14,383,878	6,361,249
294000 .....	18,551,419	19,626,172
294200 .....	2,046,305	2,986,688
300670 .....	134,699	46,762
320300 .....	325,206	158,227
320413 .....	34,224	19,221
320419 .....	5,317,759	8,815,406
320490 .....	95,972	296,648
340130 .....	0	5,432
340213 .....	302,630	5,748,664
340220 .....	695,005	55,567
380840 .....	25,826	141,991
382490 .....	11,788,166	19,957,780
390190 .....	66,799	144,661
390290 .....	253	48,903
390461 .....	329,553	126,097
390591 .....	85,051	39,183
390599 .....	6,210,725	5,474,472
390690 .....	1,495,314	2,345,630
390710 .....	59,835	860
390720 .....	292,871	521,286

See footnote at end of table.

**Table 3-2** Products imported at the pharmaceutical special rate of duty: U.S. imports for consumption, by six-digit HTS subheadings, 2004-2005<sup>a</sup> (actual dollars)—Continued

Six-digit HTS subheading	U.S. imports	
	2004	2005
390730 .....	345,875	259,489
390760 .....	609,235	690,693
390799 .....	224,270	315,617
390810 .....	28,065	82,809
390910 .....	158,212	52,795
390940 .....	86,728	319,414
391000 .....	5,555,115	603,701
391190 .....	985,271	1,214,599
391220 .....	1,422,538	3,424,655
391231 .....	14,405,022	11,359,643
391239 .....	4,468,151	4,232,859
391290 .....	730,356	216,396
391390 .....	8,697,866	18,301,952
391400 .....	3,182,288	15,462,549
Total .....	19,182,439,292	18,755,445,614

Source: Official statistics of the U.S. Department of Commerce.

<sup>a</sup>U.S. imports of products at the pharmaceutical special rate of duty are tracked using the "K" program code.

**Table 3-3** Proposed additions to the Pharmaceutical Appendix to the HTS: Estimates for U.S. imports, exports, and trade balance, 2007 (1,000 dollars)

Product grouping	U.S. imports	U.S. exports	U.S. trade balance
Proposed additions to the Pharmaceutical Appendix <sup>a</sup> .....	619,182	6,000	-613,182

Source: Compiled by Commission staff from the submissions of the PhRMA and Novus International and from additional industry sources.

<sup>a</sup>These estimates include data submitted on 180 of approximately 1,300 pharmaceutical products and chemical intermediates under consideration. An aggregate estimate has been reported to protect business confidential information.

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**APPENDIX A**

**REQUEST LETTER FROM USTR AND**

**ATTACHMENT**

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2487

EXECUTIVE OFFICE OF THE PRESIDENT  
THE UNITED STATES TRADE REPRESENTATIVE  
WASHINGTON, D.C. 20508

DOCKET  
NUMBER

2489

MAY 19 2006

Office of the  
Secretary  
Int'l Trade Commission  
The Honorable Stephen Koplan

Chairman  
United States International Trade Commission  
500 E Street, S.W.  
Washington, DC 20436

Dear Chairman Koplan:

Achieving market openings through elimination of tariff barriers has been an ongoing objective of this Administration. As one part of the market access tariff results of the Uruguay Round negotiations, the United States and 21 other countries agreed to the reciprocal elimination of duties on approximately 7,000 pharmaceutical products and chemical intermediates used primarily for the production of pharmaceuticals. Commitments to eliminate duties on these products are reflected in each participant's market access schedule.

Participants in the pharmaceutical zero-for-zero initiative agreed in the Uruguay Round to conduct periodic reviews to identify further products that could be covered by the pharmaceutical duty elimination initiative. As a result of multilateral negotiations in the WTO during 1996 and again in 1998, the United States and other participants in the initiative eliminated duties on an additional 750 international nonproprietary names (INNs) and chemical intermediates on April 1, 1997, and on an additional 630 such products on July 1, 1999.

At this time, I am requesting the Commission's continued assistance in fulfilling the statutory requirements for implementation of additional tariff reductions under authority of the Uruguay Round Agreements Act (URAA). In section 111(b) of the URAA, Congress authorized the President to proclaim further modification of any duty for articles contained in a tariff category that was part of the U.S. zero-for-zero initiative. The Statement of Administrative Action which Congress approved in the URAA notes that the President would use section 111(b) authority to grant duty-free treatment for new pharmaceutical products such as those now under consideration. This authority is subject to the conditions set forth in section 111 which include compliance with the consultation and layover provisions of section 115 of the URAA.

One of the requirements set out in section 115 is that the President "obtain advice regarding the proposed action" from the Commission. While we have received technical assistance from Commission staff on products during the recent review, I request, pursuant to section 115 and section 332 of the Tariff Act of 1930, that the Commission provide advice to USTR in the form of additional information on the pharmaceutical products and chemical intermediates currently under consideration. Specifically, I request that the Commission provide: (1) a summary description of the products contained in the existing pharmaceutical Appendix and the

modifications to be made to that Appendix; (2) an explanation of the relationship between the various elements in the Appendix and the Harmonized Tariff Schedule of the United States; and (3) an estimate of current U.S. imports and, where possible, current U.S. exports of the products included in the existing pharmaceutical Appendix and the proposed additions to the Appendix, based on product groupings as necessary.

If data are not available for certain products, particularly in the case of new products, the advice may be provided in a qualitative form. I request that the Commission provide its advice at the earliest possible date, but not later than September 1, 2006. After we receive the Commission's advice, we will take the necessary action to begin the 60-day congressional consultation and layover period.

It is the intent of this office to make the Commission's report available to the general public in its entirety. Therefore, the report should not contain any confidential business or national security classified information.

I appreciate your assistance and cooperation on this matter and look forward to working with you and your staff on these issues in the future.

Sincerely,



Rob Portman

Enclosures:

- Table 1: Pharmaceutical INNs proposed for addition to the Pharmaceutical Appendix
- Table 2: Pharmaceutical prefixes and suffixes proposed for addition to the Pharmaceutical Appendix
- Table 3: Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix

**TABLE 1**

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**PHARMACEUTICAL INTERNATIONAL NONPROPRIETARY NAMES  
PROPOSED FOR ADDITION TO THE PHARMACEUTICAL APPENDIX**

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

Product	CAS No.
Abaperidone	183849-43-6
Abatacept	332348-12-6
Abetimus	167362-48-3
Abrineurin	178535-93-8
Acolbifene	182167-02-8
Acotiamide	185106-16-5
Adalimumab	331731-18-1
Adargileukin alfa	250710-65-7
Adecatumumab	503605-66-1
Adekalant	227940-00-3
Adrogolide	171752-56-0
Afeletecan	215604-75-4
Agalsidase beta	104138-64-9
Agalsidase alfa	104138-64-9
Alagebrium chloride	341028-37-3
Alamifovir	193681-12-8
Albaconazole	187949-02-6
Alefacept	222535-22-0
Alemcinal	150785-53-8
Alemtuzumab	216503-57-0
Alfatradiol	57-91-0
Alfimeprase	259074-76-5
Alglucosidase alfa	420784-05-0
Alicaforseen	185229-68-9
Alilusem	144506-11-6
Alistikren	173334-57-1
Altretinoine	5300-03-8
Altincline	179120-92-4
Alvameline	120241-31-8
Alvimopan	156053-89-3
Alvocidib	146426-40-6
Ambrisentan	177036-94-1
Amdoxovir	145514-04-1
Amediplase	151912-11-7
Amelubant	346735-24-8
Amiglumide	119363-62-1
Amotosalene	161262-29-9
Amprenavir	161814-49-9
Anatibant	209733-45-9
Anatumomab Mafenatox	(none)
Ancestim	163545-26-4
Ancriviroc	370893-06-4
Anecortave	7753-60-8
Anidulafungin	166663-25-8
Anisperimus	170368-04-4
Antithrombin alfa	84720-88-7

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Apaziquone . . . . .	114560-48-4
Apixaban . . . . .	503612-47-3
Aplindore . . . . .	189681-70-7
Apolizumab . . . . .	267227-08-7
Apratastat . . . . .	287405-51-0
Aprepitant . . . . .	170729-80-3
Aprinocarsen . . . . .	151879-73-1
Arasertaconazole . . . . .	583057-48-1
Ardenermin . . . . .	305391-49-5
Arformoterol . . . . .	67346-49-0
Arimoclomol . . . . .	289893-25-0
Armodafinil . . . . .	112111-43-0
Artemifone . . . . .	255730-18-8
Artemotil . . . . .	75887-54-6
Artenimol . . . . .	81496-81-3
Arundic acid . . . . .	185517-21-9
Arzoxifene . . . . .	182133-25-1
Ascorbyl gamolenate . . . . .	109791-32-4
Aselizumab . . . . .	395639-53-9
Asenapine . . . . .	65576-45-6
Asoprisnil . . . . .	199396-76-4
Asoprisnil ecamate . . . . .	222732-94-7
Ataciguat . . . . .	254877-67-3
Ataquimast . . . . .	182316-31-0
Atazanavir . . . . .	198904-31-3
Atilmotin . . . . .	533927-56-9
Atocalcitol . . . . .	302904-82-1
Atorolimumab . . . . .	202833-08-7
Atrasentan . . . . .	195733-43-8
Avanafil . . . . .	330784-47-9
Avasimibe . . . . .	166518-60-1
Aviscumine . . . . .	223577-45-5
Avosentan . . . . .	290815-26-8
Axitrome . . . . .	156740-57-7
Axomadol . . . . .	187219-95-0
Balaglitazone . . . . .	199113-98-9
Balicatib . . . . .	354813-19-7
Bamirastine . . . . .	215529-47-8
Banoxantrone . . . . .	136470-65-0
Bapineuzumab . . . . .	648895-38-9
Barixibat . . . . .	263562-28-3
Barusiban . . . . .	285571-64-4
Batabulin . . . . .	195533-53-0
Bazedoxifene . . . . .	198481-32-2
Becampanel . . . . .	188696-80-2
Beocatecarin . . . . .	119673-08-4

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Becocalcidiol . . . . .	524067-21-8
Befetupitant . . . . .	290296-68-3
Belatacept . . . . .	706808-37-9
Belimumab . . . . .	356547-88-1
Belototecan . . . . .	256411-32-2
Beminafil . . . . .	566906-50-1
Bemotrizinol . . . . .	187393-00-6
Bertilimumab . . . . .	375348-49-5
Besilesomab . . . . .	537694-98-7
Bevacizumab . . . . .	216974-75-3
Bexarotene . . . . .	153559-49-0
Bexlosteride . . . . .	148905-78-6
Bifarcept . . . . .	163796-60-9
Bifeprunox . . . . .	350992-10-8
Bilastine . . . . .	202189-78-4
Bimatoprost . . . . .	155206-00-1
Bimosoamose . . . . .	187269-40-5
Binetrakin . . . . .	207137-56-2
Binodenoson . . . . .	144348-08-3
Bisotrizole . . . . .	103597-45-1
Bivatuzumab . . . . .	214559-60-1
Bortezomib . . . . .	179324-69-7
Brivaracetam . . . . .	357336-20-0
Brostallicin . . . . .	203258-60-0
Bulaquine . . . . .	223661-25-4
Cadofloxacin . . . . .	153808-85-6
Calcubutrol . . . . .	151878-23-8
Caldaret . . . . .	133804-44-1
Caloxetic acid . . . . .	135306-78-4
Canertinib . . . . .	267243-28-7
Canfosfamide . . . . .	158382-37-7
Cangrelor . . . . .	163706-06-7
Cantuzumab mertansine . . . . .	400010-39-1
Capravirine . . . . .	178979-85-6
Capromorelin . . . . .	193273-66-4
Carabersat . . . . .	184653-84-7
Carglumic acid . . . . .	1188-38-1
Caricotamide . . . . .	64881-21-6
Carmoterol . . . . .	147568-66-9
Caspofungin . . . . .	162808-62-0
Catumaxomab . . . . .	509077-98-9
Cefmatilen . . . . .	140128-74-1
Cefovecin . . . . .	234096-34-5
Ceftobiprole . . . . .	209467-52-7
Ceftobiprole medocaril . . . . .	376653-43-9
Celecoxib . . . . .	169590-42-5

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Certolizumab pegol .....	428863-50-7
Cethromycin .....	205110-48-1
Cetilistat .....	282526-98-1
Cetuximab .....	205923-56-4
Cilengitide .....	188968-51-6
Cilomilast .....	153259-65-5
Ciluprevir .....	300832-84-2
Cimicoxib .....	265114-23-6
Cinacalcet .....	226256-56-0
Cintredekin besudotox .....	372075-36-0
Cipemastat .....	190648-49-8
Cipralisant .....	213027-19-1
Clamikalant .....	158751-64-5
Clazosentan .....	180384-56-9
Clofarabine .....	123318-82-1
Coluracetam .....	135463-81-9
Conivaptan .....	210101-16-9
Corifollitropin alfa .....	195962-23-3
Cridanimod .....	38609-97-1
Crabenetine .....	221019-25-6
Dabigatran etexilate .....	211915-06-9
Dabigatran .....	211914-51-1
Dabuzalgron .....	219311-44-1
Dacinostat .....	404951-53-7
Daglutril .....	182821-27-8
Dalbavancin .....	171500-79-1
Dapiclermine .....	444069-80-1
Dapivirine .....	244767-67-7
Darbepoetin alfa .....	209810-58-2
Darbufelone .....	139226-28-1
Darunavir .....	206361-99-1
Darusentan .....	171714-84-4
Dasantafil .....	569351-91-3
Davasaicin .....	147497-64-1
Daxalipram .....	189940-24-7
Deferasirox .....	201530-41-8
Deferitinrin .....	239101-33-8
Defoslimod .....	171092-39-0
Degarelix .....	214766-78-6
Deligoparin sodium .....	9041-08-1
Delmitide .....	287096-87-1
Delucemine .....	186495-49-8
Denufosol .....	211448-85-0
Depelestat .....	506433-25-6
Depreotide .....	161982-62-3
Deracoxib .....	169590-41-4

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Dersalazine . . . . .	188913-58-8
Desloratadine . . . . .	100643-71-8
Desmoteplase . . . . .	145137-38-8
Desvenlafaxine . . . . .	93413-62-8
Detiviclovir . . . . .	220984-26-9
Deutolperisone . . . . .	474641-19-5
Dexbudesonide . . . . .	51372-29-3
Dexlansoprazole . . . . .	138530-94-6
Dexamethylphenidate . . . . .	40431-64-9
Dextiopronine . . . . .	29335-92-0
Dextofisopam . . . . .	82059-50-5
Dianicline . . . . .	292634-27-6
Diboterimin alfa . . . . .	246539-15-1
Diflomotecan . . . . .	220997-97-7
Diquafosol . . . . .	59985-21-6
Dirlotapide . . . . .	481658-94-0
Disermolide . . . . .	127943-53-7
Disufenton sodium . . . . .	168021-79-2
Dofequirad . . . . .	129716-58-1
Donitriptan . . . . .	170912-52-4
Doramapimod . . . . .	285983-48-4
Doranidazole . . . . .	149838-23-3
Doripenem . . . . .	148016-81-3
Doxercalciferol . . . . .	54573-75-0
Drotrecogin alfa (activatum) . . . . .	98530-76-8
Ecalcidene . . . . .	150337-94-3
Ecallantide . . . . .	460738-38-9
Ecopipam . . . . .	112108-01-7
Ecopladib . . . . .	381683-92-7
Ecraprost . . . . .	136892-64-3
Ecromeximab . . . . .	292819-64-8
Eculizumab . . . . .	219685-50-4
Edaglitazone . . . . .	213411-83-7
Edifolgide . . . . .	328538-04-1
Edodekin alfa . . . . .	187348-17-0
Edonentan . . . . .	210891-04-6
Edotecarin . . . . .	174402-32-5
Edotreotide . . . . .	204318-14-9
Edratide . . . . .	433922-67-9
Edronocaine . . . . .	190258-12-9
Efalizumab . . . . .	214745-43-4
Efaproxiral . . . . .	131179-95-8
Efipladib . . . . .	381683-94-9
Eflucimibe . . . . .	202340-45-2
Eganoprost . . . . .	63266-93-3
Eglumetad . . . . .	176199-48-7

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

Product	CAS No.
Elarofiban	198958-88-2
Elomotecan	220998-10-7
Elsilimomab	468715-71-1
Elvucitabine	181785-84-2
Elzasonan	361343-19-3
Embeconazol	329744-44-7
Emfilermin	159075-60-2
Emivirine	149950-60-7
Emodepside	155030-63-0
Emtricitabine	143491-57-0
Enecadin	259525-01-4
Enfuvirtide	159519-65-0
Eniporide	176644-21-6
Enrasentan	167256-08-8
Entecavir	142217-69-4
Enzastaurin	170364-57-5
Epafigase	208576-22-1
Epitumomab cituxetan	263547-71-3
Epitumomab	263547-71-3
Eplivanserin	130579-75-8
Epoetin zeta	604802-70-2
Epoetin delta	261356-80-3
Epratuzumab	205923-57-5
Eptapirone	179756-85-5
Eptaplatin	146665-77-2
Eptotermin alfa	129805-33-0
Eritoran	185955-34-4
Erlizumab	211323-03-4
Erlotinib	183321-74-6
Ertapenem	153832-46-3
Ertiprotafib	251303-04-5
Ertumaxomab	509077-99-0
Escitalopram	128196-01-0
Esketamine	33643-46-8
Eslicarbazepine	104746-04-5
Esmirtazapine	61337-87-9
Esomeprazole	119141-88-7
Esonarimod	101973-77-7
Esoxybutynin	119618-22-3
Eszopiclone	138729-47-2
Etalocib	161172-51-6
Etanercept	185243-69-0
Etilevodopa	37178-37-3
Etipredonol dicloacetate	199331-40-3
Etoricoxib	202409-33-4
Etravirin	269055-15-4

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

Product	CAS No.
Etriciguat . . . . .	402595-29-3
Eufauserase . . . . .	(none)
Evernimicin . . . . .	109545-84-8
Everolimus . . . . .	159351-69-6
Exatecan . . . . .	171335-80-1
Exatecan alideximer . . . . .	(none)
Exbivirumab . . . . .	569658-80-6
Exenatid . . . . .	141758-74-9
Exisulind . . . . .	59973-80-7
Ezetimibe . . . . .	163222-33-1
Ezlopitant . . . . .	147116-64-1
Fadolmidine . . . . .	189353-31-9
Falnidamol . . . . .	196612-93-8
Famproniil . . . . .	134183-95-2
Fanapanel . . . . .	161605-73-8
Fandosentan . . . . .	221241-63-0
Farampator . . . . .	211735-76-1
Farglitzazar . . . . .	196808-45-4
Febuxostat . . . . .	144060-53-7
Feloprentan . . . . .	204267-33-4
Fesoterodine . . . . .	286930-03-8
Fidexaban . . . . .	183305-24-0
Fiduxosin . . . . .	208993-54-8
Figopitant . . . . .	502422-74-4
Finafloxacin . . . . .	209342-40-5
Fingolimod . . . . .	162359-55-9
Finroazole . . . . .	160146-17-8
Fipamezole . . . . .	150586-58-6
Firocoxib . . . . .	189954-96-9
Fispemifene . . . . .	341524-89-8
Flindokalner . . . . .	187523-35-9
Fluorescein lisicol . . . . .	140616-46-2
Fondaparinux sodium . . . . .	114870-03-0
Fontolizumab . . . . .	326859-36-3
Forodesine . . . . .	209799-67-7
Fosamprenavir . . . . .	226700-79-4
Fosfluconazole . . . . .	194798-83-9
Fosfluridine tidoxil . . . . .	174638-15-4
Fosfructose . . . . .	488-69-7
Fosveset . . . . .	193901-91-6
Frakefamide . . . . .	188196-22-7
Freselestat . . . . .	208848-19-5
Gadocoletic acid . . . . .	280776-87-6
Gadodenterate . . . . .	544697-52-1
Gadofosveset . . . . .	193901-90-5
Gadomelitol . . . . .	227622-74-4

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Galarubicin . . . . .	140637-86-1
Galiximab . . . . .	357613-77-5
Galsulfas . . . . .	552858-79-4
Ganstigmine . . . . .	457075-21-7
Gantacurium chloride . . . . .	213998-46-0
Gantofiban . . . . .	183547-57-1
Garenoxacin . . . . .	194804-75-6
Garnocestim . . . . .	246861-96-1
Gavilimomab . . . . .	244096-20-6
Gefitinib . . . . .	184475-35-2
Gemcabene . . . . .	183293-82-5
Gemifloxacin . . . . .	204519-64-2
Gemopatrilat . . . . .	160135-92-2
Gemtuzumab . . . . .	220578-59-6
Gimatecan . . . . .	292618-32-7
Gimeracil . . . . .	103766-25-2
Glucarpidase . . . . .	9074-87-7
Golimumab . . . . .	476181-75-5
Hemoglobin raffimer . . . . .	197462-97-8
Hemoglobin glutamer . . . . .	(none)
Ibooctadekin . . . . .	479198-61-3
Ibritumomab tiuxetan . . . . .	206181-63-7
Ibrolipim . . . . .	133208-93-2
Icaridin . . . . .	119515-38-7
Iclaprim . . . . .	192314-93-5
Icofungipen . . . . .	198022-65-0
Icomucret . . . . .	54845-95-3
Icrocaptide . . . . .	169543-49-1
Idraparinux sodium . . . . .	149920-56-9
Idremcinal . . . . .	110480-13-2
Idronoxil . . . . .	81267-65-4
Idursulfase . . . . .	50936-59-9
Iferanserin . . . . .	58754-46-4
Iguratimod . . . . .	123663-49-0
Ilaprazole . . . . .	172152-36-2
Ilodecakin . . . . .	149824-15-7
Imatinib . . . . .	152459-95-5
Imidafenacin . . . . .	170105-16-5
Imiglitzazar . . . . .	250601-04-8
Implitapide . . . . .	177469-96-4
Indacaterol . . . . .	312753-06-3
Indibulin . . . . .	204205-90-3
Indiplon . . . . .	325715-02-4
Indisulam . . . . .	165668-41-7
Inecalcitol . . . . .	163217-09-2
Ingliforib . . . . .	186392-65-4

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Inotuzumab ozogamicin . . . . .	635715-01-4
Insulin detemir . . . . .	169148-63-4
Insulin glulisine . . . . .	207748-29-6
Iosimanol . . . . .	181872-90-2
Ipravacain . . . . .	166181-63-1
Irampanel . . . . .	206260-33-5
Irofulven . . . . .	158440-71-2
Iroxanadine . . . . .	276690-58-5
Isalmadol . . . . .	269079-62-1
Isatoribine . . . . .	122970-40-5
Iseganan . . . . .	257277-05-7
Ismomultin alfa . . . . .	457913-93-8
Ispinesib . . . . .	336113-53-2
Ispronicleine . . . . .	252870-53-4
Istaroxime . . . . .	203737-93-3
Itradefylline . . . . .	155270-99-8
Itriglumide . . . . .	201605-51-8
Iturelix . . . . .	112568-12-4
Ixabepilone . . . . .	219989-84-1
Izonsteride . . . . .	176975-26-1
Labetuzumab . . . . .	219649-07-7
Labradimil . . . . .	159768-75-9
Lacosamide . . . . .	175481-36-4
Ladirubicin . . . . .	171047-47-5
Ladostigil . . . . .	209394-27-4
Lanicemine . . . . .	153322-05-5
Lanimostim . . . . .	117276-75-2
Laniquidar . . . . .	197509-46-9
Lapatinib . . . . .	231277-92-2
Lapisteride . . . . .	142139-60-4
Laquinimod . . . . .	248281-84-7
Laronidase . . . . .	210589-09-6
Lasofoxifene . . . . .	180916-16-9
Latidectin (component A3) . . . . .	371918-51-3
Latidectin (component A4) . . . . .	371918-44-4
Leconotide . . . . .	247207-64-3
Lecozotan . . . . .	434283-16-6
Lemalesomab . . . . .	250242-54-7
Lemuteporfin . . . . .	215808-49-4
Lenalidomide . . . . .	191732-72-6
Lerdelimumab . . . . .	285985-06-0
Leridistim . . . . .	193700-51-5
Lestaurtinib . . . . .	111358-88-4
Leteprinim . . . . .	138117-50-7
Levmetamfetamine . . . . .	33817-09-3
Levolansoprazole . . . . .	138530-95-7

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

Product	CAS No.
Levotofisopam	82059-51-6
Liatermin	188630-14-0
Libivirumab	569658-79-3
Licarbazepine	29331-92-8
Licofelone	156897-06-2
Lidadronic acid	63132-38-7
Lidorestat	245116-90-9
Linaprazan	248919-64-4
Liraglutide	204656-20-2
Lirimilast	329306-27-6
Litomeglovir	321915-31-5
Livaraparin calcium	329306-27-6
Lixivaptan	168079-32-1
Lomeguatrib	192441-08-0
Lonafarnib	193275-84-2
Lopinavir	192725-17-0
Lubazodone	161178-07-0
Lubiprostone	333963-40-9
Luliconazole	187164-19-8
Lumiliximab	357613-86-6
Lumiracoxib	220991-20-8
Lurasidone	367514-87-2
Lusaperidone	214548-46-6
Lusupultide	200074-80-2
Manifaxine	135306-39-7
Manitimus	202057-76-9
Mantabegron	36144-08-8
Mapatumumab	658052-09-6
Maraviroc	376348-65-1
Maribavir	176161-24-3
Marimastat	154039-60-8
Maropitant	147116-67-4
Matuzumab	339186-68-4
Mecasermin rinfabate	478166-15-3
Meclintertant	146362-70-1
Meldonium	76144-81-5
Melevodopa	7101-51-1
Mepolizumab	196078-29-2
Merimepodib	198821-22-6
Metelimumab	272780-74-2
Metreleptin	186018-45-1
Micafungin	235114-32-6
Midafotel	117414-74-1
Midaxifylline	151159-23-8
Midostaurin	120685-11-2
Miglustat	72599-27-0

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Milataxel . . . . .	393101-41-2
Minopafant . . . . .	128420-61-1
Minretumomab . . . . .	195189-17-4
Miriplatin . . . . .	141977-79-9
Mirococept . . . . .	507453-82-9
Mirostipen . . . . .	244130-01-6
Mitemcinal . . . . .	154738-42-8
Mitrapapid . . . . .	179602-65-4
Mitumomab . . . . .	216503-58-1
Mivotilate . . . . .	130112-42-4
Morolimumab . . . . .	202833-07-6
Morphine glucuronide . . . . .	20290-10-2
Motexafin . . . . .	189752-49-6
Mozavaptan . . . . .	137975-06-5
Mozenavir . . . . .	174391-92-5
Mubritinib . . . . .	366017-09-6
Muraglitazar . . . . .	331741-94-7
Mureletecan . . . . .	246527-99-1
Nalfurafine . . . . .	152657-84-6
Naminidil . . . . .	220641-11-2
Nasaruplase beta . . . . .	136653-69-5
Natalizumab . . . . .	189261-10-7
Naveglitazar . . . . .	476436-68-7
Navuridine . . . . .	84472-85-5
Naxifylline . . . . .	166374-49-8
Nebentan . . . . .	403604-85-3
Nebicapone . . . . .	274925-86-9
Neboglamine . . . . .	163000-63-3
Nemifotide . . . . .	173240-15-8
Neramexane . . . . .	219810-59-0
Nerispiridine . . . . .	119229-65-1
Nesiritide . . . . .	124584-08-3
Netoglitazone . . . . .	161600-01-7
Netupitant . . . . .	290297-26-6
Nolomirole . . . . .	90060-42-7
Norelgestromin . . . . .	53016-31-2
Nortopixantrone . . . . .	156090-17-4
Oblimersen . . . . .	190977-41-4
Odiparcil . . . . .	137215-12-4
Ofatumumab . . . . .	679818-59-8
Oglufanide . . . . .	38101-59-6
Olamufloxacin . . . . .	167887-97-0
Olanexidine . . . . .	146510-36-3
Olcegepant . . . . .	204697-65-4
Olmesartan . . . . .	144689-24-7
Olmesartan medoxomil . . . . .	144689-63-4

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Omaciclovir . . . . .	124265-89-0
Omalizumab . . . . .	242138-07-4
Omiganan . . . . .	204248-78-2
Omigapil . . . . .	181296-84-4
Omcianine . . . . .	154082-13-0
Onercept . . . . .	199685-57-9
Opaviraline . . . . .	178040-94-3
Opebacan . . . . .	206254-79-7
Oregovomab . . . . .	213327-37-8
Oritavancin . . . . .	171099-57-3
Ortataxel . . . . .	186348-23-2
Oseltamivir . . . . .	196618-13-0
Osemozotan . . . . .	137275-81-1
Ospermifene . . . . .	128607-22-7
Otamixaban . . . . .	193153-04-7
Oteracil . . . . .	937-13-3
Oxeglitazar . . . . .	280585-34-4
Ozogamicin . . . . .	400046-53-9
Paclitaxel ceribate . . . . .	186040-50-6
Paclitaxel poliglumex . . . . .	263351-82-2
Pactimibe . . . . .	189198-30-9
Padoporfín . . . . .	274679-00-4
Pagibaximab . . . . .	595566-61-3
Palifermin . . . . .	162394-19-6
Paliperidone . . . . .	144598-75-4
Paliroden . . . . .	188396-77-2
Palivizumab . . . . .	188039-54-5
Palosuran . . . . .	540769-28-6
Panitumumab . . . . .	339177-26-3
Parathyroid hormone . . . . .	345663-45-8
Parecoxib . . . . .	198470-84-7
Pascolizumab . . . . .	331243-22-2
Pasireotide . . . . .	396091-73-9
Patupilone . . . . .	152044-54-7
Peforelin . . . . .	147859-97-0
Pegacaristim . . . . .	187139-68-0
Pegamotecan . . . . .	203066-49-3
Pegaptanib . . . . .	(none)
Pegfilfrastim . . . . .	208265-92-3
Peginterferon alfa-2a . . . . .	198153-51-4
Peginterferon alfa-2b . . . . .	215647-85-1
Pegnartograstim . . . . .	204565-76-4
Pegsunercept . . . . .	330988-75-5
Pegvisomant . . . . .	218620-50-9
Peliglitazar . . . . .	331744-64-0
Pelitinib . . . . .	257933-82-7

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

Product	CAS No.
Pelitrexol . . . . .	446022-33-9
Pemaglitzazar . . . . .	496050-39-6
Peramivir . . . . .	229614-55-5
Perflexane . . . . .	355-42-0
Perflisobutane . . . . .	354-92-7
Perflubrodec . . . . .	307-43-7
Perflubutane . . . . .	355-25-9
Perflutren . . . . .	76-19-7
Pertuzumab . . . . .	380610-27-5
Perzinfotel . . . . .	144912-63-0
Pexelizumab . . . . .	219685-93-5
Piboserod . . . . .	152811-62-6
Pibrozelesin . . . . .	1545889-68-6
Piclozotan . . . . .	182415-09-4
Picoplatin . . . . .	181630-15-9
Pimecrolimus . . . . .	137071-32-0
Pinokalant . . . . .	149759-26-2
Pipendoxifene . . . . .	198480-55-6
Pitavastatin . . . . .	147511-69-1
Pitrakinra . . . . .	(none)
Pixantrone . . . . .	144510-96-3
Plerixafor . . . . .	110078-46-1
Plevitrexed . . . . .	153537-73-6
Plitidepsin . . . . .	137219-37-5
Ponazuril . . . . .	69004-04-2
Posaconazole . . . . .	171228-49-2
Posizolid . . . . .	252260-02-9
Pradefovir . . . . .	625095-60-5
Pradofloxacin . . . . .	195532-12-8
Pralatrexate . . . . .	146464-95-1
Pralnacasan . . . . .	192755-52-5
Prasugrel . . . . .	150322-43-3
Pratosartan . . . . .	153804-05-8
Prazarelix . . . . .	134457-28-6
Prinomastat . . . . .	192329-42-3
Pritumumab . . . . .	499212-74-7
Protamine sulfate . . . . .	9009-65-8
Pruvanserin . . . . .	443144-26-1
Pumafentrine . . . . .	207993-12-2
Pumosetrag . . . . .	153062-94-3
Radafaxine . . . . .	192374-14-4
Radequinil . . . . .	219846-31-8
Radotermin . . . . .	575458-75-2
Rafabegron . . . . .	244081-42-3
Ragaglitzazar . . . . .	222834-30-2
Ralfinamide . . . . .	133865-88-0

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Ramelteon . . . . .	196597-26-9
Ranibizumab . . . . .	347396-82-1
Ranirestat . . . . .	147254-64-6
Ranpirnase . . . . .	196488-72-9
Rasburicase . . . . .	134774-45-1
Ravuconazole . . . . .	182760-06-1
Raxibacumab . . . . .	565451-13-0
Razaxaban . . . . .	218298-21-6
Rebimastat . . . . .	259188-38-0
Regadenoson . . . . .	313348-27-5
Reglitazar . . . . .	170861-63-9
Relcovaptan . . . . .	150375-75-0
Reparixin . . . . .	266359-83-5
Repifermin . . . . .	219527-63-6
Repinotan . . . . .	144980-29-0
Resequinil . . . . .	219846-31-8
Resiquimod . . . . .	144875-48-9
Reslizumab . . . . .	241473-69-8
Retapamulin . . . . .	224452-66-8
Revaprazan . . . . .	199463-33-7
Rilpivirine . . . . .	500287-72-9
Rimacalib . . . . .	215174-50-8
Rimeporide . . . . .	187870-78-6
Rimonabant . . . . .	168273-06-1
Risarestat . . . . .	79714-31-1
Ritobegron . . . . .	255734-04-4
Rivanicline . . . . .	15585-43-0
Rivaroxaban . . . . .	366789-02-8
Rivenprost . . . . .	256382-08-8
Rivoglitazone . . . . .	185428-18-6
Robenacoxib . . . . .	220991-32-2
Rofecoxib . . . . .	162011-90-7
Rostafuroxin . . . . .	156722-18-8
Rostaporphin . . . . .	284041-10-7
Rosuvastatin . . . . .	287714-14-4
Rotigotine . . . . .	99755-59-6
Rovelizumab . . . . .	197099-66-4
Rubitecan . . . . .	91421-42-0
Ruboxistaurin . . . . .	169939-94-0
Rupintrivir . . . . .	223537-30-2
Rupizumab . . . . .	220651-94-5
Sabarubicin . . . . .	211100-13-9
Sabiporide . . . . .	324758-66-9
Safinamide . . . . .	133865-89-1
Salcaprozic acid . . . . .	183990-46-7
Salclobuzic acid . . . . .	387825-03-8

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

Product	CAS No.
Sarakalim	148430-28-8
Sardomozide	149400-88-4
Sarizotan	177975-08-5
Satavaptan	185913-78-4
Satrapiatin	129580-63-8
Saxagliptin	361442-04-8
Segesterone	7690-08-6
Selamectin	165108-07-6
Seletracetam	357336-74-4
Seliciclib	186692-46-6
Selodenoson	110299-05-3
Semapimod	352513-83-8
Semaxanib	194413-58-6
Semparatide	154906-40-8
Senazodan	98326-32-0
Sibenadet	154189-40-9
Sibrotuzumab	216669-97-5
Silodosine	160970-54-7
Sipilizumab	288392-69-8
Sipoglitazar	342026-92-0
Siramesinum	147817-50-3
Sitamaquine	57695-04-2
Sitaxentan	184036-34-8
Sobidotin	149606-27-9
Solabegron	252920-94-8
Solifenacin	242478-37-1
Solimastat	226072-63-5
Soneclosan	3380-30-1
Sonepiprazole	170858-33-0
Sorafenib	284461-73-0
Soraprazan	261944-46-1
Squalamine	148717-90-2
Stannsoporphin	106344-20-1
Sufugolix	308831-61-0
Sugammadex	343306-71-8
Sulamserod	219757-90-1
Sumanirole	179386-43-7
Sunitinib	557795-19-4
Surinabant	288104-79-0
Tabimorelin	193079-69-5
Tacapenem	193811-33-5
Tacedinaline	112522-64-2
Tadalafil	171596-29-5
Tadekinig alfa	220712-29-8
Tafenoquine	106635-80-7
Tafluposide	179067-42-6

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Tafluprost . . . . .	209860-87-7
Talabostat . . . . .	149682-77-9
Talactoferrin alfa . . . . .	308240-58-6
Talaglumetad . . . . .	441765-98-6
Talampanel . . . . .	161832-65-1
Talaporfin . . . . .	110230-98-3
Talibegron . . . . .	146376-58-1
Talizumab . . . . .	380610-22-0
Talnetant . . . . .	174636-32-9
Taltobulin . . . . .	228266-40-8
Tanaproget . . . . .	304853-42-7
Tandutinib . . . . .	387867-13-2
Taneptacogin alfa . . . . .	465540-87-8
Tanogitran . . . . .	637328-69-9
Tanomastat . . . . .	179545-77-8
Tapentadol . . . . .	175591-23-8
Taplitumomab paptox . . . . .	235428-87-2
Taprizosin . . . . .	210538-44-6
Tariquidar . . . . .	206873-63-4
Tasidotin . . . . .	192658-64-3
Tasquinimod . . . . .	254964-60-8
Tebanicline . . . . .	198283-73-7
Tebipenem pivoxil . . . . .	161715-24-8
Tecadenoson . . . . .	204512-90-3
Tecalcelt . . . . .	148717-54-8
Tecastemizol . . . . .	75970-99-9
Technetium (99mtc) fanolesomab . . . . .	225239-31-6
Technetium (99mtc) nitridocade . . . . .	131608-78-1
Teduglutide . . . . .	287714-30-1
Tefibazumab . . . . .	521079-87-8
Tegaserod . . . . .	145158-71-0
Teglicar . . . . .	250694-07-6
Telavanicin . . . . .	372151-71-8
Telbermin . . . . .	205887-54-3
Telbivudine . . . . .	3424-98-4
Telithromycin . . . . .	173838-31-8
Temserolimus . . . . .	162635-04-3
Tenatoprazol . . . . .	113712-98-4
Tenecteplase . . . . .	191588-94-0
Teneliximab . . . . .	299423-37-3
Tenvastatin . . . . .	121009-77-6
Tenofovir . . . . .	147127-20-6
Teriflunomide . . . . .	108605-62-5
Terutroban . . . . .	165538-40-9
Tesagliptazar . . . . .	251565-85-2
Tesetaxel . . . . .	333754-36-2

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

Product	CAS No.
Tesmilifene . . . . .	98774-23-3
Tesofensine . . . . .	195875-84-4
Tetomilast . . . . .	145739-56-6
Tetrahexan . . . . .	60239-18-1
Tezacitabine . . . . .	130306-02-4
Tezosentan . . . . .	180384-57-0
Thrombomodulin alfa . . . . .	120313-91-9
Ticalopride . . . . .	202590-69-0
Tidembersat . . . . .	175013-73-7
Tifenazoxide . . . . .	279215-43-9
Tifuvirtide . . . . .	251562-00-2
Tigecycline . . . . .	220620-09-7
Tilmacoxib . . . . .	180200-68-4
Timcodar . . . . .	179033-51-3
Tipifarnib . . . . .	192185-72-1
Tiplimotide . . . . .	178823-49-9
Tipranavir . . . . .	174484-41-4
Tisocalcitate . . . . .	156965-06-9
Tiviciclovir . . . . .	103024-93-7
Tocilizumab . . . . .	375823-41-9
Tocladesine . . . . .	41941-56-4
Tofimilast . . . . .	185954-27-2
Tolevamer . . . . .	28210-41-5
Tolvaptan . . . . .	150683-30-0
Tomeglovir . . . . .	233254-24-5
Tonabersat . . . . .	175013-84-0
Topilutamide . . . . .	260980-89-0
Topixantrone . . . . .	156090-18-5
Toralizumab . . . . .	252662-47-8
Torapsel . . . . .	204658-47-9
Torcetrapib . . . . .	262352-17-0
Torcitabine . . . . .	40093-94-5
Tosagestin . . . . .	110072-15-6
Tositumomab . . . . .	192391-48-3
Trabectedin . . . . .	114899-77-3
Travoprost . . . . .	157283-68-6
Traxoprodil . . . . .	134234-12-1
Trecetilide . . . . .	180918-68-7
Treprostinal . . . . .	81846-19-7
Tretazicar . . . . .	21919-05-1
Tridolgosir . . . . .	72741-87-8
Triplatin tetranitrate . . . . .	172903-00-3
Troodusquemine . . . . .	186139-09-3
Troxacitabine . . . . .	145918-75-8
Tulathromycin B . . . . .	280755-12-6
Tulathromycin A . . . . .	217500-96-4

**Table 1**  
**Pharmaceutical international nonproprietary names (INNs) proposed for addition to the Pharmaceutical Appendix**

<b>Product</b>	<b>CAS No.</b>
Udenafil . . . . .	268203-93-6
Ulifloxacin . . . . .	112984-60-8
Uliprisnil . . . . .	159811-51-5
Upidosin . . . . .	152735-23-4
Urtoxazumab . . . . .	502496-16-4
Valategast . . . . .	220847-86-9
Valdecoxib . . . . .	181695-72-7
Valomaciclovir . . . . .	195157-34-7
Valopicitabine . . . . .	640281-90-9
Valrocemide . . . . .	92262-58-3
Valrubicin . . . . .	56124-62-0
Valtorcitabine . . . . .	380886-95-3
Vandetanib . . . . .	338992-00-0
Vangatalcite . . . . .	12539-23-0
Vapaliximab . . . . .	336801-86-6
Vardenafil . . . . .	224785-90-4
Varenicline . . . . .	249296-44-4
Varespladib . . . . .	172732-68-2
Vatalanib . . . . .	212141-54-3
Vepalimumab . . . . .	195158-85-1
Vestipitant . . . . .	334476-46-9
Vilazodone . . . . .	163521-12-8
Vildagliptin . . . . .	274901-16-5
Visilizumab . . . . .	219716-33-3
Vofopitant . . . . .	168266-90-8
Volociximab . . . . .	558480-40-3
Volpristin . . . . .	21102-49-8
Xidecaflur . . . . .	207916-33-4
Ximelagatran . . . . .	192939-46-1
Yttrium (90y) tacatuzumab . . . . .	476413-07-7
Yttrium (90Y) tacatuzumab tetraxetan . . . . .	476413-07-7
Zabofloxacin . . . . .	219680-11-2
Zalutumumab . . . . .	667901-13-5
Zanapezil . . . . .	142852-50-4
Zanolimumab . . . . .	652153-01-0
Zelandopam . . . . .	139233-53-7
Ziralimumab . . . . .	(none)
Zonampanel . . . . .	210245-80-0
Zoniporate . . . . .	241800-98-6
Zosuquidar . . . . .	167354-41-8
Zoticasone . . . . .	678160-57-1

**TABLE 2**

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**PHARMACEUTICAL PREFIXES AND SUFFIXES PROPOSED  
FOR ADDITION TO THE PHARMACEUTICAL APPENDIX**

**Table 2**  
**Pharmaceutical prefixes and suffixes proposed for addition  
 to the Pharmaceutical Appendix**

<b>Item</b>
acefurate
aceglumate
aceponate
acetofenide
acibutate
alfoscerate
alideximer
4-aminosalicylate
anisatil
arbamel
argine
aritox
aspart
aspartate
benetonide
R-camphorsulfonate
R-camphorsulfonate
S-camphorsulfonate
S-camphorsulfonate
cilexetil
cituxetan
clofibrol
crofumaryl
cyclamate
cyclohexylamine
daloxate
daropate
defalan
detemir
dicibate
dicyclohexylamine
diftitox
disoproxil
N,N-dimethyl-β-alanine
ecamate
enbutate
ethylbromide
etilsulfate
ferrous
furetonide
gadolinium
gamolenate
glargine
glulisine
glutamer

**Table 2**  
**Pharmaceutical prefixes and suffixes proposed for addition  
 to the Pharmaceutical Appendix**

<b>Item</b>
guacil
guanidine
hemisuccinate
heptahydrate
hexacetonide
hydrogen
2-(4-hydroxybenzoyl)benzoate
hydroxynaphthoate
iodine-131
lisetil
lisicol
lispro
lutetium
lysine
mafenantox
medoxomil
merpentan
mertansine
methonitrate
metiodide
mucate
pegol
pentexil
poliglumex
raffimer
septahydrate
sesquihydrate
sesquioleate
soproxil
stinoprate
succinil
sudotox
suleptanate
sulfoxylate
tafenatox
d-tartaric Acid
d-tartrate
l-tartrate
tetraxetan
tidoxil
tiuxetan
tocoferil
trioleate
tristearate
undecylate

**TABLE 3**

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**PHARMACEUTICAL INTERMEDIATES PROPOSED  
FOR ADDITION TO THE PHARMACEUTICAL APPENDIX**

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
1,2-Bis[2-[2-(2-methoxyethoxy)ethoxy]ethoxy]-4,5-dinitrobenzene . . . . .	165254-21-7
2,2'-(3,4-diethyl-1H-pyrrole-2,5-diy)bis(methylene)] bis[4-methyl-5-[(phenylmethoxy)carbonyl]-1H-pyrrole-3-propanoic acid], dimethyl ester . . . . .	149365-59-3
5,5'-(3,4-diethyl-1H-pyrrole-2,5-diy)bis(methylene)]bis[4-(3-hydroxypropyl)-3-methyl-1H-pyrrole-2-carboxaldehyde]	149365-62-8
6-{(E)-2-[4-(4-fluorophenyl)-2,6-diisopropyl-5-(methoxymethyl)-3-pyridinyl]ethenyl}-4-hydroxytetrahydro-2H-pyran-2-one . . . . .	158878-46-7
(2E)-3-[4-(4-fluorophenyl)-2,6-diisopropyl-5-(methoxymethyl)-3-pyridinyl]-2-propenal	177964-68-0
N-formylhexopyranosylamine . . . . .	65293-32-5
1-deoxy-1-(formylamino)hexitol . . . . .	89182-60-5
N-(3-acetyl-4-(2-oxiranylmethoxy)phenyl]butanamide . . . . .	28197-66-2
rel-(3R,5S,6E)-7-[4-(4-fluorophenyl)-2,6-diisopropyl-5-(methoxymethyl)pyridin-3-yl]-3,5-dihydroxyhept-6-enoic acid .	159813-78-2
(2R,3R,4R,5S)-2-(hydroxymethyl)-3,4,5-piperidonetriol . . . . .	19130-96-2
rel-(3R,5R)-3-{(E)-2-[4-(4-fluorophenyl)-2,6-diisopropyl-5-(methoxymethyl)pyridin-3-yl]vinyl}-5-hydroxycyclohexanone	158878-47-8
1-[4-(benzyloxy)phenyl]-1-propanone . . . . .	4495-66-3
1-[4-(Benzylxy)phenyl]-2-[(1-methyl-3-phenylpropyl)amino]-1-propanone . . . . .	96072-82-1
(tert-Butoxycarbonyl)methyl 2-[1-[(4-chlorophenyl)carbonyl]-5-methoxy-2-methylindol-3-yl]acetate . . . . .	75302-98-6
2-methoxyethyl(2E)-2-acetyl-3-(3-nitrophenyl)-2-propenoate . . . . .	39562-22-6
ethyl(2E)-2-acetyl-3-(3-nitrophenyl)-2-propenoate . . . . .	39562-16-8
Methyl (2E)-2-acetyl-3-(2-nitrophenyl)-2-propenoate . . . . .	39562-27-1
4-Chlorophenyl 4-(methylsulfanyl)phenyl ether . . . . .	225652-11-9
(R)-3H-Pyrazolo[4,3-c]pyridin-3-one, 2,3a,4,5,6,7-hexahydro-2-methyl-3a-(phenylmethyl)-, L-tartaric acid salt .	193274-37-2
7-Methoxy-6-(3-morpholinopropoxy)-3,4-dihydroquinazolin-4-one . . . . .	199327-61-2
(2S)-1-{(2S)-2-[(methoxycarbonyl)amino]-3-methylbutanoyl}tetrahydro-1H-pyrrole-2-carboxylic acid . . . . .	181827-47-4
N-(tert-Butyl)-hydroxylamine acetate . . . . .	253605-31-1
(S)-1-[(S)-2-(4-methoxybenzamido)-3-methylbutyryl]-N-[(S)-2-methyl-1-(trifluoroacetyl)propyl]pyrrolidine-2-carboxamide . . . . .	171964-73-1
3-[(4S)-5-oxo-2-(trifluoromethyl)-1,4,5,6,7,8-hexahydro-4-quinolinyl]benzonitrile . . . . .	172649-40-0
tert-Butyl 2-[(4R,6S)-6-(hydroxymethyl)-2,2-dimethyl-1,3-dioxan-4-yl] acetate . . . . .	124655-09-0
Methyl 4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidine-5-carboxylate . . . . .	160009-37-0
4-{{(3-[(2,2-dimethylpropanoyl)oxy]methyl)-2,7-dimethyl-4-oxo-3,4-dihydroquinazolin-6-yl)methyl}(prop-2-ynyl)amino}-2-fluorobenzoic acid . . . . .	140373-09-7
{1S-Benzyl-2R-hydroxy-3-[isobutyl-(4-nitrobenzenesulfonyl)amino]propyl}-carbamic acid tetrahydro-furan-3S-yl ester	160231-69-6
N-[(2R,3S)-3-amino-2-hydroxy-4-phenylbutyl]-N-isobutyl-4-nitrobenzenesulfonamide hydrochloride . . . . .	244634-31-9
(2R)-2-aminopropan-1-ol . . . . .	35320-23-1
1-(3,5-difluorophenyl)propan-1-one . . . . .	135306-45-5
Diethylphosphoryl-(Z)-2-(2-aminothiazol-4-yl)-2-(tert-butoxycarbonyl-isopropoxy)iminoacetate . . . . .	179258-52-7
N-(2-Benzoyl-phenyl)-L-tyrosine methyl ester . . . . .	196810-09-0
Bis(N-methyl-N-phenylhydrazine) sulfate . . . . .	618-26-8
4-Hydroxy-2-oxo-1,2,5,6-tetrahydropyridine-3-carboxylic acid methyl ester sodium salt . . . . .	198213-15-9
1-{{(6R,7R)-7-amino-2-carboxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl)methyl}pyridinium iodide . . . . .	100988-63-4
(4S,5R,6R)-5-Acetylamino-4-azido-6-(1S,2R,3-triacetoxypropyl)-5,6-dihydro-4H-pyran-2-carboxylic acid methyl ester hydrate . . . . .	130525-58-5
2-(5-Methyl-2-phenyl-oxazol-4-yl)ethanol . . . . .	103788-65-4
[4-(methylthio)phenyl]acetic acid . . . . .	16188-55-9
tert-Butyl (diethoxyphosphoryl)acetate . . . . .	27784-76-5
4,6-Difluoroindan-1-one . . . . .	162548-73-4
(2-oxo-1-phenylpyrrolidin-3-yl)(triphenyl)phosphonium bromide . . . . .	148776-18-5
2-acetamido-2-deoxy-, $\beta$ -D-Mannopyranose . . . . .	7772-94-3
2-Bromo-4'-hydroxy-3'-(hydroxymethyl)acetophenone . . . . .	62932-94-9

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
[4-(methylsulfonyl)phenyl]acetic acid . . . . .	90536-66-6
Dihydroxyacetic acid, 2S-isopropyl-5R-methyl-1R-cyclohexyl ester . . . . .	111969-64-3
(4-Hydrazinophenyl)-N-methylmethanesulfonamide hydrochloride . . . . .	88933-16-8
1-(2,4-Difluorophenyl)-2-(1H-1,2,4-triazol-1-yl)-1-ethanone . . . . .	86404-63-9
(2RS,3SR)-3-(6-chloro-5-fluoro-4-pyrimidinyl)-2-(2,4-difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)-2-butanol hydrochloride	188416-20-8
2-Ethoxy-5-(4-ethyl-1-piperazinylsulfonyl)nicotinic acid . . . . .	247582-73-6
(25S)-25-cyclohexyl-5-O-demethyl-25-de(1-methylpropyl)-22,23-dihydroavermectin A <sub>1a</sub> . . . . .	142680-85-1
(25S)-25-cyclohexyl-5-demethoxy-25-de(1-methylpropyl)-22,23-dihydro-5-oxoavermectin A <sub>1a</sub> . . . . .	220119-16-4
4-Chloro-6-ethyl-5-fluoropyrimidine . . . . .	137234-74-3
4-(1-Bromoethyl)-6-chloro-5-fluoropyrimidine . . . . .	188416-28-6
(S)-2-{1-[2,3-Dihydrobenzofuran-5-yl]ethyl}-3-pyrrolidinyl]-2,2-diphenylacetonitrile . . . . .	252317-48-9
N-methyl-4-nitro-N-[2-(4-nitrophenoxy)ethyl]phenethylamine . . . . .	115287-37-1
4-Amino-N-[2-(4-aminophenoxy)ethyl]-N-methylphenylethylamine . . . . .	115256-13-8
(R)-1-Acetyl-3-(1-methyl-2-pyrrolidinylmethyl)-5-[(E)-2-(phenylsulfonyl)vinyl]-1H-indole . . . . .	188113-71-5
(R)-3-(1-Methyl-2-pyrrolidinylmethyl)-5-[(E)-2-(phenylsulfonyl)vinyl]-1-indole . . . . .	180637-89-2
4-[2-Ethoxy-5-(4-methyl-1-piperazinylsulfonyl)benzamido]-1-3-propyl-1H-pyrazole-5-carboxamide . . . . .	200575-15-1
[2R-(2R*,3S*,4R*,5R*,8R*,10R*,11R*,12S*,13S*,14R*)]-, 13-[(2,6-dideoxy-3-C-methyl-3-O-methyl- $\alpha$ -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- $\beta$ -D-xylo-hexopyranosyl]oxy]-1-Oxa-6-azacyclopentadecan-15-one . . . . .	76801-85-9
2-Quinoxalinecarboxaldehyde 1,4-dioxide dimethyl acetal . . . . .	32065-66-0
6,6-Dibromopenicillanic acid, 1,1-dioxide . . . . .	76646-91-8
Carbamic acid 2-(2-chlorophenyl)-2-hydroxyethyl ester . . . . .	194085-75-1
7-[2-(2-Amino-5-chloro-thiazol-4-yl)-2-hydroxyiminoacetylamino]-3-[3-(2-amino-ethylsulfanyl methyl)pyridin-4-ylsulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid . . . . .	189448-35-9
(2,6-Dimethylphenoxy)acetic acid . . . . .	13335-71-2
N'-((1S)-1-[(2,5-Dioxopyrrolidin-1-yl)oxy]carbonyl)-2-methylpropyl)-N-methyl-N-[(2-isopropyl-1,3-thiazol-4-yl)methyl]urea . . . . .	224631-15-6
(2S)-3-Methyl-2-(2-oxotetrahydropyrimidin-1(2H)-yl)butanoic acid . . . . .	192725-50-1
5-Methoxy-2H-chromen-2-one . . . . .	51559-36-5
3,4-di(1H-indol-3-yl)-1-methyl-1H-pyrrole-2,5-dione . . . . .	113963-68-1
(2R)-1-{4-[(1aR,10bS)-1,1-difluoro-1,1a,6,10b-tetrahydrodibenzo[a,e]cyclopropane[c]cyclohepten-6-yl]-1-piperazinyl}-3-(5-quinolinyl oxy)-2-propanol trihydrochloride . . . . .	167465-36-3
(3S)-3-{2-[(Methylsulfonyl)oxy]ethoxy}-4-(trytoxy)butyl methanesulfonate . . . . .	170277-77-7
6-(Benzylxy)-3-bromo-2-(4-methoxyphenyl)-1-benzothiophene, 1-oxide . . . . .	182133-09-1
(7S)-7-Methyl-5-(4-nitrophenyl)-7,8-dihydro-5H-[1,3]dioxolo[4,5-g]isochromene . . . . .	196303-01-2
Blood-coagulation factor XIVa . . . . .	42617-41-4
4-[2-(1-piperidinyl)ethoxy]benzoyl chloride hydrochloride in the form of a solution in 1,2-dichloroethane . . . . .	84449-81-0
N-(4-Amino-1-benzyl-3-hydroxy-5-phenyl-pentyl)-3-methyl-2-(2-oxo-tetrahydro-pyrimidin-1-yl)-butyramide; compound with 5-oxo-pyrrolidine-2-carboxylic acid . . . . .	192726-06-0
(3Z)-4-(Aminomethyl)-3-pyrrolidinone O-methyloxime dihydrochloride . . . . .	197143-35-4
[(2S)-7-iodo-4-methyl-3-oxo-2,3,4,5-tetrahydro-1H-1,4-benzodiazepin-2-yl]acetic acid . . . . .	210288-67-8
{(2S)-4-methyl-7-[2-(methoxy)-2-oxoethyl]-3-oxo-2,3,4,5-tetrahydro-1H-1,4-benzodiazepin-2-yl}acetic acid . . . . .	193077-87-1
1-[3-(cyclopentyloxy)-4-(methoxy)phenyl]-4-oxocyclohexanecarbonitrile . . . . .	152630-47-2
Dimethyl 4-cyano-4-[3-(cyclopentyloxy)-4-(methoxy)phenyl]heptanedioate . . . . .	152630-48-3
2-[(Carboxyacetyl)amino]benzoic acid . . . . .	53947-84-5
2-(4-Oxopentyl)-1H-isoindole-1,3(2H)-dione . . . . .	3197-25-9
4-Methyl-2,6-bis(methoxy)-5-[(3-(trifluoromethyl)phenyl)oxy]-8-quinolinamine . . . . .	106635-86-3
4-Methyl-2,6-bis(methoxy)-8-nitro-5-[(3-(trifluoromethyl)phenyl)oxy]quinoline . . . . .	189746-15-4
5-Chloro-4-methyl-2,6-bis(methoxy)-8-nitroquinoline . . . . .	189746-21-2

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
5-Chloro-4-methyl-2,6-bis(methyloxy)quinoline . . . . .	189746-19-8
4-Methyl-2,6-bis(methyloxy)quinoline . . . . .	6340-55-2
4-Methyl-6-(methyloxy)-2(1H)-quinolinone . . . . .	5342-23-4
Methyl (1S,2S)-1-(1,3-benzodioxol-5-yl)-3-[2-hydroxy-4-(methyloxy)phenyl]-5-(propyloxy)-2,3-dihydro-1H-indene-2-carboxylate . . . . .	167256-05-5
Methyl (1S,2S)-1-(1,3-benzodioxol-5-yl)-3-{4-(methyloxy)-2-[(phenylmethyl)oxy]phenyl}-5-(propyloxy)-2,3-dihydro-1H-indene-2-carboxylate . . . . .	191106-49-7
[2-Bromo-5-(propyloxy)phenyl][2-hydroxy-4-(methyloxy)phenyl]methanone . . . . .	190965-45-8
(R)-(-)-α-(p-Chlorophenyl)-4-(p-fluorobenzyl)-1-piperidineethanol . . . . .	127293-57-6
(R)-(-)-α-(p-Chlorophenyl)-4-(p-fluorobenzyl)-1-piperidineethanol HCl salt . . . . .	178460-82-7
1-[2-(4-phenylphenyl)ethyl]-4-[3-(trifluoromethyl)phenyl]-1,2,5,6-tetrahydropyridine, hydrochloride . . . . .	188396-54-5
N-(1-{2-[2-(3,4-difluorophenyl)-4-(phenylcarbonyl)morpholin-2-yl]ethyl}-4-phenyl(4-piperidyl))(dimethylamino)carboxamide, hydrochloride . . . . .	181640-09-5
1-ethyl-9-methoxy-2,3,5,6,7-pentahydropyridino[2,1-a]β-carbolin-4-one . . . . .	244080-24-8
N-[(1-{[2-(diethylamino)ethyl]amino}-8-methoxy-10-oxobenzo[e]benzo[2,3-β]thiin-4-yl)methyl]carboxamide . . . . .	155990-20-8
2-{N-[4-(4-chloro-2,5-dimethoxyphenyl)-5-(2-cyclohexylethyl)(1,3-thiazol-2-yl)]carbamoyl}-5,7-dimethylindolinyl)acetic acid, potassium salt . . . . .	221671-63-2
[3-(2-amino-1-hydroxyethyl)-4-fluorophenyl](methylsulfonyl)amine . . . . .	137431-02-8
3-(2-amino-1-hydroxyethyl)-4-methoxybenzenesulfonamide . . . . .	189814-01-5
3-(Methoxymethyl)-7-(4,4,4-trifluorobutoxy)-4,5,10,3aH-1,3-oxazolidino[3,4-a]quinolin-1-one . . . . .	176773-87-8
(5S)-5-(Methoxymethyl)-3-[6-(4,4,4-trifluorobutoxy)benzo[d]isoxazol-3-yl]-1,3-oxazolidin-2-one . . . . .	185835-97-6
N-(3,4-dichlorophenyl)-N-[3-(indan-2-ylmethylamino)propyl]-2-5,6,7,8-tetrahydronaphthalylcarboxamide . . . . .	170361-49-6
7,8-Dihydro-6-oxa-1,8a-diazaacenaphthylene-2-carboxylic acid 8-methyl-8-aza-bicyclo[3.2.1]oct-3-yl ester . . . . .	223570-85-2
N-[(2R)-1,4-diazabicyclo[2.2.2]oct-2-yl)methyl](8-amino-7-chloro(2H,3H-benzo[e]1,4-dioxan-5-yl))carboxamide . . . . .	186348-69-6
5-(8-amino-7-chloro(2H,3H-benzo[e]1,4-dioxan-5-yl))-3-[1-(2-phenylethyl)(4-piperidyl)]-1,3,4-oxadiazolin-2-one . . . . .	191023-43-5
2-{7-fluoro-2-oxo-4-[2-(4-thiopheno[3,2-c]pyridin-4-yl)piperazinyl]ethyl}hydroquinolylacetamide . . . . .	189003-92-7
6-Fluoro-9-methyl-2-phenyl-4-(pyrrolidinylcarbonyl)-2-hydro-β-carbolin-1-one . . . . .	205881-86-3
2-{(3-[5-(6-methoxynaphthyl)(1,3-dioxan-2-yl)]propyl)methylamino)-N-methylacetamide . . . . .	192201-93-7
N-1-(tert-butoxycarbonyl)-N-2-[4-(pyridin-2-yl)benzyl]hydrazine . . . . .	198904-85-7
N-(tert-butoxycarbonyl)-2(S)-amino-1-phenyl-2(R)-3,4-epoxybutane . . . . .	98760-08-8
N-methoxycarbonyl-L-tert-leucine . . . . .	162537-11-3
N-1-(tert-butoxycarbonyl)-N-2-[2(S)-hydroxy-3(S)-(tert-butoxycarbonyl)-4-phenylbutyl]-N-2-[4-(pyridin-2-yl)benzyl]hydrazine . . . . .	198904-86-8
Cephalosporin D cyclohexylamine salt . . . . .	54122-50-8
(R*,S*)-(±)-{(4-phenylbutyl)[1-(propionyloxy)isobutoxy]phosphinyl}acetic acid . . . . .	123599-82-6
1,4-Dithia-7-azaspiro[4.4]nonane-8-carboxylic acid, hydrobromide . . . . .	75776-79-3
3-Methylpyridine-2-carboxylic acid . . . . .	4021-07-2
5-(4-fluorophenyl)-5-oxopentanoic acid . . . . .	149437-76-3
4-[(4-fluorophenyl)imino]methylphenol . . . . .	3382-63-6
(4S)-3-[(5R)-5-(4-fluorophenyl)-5-hydroxypentanoyl]-4-phenyl-1,3-oxazolidin-2-one . . . . .	189028-95-3
5-Bromotryptophan . . . . .	6548-09-0
Tert-Butyl(6-{2-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methanesulfonyl)amino]pyrimidin-5-yl}vinyl)(4R,6S)-2,2-dimethyl[1,3]dioxan-4-yl) acetate . . . . .	289042-12-2
(3R)-N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]-1-propanamine hydrochloride . . . . .	114247-09-5
methyl (2R)-2-amino-3-(1H-indol-3-yl)propanoate hydrochloride . . . . .	14907-27-8
Sodium ({3-[amino(oxo)acetyl]-1-benzyl-2-ethyl-1H-indol-4-yl}oxy)acetate . . . . .	172733-42-5
2-Amino-bicyclo[3.1.0]hexane-2,6-dicarboxylic acid; hydrate . . . . .	209216-09-1
tert-Butyl (4S)-4-ethyl-4,6-dihydroxy-3,10-dioxo-3,4,8,10-tetrahydro-1H-pyrano[3,4-f]indolizine-7-carboxylate . . . . .	183434-04-0
(4S)-4,11-diethyl-4,9-dihydroxy-1H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione . . . . .	86639-52-3

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
(3 $\alpha$ R, 4R, 5R, 6 $\alpha$ S)-5-Hydroxy-4-[(3R)-3-hydroxy-5-phenylpentyl]hexahydro-2H-cyclopenta[b]furan-2-one	145667-75-0
1-Benzyl-4H-imidazo[4,5,1-ij]quinolin-2(1H)-one	227025-33-4
(5R,6R)-1-benzyl-5-hydroxy-6-(methylamino)-5,6-dihydro-4H-imidazo[4,5,1-ij]quinolin-2(1H)-one	269731-84-2
3-{(2S,3S)-2-hydroxy-3-[(3-hydroxy-2-methylbenzoyl)amino]-4-phenylbutanoyl}-5,5-dimethyl-N-(2-methylbenzyl)-1,3-thiazolidine-4-carboxamide	186538-00-1
(2S)-3-chloropropane-1,2-diol	60827-45-4
Methyl (2R)-3-{2-[(5R)-3-(4-cyanophenyl)(4,5-dihydroisoxazol-5-yl)]acetylamino}-2-(butoxycarbonylamino)propanoate	188016-51-5
3-((1R)-1-phenylethyl)(4S)-6-chloro-4-(2-cyclopropylethynyl)-4-(trifluoromethyl)-1,3,4-trihydroquinazolin-2-one	247565-04-4
4-((1E)-2-cyclopropylvinyl)(4S)-6-chloro-4-(trifluoromethyl)-1,3,4-trihydroquinazolin-2-one	214287-99-7
4-amino-1-[(2R,5S)-2,5-dihydro-5-(hydroxymethyl)-2-furanyl]-5-fluoro-2(1H)-pyrimidone	134379-77-4
(4S)-6-chloro-4-(2-cyclopropylethynyl)-4-(trifluoromethyl)-1,3,4-trihydroquinazolin-2-one	214287-88-4
2-(Benzoyloxymethyl)-4-isopropyl-1H-imidazole	178982-67-7
5-[3,5-dichlorophenyl]thio]-4-(1-methylethyl)-1-(4-pyridinylmethyl)-1H-imidazole-2-methanol	178981-89-0
2-(2-chloro-4-iodophenylamino)-N-(cyclopropylmethoxy)-3,4-difluorobenzamide	212631-79-3
6-(2-(4-(4-fluorobenzyl)piperidin-1-yl)ethylsulfinyl)benzo[d]oxazol-2(3H)-one	253450-09-8
tert-butyl (2-((4,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)methyl)cyclohexyl)methylcarbamate	227626-65-5
3-((2-(aminomethyl)cyclohexyl)methyl)-1,2,4-oxadiazol-5(4H)-one	227625-35-6
3,4'-Dichloro-2'-(5-chloro-2-pyridyl)carbamoyl]-6'-methoxy-4-[(2-methylamino-1H-imidazol-1-yl)methyl]thiophene-2-carboxanilide	229336-92-9
(1AR,10bS)-1,1-difluoro-1,1a,6,10b-tetrahydrodibenzo[a,e]cyclopropa[c]cyclohepten-6-ol	167155-76-2
(2S)-2-((3[(tert-butoxycarbonyl)amino]-2,2-dimethylpropanoyl)oxy)-4-methylpentanoic acid	186193-10-2
(3S,10R,16S)-10-(3-Chloro-4-methoxybenzyl)-3-isobutyl-6,6-dimethyl-16-((1S)-1-[(2R,3R)-3-phenyloxiranyl]ethyl)-1,4-dioxa-8,11,diazacyclohexadec-13-ene-2,5,9,12-tetrone	204990-60-3
3-Amino-2-pyrazinecarboxylic acid	5424-01-1
Methyl 3-amino-2-pyrazinecarboxylate	16298-03-6
2,4(3H,8H)-Pteridinedione	487-21-8
1-(2,3-Dichloro-4-hydroxyphenyl)-1-butanone	2350-46-1
[(4-Butanoyl-2,3-dichlorophenyl)oxy]acetic acid	1217-67-0
(1R)-1-Hydroxy-1-(3-hydroxyphenyl)-2-propanone	82499-20-5
N-[2-Chloro-3-(dimethylamino)-2-propenylidene]-N-methylmethanaminium hexafluorophosphate	249561-98-6
1-(6-Methyl-3-pyridinyl)-2-[4-(methylsulfonyl)phenyl]ethanone	221615-75-4
3-[(4S)-4-Sulfanyl-L-prolyl]amino]benzoic acid monohydrochloride	219909-83-8
(1R)-1-[3,5-Bis(trifluoromethyl)phenyl]ethanol	127852-28-2
(1R)-1-[3,5-Bis(trifluoromethyl)phenyl]ethanol as a solution in acetonitrile	127852-28-2
4-(1H-1,2,4-Triazol-1-ylmethyl)phenylamine	119192-10-8
2-[5-(1H-1,2,4-Triazol-1-ylmethyl)-1H-indol-3-yl]ethanol	160194-39-8
2-Bromo-1-[4-(methylsulfonyl)phenyl]ethanone	50413-24-6
4-(4-Chloro-1,2,5-thiadiazol-3-yl)morpholine	30165-96-9
4-(4-Chloro-1,2,5-thiadiazol-3-yl)morpholine as a solution in toluene	30165-96-9
[(5S)-3-(1,1-Dimethylethyl)-2-phenyl-1,3-oxazolidin-5-yl]methanol	194861-99-9
N-(Butylsulfonyl)-O-[4-(4-pyridinyl)butyl]-L-tyrosine	149490-61-9
N-(Butylsulfonyl)-L-tyrosine	149490-60-8
Mixture of sennoside A and B	517-43-1
Mixture of sennoside A and B calcium salts	52730-36-6
Mixture of sennoside A and B calcium salts	52730-37-7
(2-Mercapto-4-methyl-thiazol-5-yl)acetic acid	34272-64-5
2,4-Dichloro-5-methanesulfonylbenzoic acid	2736-23-4

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
1-[[(6R,7R)-7-[(Z)-2-(5-Amino-1,2,4-thiadiazol-3-yl)-2-(methoxyimino)acetyl]amino]-2-carboxylat-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]imidazo[1,2-b]pyridazin-4-iun monohydrochloride . . . . .	197897-11-3
Diphenylmethyl (6R,7R)-3-methylsulfonyloxy-8-oxo-7-phenylacetylamino-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate . . . . .	92096-37-2
Diphenymethyl (6R,7R)-7-amino-3-methanesulfonyloxy-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate monohydrochloride . . . . .	127111-98-2
Diphenylmethyl (6R,7R)-7-[(Z)-2-(2-tert-butoxycarbonylaminothiazol-4-yl)-2-(triphenylmethoxyimino)acetamido]-8-oxo-3-(1H-1,2,3-triazol-4-yl)thiomethylthio-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate . . . . .	140128-37-6
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-L-alanine . . . . .	35661-39-3
N- $\alpha$ -Fluorenylmethoxycarbonyl-N- $\beta$ -trityl-L-asparagine . . . . .	132388-59-1
N- $\alpha$ -Fluorenylmethoxycarbonyl-L-leucine . . . . .	35661-60-0
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-L-aspartic acid $\beta$ -t-butyl ester . . . . .	71989-14-5
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-L-glutamic acid $\gamma$ -t-butyl ester . . . . .	71989-18-9
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-N- $\gamma$ -trityl-L-glutamine . . . . .	132327-80-1
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-L-glutamine . . . . .	71989-20-3
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-N-im-trityl-L-histidine . . . . .	109425-51-6
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-L-isoleucine . . . . .	71989-23-6
N- $\alpha$ -9-Fluorenylmethoxycarbonyl-N- $\alpha$ -t-butyloxycarbonyl-L-lysine . . . . .	71989-26-9
Dithiothreitol . . . . .	3483-12-3
L-Glutamine, N-acetyl-O-(1,1-dimethylethyl)-L-tyrosyl-O-(1,1-dimethylethyl)-L-threonyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-L-isoleucyl-1-(triphenylmethyl)-L-histidyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-L-isoleucyl-L- $\alpha$ -glutamyl-L- $\alpha$ -glutamyl-O-(1,1-dimethylethyl)-L-seryl-N-trityl-L-glutamyl-N-trityl-L-asparaginyl-N-trityl-L-glutaminyl-, 10,11-bis(1,1-dimethylethyl) ester . . . . .	244191-88-6
L-Leucine, N-[(9H-fluoren-9-ylmethoxy)carbonyl]-L- $\alpha$ -glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L- $\alpha$ -glutamyl-N-trityl-L-glutamyl-L- $\alpha$ -glutamyl-L-leucyl-L- $\alpha$ -glutamyl-, 1,4,6,9-tetrakis(1,1-dimethylethyl) ester . . . . .	244191-94-4
L-Tryptophan, N-[(9H-fluoren-9-ylmethoxy)carbonyl]-L- $\alpha$ -aspartyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-L-alanyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-N-trityl-L-asparaginyl-1-[(1,1-dimethylethoxy)carbonyl]-, 1-(1,1-dimethylethyl) ester . . . . .	244191-96-6
L-Phenylalaninamide, L- $\alpha$ -aspartyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-L-alanyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-N-trityl-L-asparaginyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-, 1,1-dimethylethyl ester . . . . .	244191-95-5
L-Phenylalaninamide, N-[(9H-fluoren-9-ylmethoxy)carbonyl]-L- $\alpha$ -glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L- $\alpha$ -glutamyl-N-trityl-L- $\alpha$ -glutamyl-L-leucyl-L- $\alpha$ -glutamyl-L-leucyl-L- $\alpha$ -glutamyl-L- $\alpha$ -aspartyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-L-alanyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-N-trityl-L-asparaginyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-, pentakis(1,1-dimethylethyl) ester . . . . .	244244-29-9
L-Phenylalaninamide, L- $\alpha$ -glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L- $\alpha$ -glutamyl-N-trityl-L-glutamyl-L- $\alpha$ -glutamyl-L-leucyl-L- $\alpha$ -glutamyl-L-leucyl-L- $\alpha$ -aspartyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-L-alanyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-N-trityl-L-asparaginyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-, pentakis(1,1-dimethylethyl) ester, monohydrochloride . . . . .	244244-31-3

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
L-Phenylalaninamide, N-acetyl-O-(1,1-dimethylethyl)-L-tyrosyl-O-(1,1-dimethylethyl)-L-threonyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-L-isoleucyl-1-trityl-L-histidyl-O-(1,1-dimethylethyl)-L-seryl-L-leucyl-L-isoleucyl-L- $\alpha$ -glutamyl-L- $\alpha$ -glutamyl-O-(1,1-dimethylethyl)-L-seryl-N-trityl-L-glutaminyl-N-trityl-L-asparaginyl-N-trityl-L-glutaminyl-L- $\alpha$ -glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L- $\alpha$ -glutamyl-N-trityl-L-glutaminyl-L- $\alpha$ -glutamyl-L-leucyl-L-leucyl-L- $\alpha$ -glutamyl-L-leucyl-L- $\alpha$ -aspartyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-N-trityl-L-asparaginyl-1-[(1,1-dimethylethoxy)carbonyl]-L-tryptophyl-, heptakis(1,1-dimethylethyl) ester	244244-26-6
N- $\alpha$ -Fluorenylmethoxycarbonyl-O-t-butyl-L-serine	71989-33-8
N- $\alpha$ -Fluorenylmethoxycarbonyl-O-t-butyl-L-threonine	71989-35-0
N- $\alpha$ -Fluorenylmethoxycarbonyl-N-in-t-butyloxycarbonyl-L-tryptophan	143824-78-6
N- $\alpha$ -Fluorenylmethoxycarbonyl-O-t-butyl-L-tyrosine	71989-38-3
L-Phenylalanine amide	65864-22-4
N-Hydroxy-7-azabenzotriazole	39968-33-7
3,5,9-trioxa-4-phosphaheptacosan-1-aminium,4-hydroxy-7-methoxy-N,N,N-trimethyl-, inner salt, 4-oxide, (R)-	77286-66-9
9, 11, 15-trioxa-6-aza-10-phosphatritriacont-24-enoic acid, 10-hydroxy-5, 16-dioxo-13-[(9Z)-1-oxo-9-octadecenyl]oxy]-10-oxide, (13R,24Z)-	228706-30-7
3,5,9-Trioxa-4-phosphaheptacos-18-en-1-aminium, 4-hydroxy-N,N,N-trimethyl-10-oxo-7-[(9Z)-1-oxo-9-octadecenyl]oxy]-inner salt, 4-oxide, (7R,18Z)-	4235-95-4
(2R,3S)-2-[(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)morpholine hydrochloride	171482-05-6
2-Hydroxy-4-(phenylmethyl)-3-morpholinone	287930-73-8
(2R)-2-[(1R)-1-[3,5-Bis(trifluoromethyl)phenyl]ethyl]oxy]-4-(phenylmethyl)-3-morpholinone	287930-75-0
(1S)-1-[3-[(E)-2-(7-Chloro-2-quinolinyloxy)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]-1-propanol	287930-77-2
Methyl 2-[(3S)-3-[3-[(E)-2-(7-chloro-2-quinolinyloxy)ethenyl]phenyl]-3-hydroxypropyl]benzoate monohydrate	287930-78-3
5-[(2,4-Dioxo-1,3-thiazolidin-5-yl)methyl]-2-(methoxy)-N-[[4-(trifluoromethyl)phenyl]methyl]benzamide	213252-19-8
[(1S,4R)-4-Aminocyclopent-2-en-1-yl]methanol hydrochloride	168960-19-8
(4-Phenylbutyl)-phosphinic acid	86552-32-1
4-Cyclohexyl-pyrrolidine-2-carboxylic acid	103201-78-1
2-Methyl-2-phenyl-propionic acid ethyl ester	2901-13-5
1H-Pyrrolizine-1,7-dicarboxylic acid, 2,3-dihydro-, 1-methyl ester	92992-17-1
6,6-Dimethyl-2(E)-Hepten-4-yn-1-ol	173200-56-1
5-amino-2,4,6-triiodo-3-(N-2-hydroxyethyl) carbamoyl benzoic acid	22871-58-5
(R)-2-Benzoyloxycarbonylamino-3-phenylsulfanylpropionic acid methyl ester	153277-33-9
(1S,5R,6S)-5-(1-Ethylpropoxy)-7-oxabicyclo[4.1.0]hept-3-ene-3-carboxylic acid ethyl ester	204254-96-6
(3R,4S,5R)-5-Azido-3-(1-ethylpropoxy)-4-hydroxy-cyclohex-1-enecarboxylic acid ethyl ester	204254-98-8
(1R,5R,6R)-5-(1-Ethylpropoxy)-7-aza-bicyclo[4.1.0]hept-3-ene-3-carboxylic acid ethyl ester	204255-02-7
(3R,4R,5S)-4-Acetylamino-5-azido-3-(1-ethylpropoxy)cyclohex-1-enecarboxylic acid ethyl ester	204255-06-1
(2S)-hydroxy(phenyl)ethanoic acid compound with (1S)-3-(dimethylamino)-1-(2-thienyl)-1-propanol (1:1)	287737-72-8
(2S-3R)-4-Dimethylamino-3-methyl-1,2-diphenylbutan-2-ol in the form of a solution in toluene	38345-66-3
Benzyl (1S,2R)-1-carbamoyl-2-hydroxypropylcarbamate	49705-98-8
Methanesulfonic acid 2-benzyloxycarbonylamino-2-carbamoyl-1-methyl-ethyl ester	80082-51-5
1-Butanaminium, N,N,N-tributyl-, salt with (2S-trans)-2-methyl-4-oxo- 3 -[(phenylmethoxy)carbonyl]amino]-1-azetidinesulfonic acid (1:1)	80082-62-8
(2S,3S)-3-amino-2-methyl-4-oxoazetidine-1-sulfonic acid	80082-65-1
Potassium 3-[2-(2-formylaminothiazol-4-yl)-2-oxoacetyl]amino]-2-methyl-4-oxoazetidine-1-sulfonate	88023-65-8
(2S,4S)-4-phenylpyrrolidine-2-carboxylic acid	96314-26-0
1-Bromo-2-methyl propyl propionate	158894-67-8
1-Benzoyl-4-hydroxy-pyrrolidine-2-carboxylic acid	31560-19-7
1-Benzoyl-4-hydroxy-pyrrolidine-2-carboxylic acid methyl ester	31560-20-0
(Cis)-1-Benzoyl-4-[(4-methylsulfonyl)oxy]-L-proline	120807-02-5

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
(R)-5-(1,3,6,2-dioxazaborocan-2-yl)-1-methyl-2-tritylisouindoline	223595-20-8
Ethyl 7-bromo-1-cyclopropyl-8-(difluoromethoxy)-1,4-dihydro-4-oxoquinoline-3-carboxylate	194805-07-7
Ethyl 1-cyclopropyl-8-(difluoromethoxy)-1,4-dihydro-7-((1R)-1-methyl-2-tritylisouindolin-5-yl)-4-oxoquinoline-3-carboxylate	194804-45-0
4-(Nitroxy)butyl (2S)-2-(6-methoxy-2-naphthyl)propanoate	163133-43-5
5-(3-Chloropropyl)-3-methylisoxazole	130800-76-9
Phenol, 2, 2'-(4-hydroxyphenyl)methylene]bis[4-[(5-methyl-1H-tetrazol-1-yl)imino]methyl]-	235106-62-4
4-Amino-5-chloro-2-methoxy-N-(3-methoxy-piperidin-4-yl)-benzamide	221180-26-3
(2-Chlorophenyl)acetic acid	2444-36-2
(2R)-2-(2-chlorophenyl)-2-hydroxyethanoic acid	52950-18-2
2-thienylacetonitrile	20893-30-5
2,2-Dimethylpropionyloxymethyl(6R,7R)-7-[ (2z)-[2-[[2 ]-[(1,1-dimethylethoxy)carbonyl]amino]-4-thiazolyl](methoxyimino)acetyl]amino]-8-oxo-5-thia-1-azabicyclo[4.2.0]octa-2-ene-2-carboxylate	135790-89-5
(6R,7R)-7-Amino-8-oxo-5-thia-1-azabicyclo[4.2.0]octa-2-ene-2-carboxylic acid	36923-17-8
Diphenylmethyl(2S,5R)-6,6-dibromo-3,3-dimethyl-7-oxo-4-thia-1-[3.2.0]heptane-2-carboxylate 4-oxide	113891-01-3
1-(2,3-Dichlorophenyl) piperazine	119532-26-2
2-(2S,3R)-2-(1S)-2-[(4-Chlorophenyl)sulfanyl]-1-methyl-2-oxoethyl-3-[(1S)-1-hydroxyethyl]-4-oxoazetanylic acid	105318-28-3
3-(Methylphenylamino)-2-propenal	14189-82-3
N,N'-Bis(phenylmethyl)-1,2-ethanediamine diacetate	140-28-3
5,6,7,8-Tetrahydroquinoline	10500-57-9
O-[(2Z)-2-(2-Amino-1,3-thiazol-4-yl)-2-(methoxyimino)ethanoyl] 0,0-diethyl thiophosphate	162208-27-7
Sodium (2R)-cyclohexa-1,4-dien-1-yl {[[(1E)-1-(methoxycarbonyl)prop-1-enyl]amino}acetate	26774-89-0
(2R)-2-Amino-2-phenylacetamide	6485-67-2
{[(6-Ethyl-4,5-dioxohexahydroxypyridazin-3-yl)carbonyl]amino}(4-hydroxyphenyl)acetic acid	62893-24-7
N-[2-Fluoro-5-({3-[(E)-2-pyridin-2-ylvinyl]-1H-indazol-6-yl}amino)phenyl]-1,3-dimethyl-1H-pyrazole-5-carboxamide	319460-94-1
N-Methyl-2-({3-[(E)-2-pyridin-2-y vinyl]-1H-indazol-6-yl}thio)benzamide	319460-85-0
8-Fluoro-2-{4-[(methylamino)methyl]phenyl}-1,3,4,5-tetrahydro-6H-azepino[5,4,3-cd]indol-6-one	283173-50-2
2-Oxo-bicyclo[3.1.0]hexane-6-carboxylic acid ethyl ester	134176-18-4
4-[2-(2-amino-4-oxo-4,7-dihydro-3H-pyrrolo[2,3-d]pyrimidin-5-yl)ethyl]benzoic acid	137281-39-1
(3S)-3-{2-[(Methylsulfonyl)oxy]ethoxy}-4-(trityloxy)butyl methanesulfonate in the form of a solution in N,N-dimethyl-Formamide	170277-77-7 & 68-12-2
8,10-Dioxospiro[bicyclo[3.1.0]hexane-2,5'-imidazolidine]-6-carboxylic acid	186462-71-5
3-(Methylamino)-1-phenyl-1-propanol	42142-52-9
4-[2-(1-piperidinyl)ethoxy]benzoyl chloride hydrochloride	84449-81-0
(2S)-2-[(S)-(2-ethoxyphenoxy)(phenyl)methyl]morpholine	98819-76-2
(1S,4R)-4-Hydroxycyclopent-2-en-1-yl acetate	60176-77-4
(2R,3S,5S)-5-(4-(Benzoylamino)-2-oxo-1(2H)-pyrimidinyl)-2-[(bis(4-methoxyphenyl)(phenyl)methoxy]methyl]tetrahydrofuranyl 2-cyanoethyl diisopropylamidophosphite	102212-98-6
(2R,3S,5S)-2-[(bis(4-methoxyphenyl)(phenyl)methoxy]methyl]-5-[2-(isobutyrylamino)-6-oxo-1,6-dihydro-9H-purin-9-yl]tetrahydrofuranyl 2-cyanoethyl diisopropylamidophosphite	93183-15-4
(2R,3S,5S)-2-[(bis(4-methoxyphenyl)(phenyl)methoxy]methyl]-5-(5-methyl-2,4-dioxo-3,4-dihydro-1(2H)-pyrimidinyl)tetrahydrofuranyl 2-cyanoethyl diisopropylamidophosphite	98796-51-1
(2R,3S,5S)-5-[6-(Benzoylamino)-9H-purin-9-yl]-2-[(bis(4-methoxyphenyl)(phenyl)methoxy]methyl]tetrahydrofuranyl 2-cyanoethyl diisopropylamidophosphite	98796-53-3
(±)-N-[1-Cyano-2-(4-hydroxyphenyl)-1-methylethyl]acetamide	31915-40-9
2-Pyrimidinecarbonitrile	14080-23-0
Dimethyl (o-methoxyphenoxy)malonate	150726-89-9
1-(4-Fluorobenzyl)-2-chlorobenzimidazole hydrochloride	84946-20-3
4-Amino-1-carbethoxypiperidine	58859-46-4

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
1-(4-chlorophenyl)cyclobutanecarbonitrile	28049-61-8
(1R)-1-[1-(4-chlorophenyl)cyclobutyl]-3-methylbutan-1-amine with (2S,3S)-2,3-dihydroxysuccinic acid	259729-93-6
3-Ethyl 5-methyl 2-[(2-aminoethoxy)methyl]-4-(2-chlorophenyl)-6-methyl-1,4-dihydropyridine-3,5-dicarboxylate	103129-82-4
(2S)-Cyclohexyl(hydroxy)phenylacetic acid	20585-34-6
Cyclohexyl(hydroxy)phenylacetic acid	4335-77-7
1,3-Benzenedimethanol, 1-[(1,1-dimethylethyl)amino]methyl]-4-(phenylmethoxy)-	56796-66-8
4-[(1R)-2-(tert-Butylamino)-1-hydroxyethyl]-2-(hydroxymethyl)phenol hydrochloride	50293-90-8
(1R)-2-(tert-butylamino)-1-[4-(benzyloxy)-3-(hydroxymethyl)phenyl]ethanol	174607-68-2
1-[4-(Benzoyloxy)-3-nitrophenyl]-2-bromoethanone	43229-01-2
(2S)-hydroxy(phenyl)acetic acid compound with (1R)-2-(4-methoxyphenyl)-1-methylethylamine (1:1)	188690-84-8
N1-{4-[4-(4-hydroxyphenyl)piperazino]phenyl}-1-[(1S,2S)-1-ethyl-2-methyl-3-phenoxypropyl]-1-hydrazinecarboxamide	345217-02-9
1-[1-(4-Chlorophenyl)cyclobutyl]-3-methylbutan-1-amine	84467-54-9
(1S)-1-[1-(4-Chlorophenyl)cyclobutyl]-3-methylbutan-1-amine with (2S,3S)-2,3-dihydroxysuccinic acid	389056-74-0
6-(5-Chloropyridin-2-yl)-5H-pyrrolo[3,4-b]pyrazine-5,7(6H)-dione	43200-82-4
6-(5-Chloropyridin-2-yl)-7-oxo-6,7-dihydro-5H-pyrrolo[3,4-b]pyrazin-5-yl piperazine-1-carboxylate	59878-63-6
N-[(2R,3S)-3-amino-2-hydroxy-4-phenylbutyl]-N-(2-methylpropyl)-4-aminobenesulfonamide	169280-56-2
3,10-Dibromo-8-chloro-5,6-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine	272107-22-9
1-[2-[(tert-Butoxycarbonyl)piperidin-4-yl]acetyl]-4-mesyloxypiperidine	440634-25-3
4-(2-Piperidinoethoxy)benzaldehyde	26815-04-3
2',4'-Dihydroxy-2-(4-hydroxyphenyl)acetophenone	17720-60-4
1-[2-hydroxy-4-[(tetrahydro-2H-pyran-2-yl)oxy]phenyl]-2-[4-[(tetrahydro-2H-pyran-2-yl)oxy]phenyl]ethanone	130064-21-0
2-(Dimethylamino)-2-phenylbutan-1-ol	58997-87-8
2,3-Dimethyl-4-nitropyridine 1-oxide	37699-43-7
5-(chloromethyl)-1,2-dihydro-3H-1,2,4-triazol-3-one	252742-72-6
(2R,3R)-2-[(Benzoyloxy)methyl]-4,4-difluoro-5-oxotetrahydrofuranyl benzoate	122111-01-7
(2-Butyl-1H-imidazol-5-yl)methanol	68283-19-2
Thiophene-2-carboxaldehyde	98-03-3
2-Iodo-3,4-dimethoxy-6-nitrobenzonitrile	192869-10-6
6-Amino-2-iodo-3,4-dimethoxybenzonitrile	192869-24-2
N-(1,2,3,4-Tetrahydro-5-isoquinolyl)methanesulfonamide hydrochloride	210538-75-3
4-Amino-5-ethyl-1-(2-methoxyethyl)-1H-pyrazole-3-carboxamide	334828-10-3
N-[3-Carbamoyl-5-ethyl-1-(2-methoxyethyl)-1H-pyrazol-4-yl]-2-ethoxy-5-(4-ethyl-1-piperazinylsulfonyl)nicotinamide	334828-19-2
1-{6-Ethoxy-5-[3-ethyl-6,7-dihydro-2-(2-methoxyethyl)-7-oxo-2H-pyrazolo[4,3-d]pyrimidin-5-yl]-3-pyridylsulfonyl}-4-ethylpiperazine	334826-98-1
1-{6-Ethoxy-5-[3-ethyl-6,7-dihydro-2-(2-methoxyethyl)-7-oxo-2H-pyrazolo[4,3-d]pyrimidin-5-yl]-3-pyridylsulfonyl}-4-ethylpiperazine benzenesulfonate	334827-99-5
2-[4-(Methylthio)phenoxy]benzaldehyde	364323-64-8
N,N-Dimethyl-2-[4-(methylthio)phenoxy]benzylamine hydrochloride	289717-37-9
3-[(Dimethylamino)methyl]-4-[4-(methylthio)phenoxy]benzenesulfonamide	364321-71-1
3-[(Dimethylamino)methyl]-4-[4-(methylthio)phenoxy]benzenesulfonamide (R,R)-tartrate	364323-49-9
Ethyl (S)-3-[(4,4-difluorocyclohexyl)carboxamido]-3-phenylpropanoate	376348-76-4
(S)-4,4-Difluoro-N-(3-hydroxy-1-phenylpropyl)cyclohexanecarboxamide	376348-77-5
(S)-4,4-Difluoro-N-(3-oxo-1-phenylpropyl)cyclohexanecarboxamide	376348-78-6
7,11-Methano-5H-cyclodeca [3,4]benz[1,2-b]oxet-5-one,12β-(acetoxy)-12-(benzoyloxy)-1,2α,3,4,4α,6,9,10,11,12,12α,12β-dodecahydro-9-11-trihydroxy-4α,8,13,13-tetramethyl-4-[(triethylsilyl)oxy]-,(2αR,4S,4αS,6R,9S,11S,12S,12αR,12βS)-	115437-18-8
7,11-Methano-5H-cyclodeca [3,4]benz[1,2-β]oxet-5-one,6,12β-bis(acetoxy)-12-(benzoyloxy)-1,2α,3,4,4α,6,9,10,11,12,12α,12β-dodecahydro-9-11-dihydroxy-4α,8,13,13-	115437-21-3

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**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
tetramethyl-4-[(triethylsilyl)oxy]-, (2αR,4S,4αS,6R,9S,11S,12S,12αR,12βS)-	
Benzene propanoic acid, β,-(benzoylamino)-α-(1-methoxy-1-methylethoxy)-	
(2αR,4S,4αS,6R,9S,11S,12S,12αR,12βS)-6,12-β-bis(acetoxy)-12-(benzoyloxy)-2α,3,4,4α,5,6,9,10,11,12,12-	
α,12β-dodecahydro-11-hydroxy-4α,8,13,13-tetramethyl-5-oxo-4-[(triethylsilyl)oxy]-7,11-methano-1H-	
cyclodeca[3,4]benz[1,2-b]oxet-9-yl ester (αR.β.S)-	149107-93-7
(3R, 4S)-rel-3-(Acetoxy)-4-phenyl-2-azetidinone	133066-59-8
1-Benzoyl-3-(1-methoxy-1-methyl-ethoxy)-4-phenyl-azetidin-2-one	149107-92-6
D-Glucopyranose, 2,3,4,6-tetrakis-O-(phenylmethyl)	6564-72-3
Carbonic acid, 4-[(5R,5aR,8aR,9S)-5,5a,6,8,8a,9-hexahydro-6-oxo-9-[[2,3,4,6-tetrakis-O-(phenylmethyl)-β-D-glucopyranosyl]oxy]furo[3',4':6,7]naphtho[2,3-d]-1,3-dioxol-5-yl]-2,6-dimethoxyphenyl phenylmethyl ester	270071-40-4
Uridine, 2'-bromo-2'-deoxy-5-methyl-, 3',5'-diacetate	110483-43-7
(S)-4-Benzyloxycarbonylamino-2-hydroxybutyric acid	40371-50-4
tert-Butyl (2S)-2-(hydroxymethyl)pyrrolidine-1-carboxylate	69610-40-8
1-(6-Amino-3,5-difluoropyridin-2-yl)-8-chloro-6-fluoro-7-(3-hydroxyazetidin-1-yl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid	189279-58-1
4-[(3-aminopyridin-2-yl)amino]phenol	78750-68-2
(2R,3R,4S)-4-(1,3-Benzodioxol-5-yl)-3-(ethoxycarbonyl)-2-(4-methoxyphenyl)pyrrolidinium (2S)-hydroxy(phenyl)acetate	195708-14-6
2-(4-Fluorophenyl)-4-(3-hydroxy-3-methylbutoxy)-5-[4-(methylsulfonyl)phenyl]pyridazin-3(2H)-one	221030-56-4
4'-Chloro-1,1'-biphenyl-4-carbaldehyde	80565-30-6
Ethyl 2-(3-formyl-4-isobutoxyphenyl)-4-methyl-1,3-thiazole-5-carboxylate	161798-03-4
Methyl N-[(benzyloxy)carbonyl]-L-valyl-D-isoleucylthreonyl-L-norvalinate	653574-13-1
L-Isoleucyl-L-arginyl-N-ethyl-L-prolinamide dihydrochloride	442526-89-8
N-Acetyl-N-methyl-glycyl-glycyl-L-valyl-D-isoleucyl-L-threonyl-L-norvalyl-L-isoleucyl-L-arginyl-N-ethyl-L-prolinamide acetate	251579-55-2
(+)-(S)-1-Phenyl-1,2,3,4-tetrahydroisoquinoline	118864-75-8
exo-8-Benzyl-3-(3-isopropyl-5-methyl-4H-1,2,4-triazol-4-yl)-8-azabicyclo[3.2.1]octane	423165-13-3
(Z)-5-[4-[2-(5-Ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione	136401-69-9
(1S,2S,3R,4S,7R,9S,10S,12R,15S)-4,12-bis(acetoxy)-15-((2R,3S)-3-(benzoylamino)-2-[4Z,7Z,10Z,13Z,16Z,19Z]-docosa-4,7,10,13,16,19-hexaenoyloxy)-3-phenylpropanoyloxy)-1,9-dihydroxy-10,14,17,17-tetramethyl-11-oxo-6-oxatetracyclo[11.3.1.03,10.04,7]heptadec-13-en-2-yl benzoate	199796-52-6
8-chloro-5-[(4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenoyl]-11-(4-methylpiperazin-1-yl)-5H-dibenzo[b,e][1,4]diazepine	225916-82-5
(6R,7R)-7-Amino-3-chloro-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid	53994-69-7
1,3,4-Thiadiazole-2-thiol	18686-82-3
6-chloro-4-(2-ethyl-1,3-dioxolan-2-yl)-2-methoxypyridin-3-yl)methanol	183433-66-1
Spiro[17H-cyclopenta[a]phenanthrene-17,2'(5'H)-furan], pregra-4,9(11)-diene-7,21-dicarboxylic acid deriv.	95716-70-4
1-(4,5-Dinitro-10-aza-tricyclo[6.3.1.0 <sup>2,7</sup> ]dodeca-2(7),3,5-trien-10-yl)-2,2,2-trifluoro-ethanone	230615-59-5
tert-Butyl (S)-1,2,3,4-tetrahydro-3-isoquinolinecarboxylate tosylate	79276-06-5
1-((1R,3R,5R)-2,6-dioxa-bicyclo[3.2.0]heptan-3-yl)-5-methylpyrimidine-2,4(1H,3H)-dione	7481-90-5
[S-(R*,S*)]-[2-Methyl-1-(1-oxopropoxy)propoxy](4-phenylbutyl)phosphinyl]acetic acid, cinchonidine (1:1) salt	467430-13-3
(2R,4αR,7R,8S,8αR)-7,8-bis(benzyloxy)hexahydro-2-methylpyrano[3,2-d][1,3]dioxin-6-ol	471863-88-4
9-(7,8-Bis-benzyloxy-2-methyl-hexahdropyrano[3,2-d][1,3]dioxin-6-yloxy)- 5-(4-hydroxy-3,5-dimethoxyphenyl)-5,8,8α,9-tetrahydro-5αH-furo[3',4':6,7]naphtho[2,3-d][1,3]dioxol-6-one	473799-30-3
(R)-2-(2-amino-5-chlorophenyl)-4-cyclopropyl-1,1,1-trifluorobut-3-yn-2-ol, monohydrochloride salt	214353-17-0
1-(2-amino-5-chlorophenyl)-2,2,2-trifluoroethane-1,1-diol, methane sulfonic acid salt (1:1.5)	467426-34-2
(3R)-3-Aminopentanenitrile, monomethanesulfonate	474645-97-1
(2-Ethyl-6-trifluoromethyl-1,2,3,4-tetrahydro-quinolin-4-yl)-carbamic acid methyl ester	474645-93-7
1-{2-[4-(2-Bromo-6-methoxy-3,4-dihydro-naphthalen-1-yl)-phenoxy]ethyl}pyrrolidine	180915-95-1
1-{2-[4-(6-Methoxy-3,4-dihydronaphthalen-1-yl)phenoxy]ethyl}pyrrolidine	180915-94-0

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**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
4,4-Difluorocyclohexylcarboxylic acid .....	122665-97-8
N-(3-acetylphenyl)-N-methyl-acetamide .....	325715-13-7
(3-Amino-1H-pyrazol-4-yl)-2-thienylmethanone .....	96219-87-3
10-Azatricyclo[6.3.1.0 <sup>2,7</sup> ]dodeca-2,4,6-triene, hydrochloride .....	230615-52-8
N-(3-methoxy-5-methylpyrazin-2-yl)-2-(4-[1,3,4-oxadiazol-2-yl]phenyl)pyridine-3-sulfonamide .....	186497-07-4
1-Cyclopentyl-3-ethyl-1,4,5,6-tetrahydropyrazolo[3,4-c]pyridin-7-one .....	162142-14-5
1-Cyclopentyl-3-ethyl-6-(4-methoxybenzyl)-1,4,5,6-tetrahydropyrazolo[3,4-c]pyridin-7-one, p-toluenesulfonate .....	303752-13-8
3-(4-Trifluoromethylphenylamino)pentanoic acid amide .....	667937-05-5
(1R,5R)-2-(3-Benzyl-7-oxo-4-thia-2,6-diaza-bicyclo[3.2.0]hept-2-en-6-yl)-3-methyl -but-2-enoic acid 4-nitrobenzyl ester .....	192049-49-3
(2S)-Tetrahydrofuran-2-carboxylic acid .....	87392-07-2
(6R,7R)-7-Amino-8-oxo-3-[(2S)-tetrahydrofuran-2-yl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid 4-nitrobenzyl ester hydrochloride .....	655233-39-9
N-Formyl-L-leucine (1S,3Z,6Z)-1-[(2S,3S)-3-hexyl-4-oxo-2-oxetamyl]methyl]-3,6-dodecadienyl ester .....	96829-59-3
(5R)-5-Ethyl-1,4,5,8-tetrahydro-5-hydroxyxepino[3,4-c]pyridine-3,9-dione .....	221054-70-2
4-[2-(5-methyl-2-phenyl-4-oxazolyl)ethoxybenzo[b]thiophene-7-carboxaldehyde .....	475480-88-7
2-(5-Methyl-2-phenyl-4-oxazolyl)ethyl methanesulfonate .....	227029-27-8
4-[5-(4-Fluorophenyl)-3-(trifluoromethyl)-1H-pyrazol-1-yl]benzenesulfonamide .....	170569-88-7
(4S)-4-(3,4-Dichlorophenyl)-3,4-dihydronaphthalen-1(2H)-one .....	124379-29-9
6-(5-Chloropyridin-2-yl)-7-hydroxy-6,7-dihydro-5H-pyrrolo[3,4-b]pyrazin-5-one .....	43200-81-3
5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-amino-3-ethenyl-8-oxo-, (6R-trans) .....	79349-82-9
(6R,7R)-7-amino-8-oxo-3-[(1H-1,2,3-triazol-4-ylthio)methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid .....	37539-03-0
(6R,7S)-7-(2-Bromo-acetylamino)-7-methoxy-3-(1-methyl-1H-tetrazol-5-ylsulfanyl)methyl)-8-oxo-5-thia-1-aza-bicyclo[4.2.0]oct-2-ene-2-carboxylic acid benzhydryl ester .....	70035-75-5
7-[(bromoacetyl)amino]-7-methoxy-3-[(1-methyl-1H-tetrazol-5-yl)thio]-methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid .....	61807-78-1
(6R,7R)-7-amino-3-[(1-methyl-1H-tetrazol-5-yl)thio]methyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid hydrochloride .....	68350-02-7
(6R,7R)-7-amino-8-oxo-3-[2-(1,3,4-thiadiazol-2-ylthio)ethyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid .....	24209-43-6
(2-amino-1,3-thiazol-4-yl)acetic acid .....	29676-71-9
1-[2-(dimethylamino)ethyl]-1,4-dihydro-5H-tetrazole-5-thione .....	61607-68-9
tert-Butyl (7E)-4-ethoxy-10,10-dimethyl-6-oxo-7-(2-amino-1,3-thiazol-4-yl)-3,5,9-trioxa-8-aza-4-phosphaunder-7-en-11-oate 4-sulfide .....	162208-28-8
4-Chloromethyl-5-methyl-1,3-dioxol-2-one .....	80841-78-7
Ethyl 1-methyl-5-nitro-1H-indole-2-carboxylate .....	71056-57-0
Ethyl 1-methyl-5-[4'-(trifluoromethyl)][1,1'-biphenyl]-2-carboxamido]-1H-indole-2-carboxylate .....	481659-93-2
1-Methyl-5-[4'-(trifluoromethyl)][1,1'-biphenyl]-2-carboxamido]-1H-indole-2-carboxylic acid potassium salt .....	481659-96-5
tert-Butyl (S)-2-[benzyl(methyl)amino]-2-oxo-1-phenylethylcarbamate hydrochloride .....	481659-97-6
3-(2-Bromopropionyl)-4,4-dimethyl-1,3-oxazolan-2-one .....	114341-88-7
2-Pentenedioic acid, 2-[2-[(phenylmethoxy)carbonyl]amino]-4-thiazolyl]-, 5-(3-methyl-2-butenyl) ester .....	115065-79-7
4-Thia-2,6-diazabicyclo[3.2.0]hept-2-ene-6-acetic acid, $\alpha$ -(1-methylethenyl)-7-oxo-3-(phenylmethyl)-, diphenylmethyl ester .....	63457-21-6
1-aminopyridazin-1-ium hexafluorophosphate .....	346412-97-3
1-[4-(Ethoxy)phenyl]-2-[4-(methylsulfonyl)phenyl]ethanone .....	346413-00-1
2-[4-(Ethoxy)phenyl]-3-[4-(methylsulfonyl)phenyl]pyrazolo[1,5-b]pyridazine .....	221148-46-5
6-Iodo-4(1H)-quinazolinone .....	16064-08-7
3-Chloro-4-{[(3-fluorophenyl)methyl]oxy}aniline .....	202197-26-0
N-(3-Chloro-4-[(3-fluorophenyl)methyl]oxy)phenyl)-6-iodo-4-quinazolinamine .....	231278-20-9
(5-Formyl-2-furanyl)boronic acid .....	27329-70-0

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Product name	CAS No.
[2-(Methylsulfonyl)ethyl]amine hydrochloride . . . . .	104458-24-4
2-oxo-2-phenylethyl acetate . . . . .	2243-35-8
(1S)-1-phenyl-1-propanamine . . . . .	3789-59-1
(3R,4S,5R)-3,4,5-Trihydroxy-1-cyclohexene-1-carboxylic acid . . . . .	138-59-0
5-Deoxy-D-ribofuranose triacetate . . . . .	37076-71-4
(R)(--)-1-Azabicyclo[2.2.2]octan-3-ol . . . . .	25333-42-0
RS-3-(Dimethylamino)-1-(2-thienyl)-1-propanol . . . . .	13636-02-7
N-Methyl-3-oxo-3-(2-thienyl)propenamine . . . . .	663603-70-1
(S)-3-Methylamino-1-(2-thienyl)-1-propanol . . . . .	116539-55-0
(S)-N-Methyl-3-(1-naphthalenyl)-2-thiophenepropanamine phosphoric acid salt . . . . .	164015-32-1
(Z)-N-[2-(Diethylamino)ethyl]-5-[(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethyl-1H-pyrrole-3-carboxamide (S)-2-hydroxysuccinate . . . . .	341031-54-7
(1R,5S)-2-(hydroxymethyl)-5-(dimethyl(phenyl)silyl)cyclopent-2-enecarboxylic acid, compound with (1R,2R)-2-amino-1-(4-nitrophenyl)-1,3-propanediol (1:1) . . . . .	649761-22-8
6-(Benzyl)-9H-purin-2-amine . . . . .	19916-73-5
(1S,2S,3S,5S)-5-(2-amino-6-(benzyloxy)-9H-purin-9-yl)-2-((benzyloxy)methyl)-1-(hydroxymethyl)-3-(dimethyl(phenyl)silyl)cyclopentanol . . . . .	649761-23-9
2-Amino-9-((1S,3R,4S)-3-((benzyloxy)methyl)-4-(dimethyl(phenyl)silyl)-2-methylenecyclopentyl)-1H-purin-6(9H)-one . . . . .	649761-24-0
Ethyneylcyclopropane . . . . .	6746-94-7
( $\alpha$ R, $\beta$ S)- $\beta$ -methyl- $\alpha$ -phenyl-1-pyrrolidineethanol hydrochloride . . . . .	210558-66-0
4-(2-(5-methyl-2-phenyloxazol-4-yl)ethoxy)benzaldehyde . . . . .	103788-59-6
4-Methoxyphenyl chloroformate . . . . .	7693-41-6
Methyl 2-(4-(2-(5-methyl-2-phenyloxazol-4-yl)ethoxy)benzylamino)acetate, hydrochloride salt . . . . .	649761-25-1
(Z)-3-Cyano-5-methylhex-3-enoic acid tert-butylamine salt . . . . .	604784-44-3
1-[(1S,2S)-2-(benzyloxy)-1-ethylpropyl]-N-{4-[4-(4-[[3(R,5R)-5-(2,4-difluorophenyl)-5-(1H-1,2,4-triazol-1-yl)methyl]tetrahydrofuran-3-yl]methoxy]phenyl}piperazin-1-yl]phenyl}hydrazinecarboxamide . . . . .	345217-03-0
2-Methoxy-1-[4-trifluoromethyl]phenyl]-ethanone . . . . .	26771-69-7
1-[(1R)-2-methoxymethyl-1-[4-(trifluoromethyl)phenyl]ethyl]-2(S)-methylpiperazine, (2S,3S)-2,3-dihydroxybutanedioate (1:1) salt . . . . .	612494-10-7
1-[(4,6-Dimethyl-5-pyrimidinyl)carbonyl]-4-piperidinone . . . . .	612543-01-8
1-[(4,6-Dimethyl-5-pyrimidinyl)carbonyl]-4-[(2-methoxy-1-[R]-4-(trifluoromethyl)phenyl)ethyl]-3(S)-methyl-1-piperazinyl]-4-methylpiperidine, 2(Z)-butenedioate (1:1) . . . . .	599179-03-0
2-(2-Furanyl)-7-[2-[4-[4-(2-methoxyethoxy)phenyl]-1-piperazinyl]ethyl]-7H-pyrazolo[4,3-e][1,2,4]triazolo[1,5-c]pyrimidin-5-amine . . . . .	377727-87-2
7-[(3R)-3-amino-1-oxo-4-(2,4,5-trifluorophenyl)butyl]-5,6,7,8-tetrahydro-3-(trifluoromethyl)-1,2,4-triazolo[4,3-a]pyrazine phosphate (1:1) monohydrate . . . . .	654671-77-9
Glycine, N-[2-[5-(aminoiminomethyl)-2-hydroxyphenoxy]-6-[3-(4,5-dihydro-1-methyl-1H-imidazol-2-yl)phenoxy]-3,5-difluoro-4-pyridinyl]-N-methyl-, dihydrochloride . . . . .	213839-64-6
2(3H)-Benzoxazolone, 6-[[2-[4-(phenylmethyl)-1-piperidinyl]ethyl]sulfinyl]- . . . . .	253450-12-3
Pyridine, 4-[[4-(1-methylethyl)-2-[(phenylmethoxy) methyl]-1H-imidazol-1-yl] methyl]- ethanedioate (1:2) . . . . .	280129-82-0
DNA, d(P-thio) (C-T-A-G-A-T-T-C-C-G-C-G), tridecasodium salt . . . . .	362543-73-5
DNA d(P-thio) (G-A-T-C-C-G-C-G-G-A-A-T) , tridecasodium salt . . . . .	744239-10-9
(+)-(3S,4S)-1-(Aminomethyl)-3,4-dimethylcyclopentaneacetic acid . . . . .	223445-75-8
(4R)-3-[(2S,3S)-2-Hydroxy-3-(3-hydroxy-2-methyl-benzoylamino)-4-phenyl-butryryl]-5,5-dimethyl-thiazolidine-4-carboxylic acid allylamide . . . . .	478410-84-3
(2S,3S)-3-Amino-2-hydroxy-4-phenyl-butryric acid . . . . .	62023-62-5
Benzenethiol, 3-methoxy- . . . . .	15570-12-4
Ethanone, 2-chloro-1-(4-methoxyphenyl)- . . . . .	2196-99-8
Phenol, 3-mercaptop- . . . . .	40248-84-8
Sodium Phenylbutyrate . . . . .	1716-12-7

**Table 3**  
**Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix**

Product name	CAS No.
N-(2-Chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide . . . . .	302962-49-8
2-piperidineacetamide, $\alpha$ -phenyl- . . . . .	19395-39-2
(6 <i>R</i> )-5,6,6 <i>a</i> ,7-tetrahydro-6-methyl-4 <i>H</i> -dibenzo[ <i>d,e,g</i> ]quinoline-10,11-diol . . . . .	58-00-4
4'-Bromomethyl-(1,1'-biphenyl)-2-carboxylic acid 1,1-dimethylethylester . . . . .	114772-40-6
4'-(Bromomethyl)-(1,1'-biphenyl)-2-carbonitrile . . . . .	114772-54-2
4-Methyl-2-propylbenzimidazole-6-carboxylic acid . . . . .	152628-03-0
2-Propyl-4-methyl-6-(1-methylbenzimidazole 1,7'-Dimethyl-2'-propyl-1 <i>H</i> ,3' <i>H</i> -[2,5']bibenzimidazolyl . . . . .	152628-02-9
(6 <i>R</i> )-5,6-Dihydro-4-hydroxy-6-(1-(2-phenyl)ethyl)-6-propyl-2 <i>H</i> -pyran-2-one . . . . .	221129-55-1
3-Hydroxy-2'-(N-benzyl-N-methylamino)acetophenone Hydrochloride . . . . .	71786-67-9
2,6-Dichloro-4,8-dipiperidinopyrimido(5,4-d)pyrimidine . . . . .	7139-02-8
2-(Ethylamino)-5-[2-quinolin-4-yloxy]ethyl]nicotinic acid . . . . .	
Piperazine, 1-(2-Chloroethyl)-4-(3-(trifluoromethyl) phenyl) dihydrochloride . . . . .	57061-71-9
N-(4-(Methylamino)-3-nitrobenzoyl)-N-2-pyridinyl- $\beta$ -alanine-ethylester . . . . .	429659-01-8
(4-(5-Oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)-phenylamino)-acetic acid . . . . .	872728-82-0
11-Ethyl-6-methyl-3-(2-(quinolin-1-oxid-4-yloxy)-ethyl)-4 <i>a</i> ,6,11, 11 <i>a</i> -tetrahydro-pyrido(2,3- <i>b</i> )(1,5)benzodiazepin-5-one (Dihydrate) . . . . .	(none)
Potassium 5-methyl-1,3,4-oxadiazole-2-carboxylate or oxadiazole K salt . . . . .	(none)
2-(1-Amino-1-methylethyl)-N-(4-fluorobenzyl)-5-hydroxy-1-methyl-6-oxo-1,6-dihydropyrimidine-4-carboxamide . . . . .	518048-03-8
N-[(4-Fluorophenyl)methyl]-1,6-dihydro-5-hydroxy-1-methyl-2-[1-methyl-1-[(5-methyl-1,3,4-oxadiazol-2-yl)carbonyl]amino]ethyl]-6-oxo-4-pyrimidinecarboxamide monopotassium salt or L-612 K salt . . . . .	518048-05-0
(2S)-2-[(S)-(2-Ethoxyphenoxy)(phenyl)methyl]morpholine compound with butanedioic acid . . . . .	635724-55-9
N-[(5-{2-[(6 <i>S</i> )-2-Amino-4-oxo-3,4,5,6,7,8-hexahydropyrido[2,3- <i>d</i> ]pyrimidin-6-yl]ethyl}-4-methylthien-2-yl)carbonyl]-L-glutamic acid . . . . .	177587-08-5
3-((2-(aminomethyl)cyclohexyl)methyl)-1,2,4-oxadiazol-5(4 <i>H</i> )-one hydrochloride . . . . .	227626-75-7
3,4'-Dichloro-2'-(5-chloro-2-pyridyl)carbamoyl]-6'-methoxy-4-[(2-methylamino-1 <i>H</i> -imidazol-1-yl)methyl]thiophene-2-carboxanilide trifluoroacetate . . . . .	229340-73-2
(R)-5-(2-Aminopropyl)-2-methoxybenzenesulfonamide . . . . .	112101-81-2
2-Methyl-3-[(2 <i>S</i> )-pyrrolidin-2-ylmethoxy]pyridine . . . . .	161417-03-4
N-2-[(4-Hydroxyphenyl)amino]pyridin-3-yl]-4-methoxybenzenesulfonamide . . . . .	141430-65-1
2,7-Dichloro-6-methyl-4-[(4-methylpiperidino)methyl]-3-quinolinemethanol . . . . .	220998-08-3
9-chloro-5-ethyl-1,4,5,13-tetrahydro-5-hydroxy-10-methyl-12-[(4-methylpiperidino)methyl]-3 <i>H</i> ,15 <i>H</i> -oxepino[3',4':6,7]indolizino[1,2- <i>b</i> ]quinoline-3,15-dione monohydrochloride . . . . .	220997-99-9
2-chloro-6,7-difluoro-3-quinolinemethanol . . . . .	209909-03-5
(S)- $\alpha$ -Methoxy-4-[2-(5-methyl-2-phenyl-4-oxazolyl)ethoxy]benzo[b]thiophene-7-propionic acid . . . . .	475479-34-6
(S)-1-[[2-(5-Methyl-2-phenyl-4-oxazolyl)ethyl]amino]acetyl]-2-pyrrolidinecarbonitrile . . . . .	521266-46-6
2-[(1 <i>S</i> ,2 <i>S</i> )-2-(benzyloxy)-1-ethylpropyl]-4-{4-[4-(4-((3 <i>R</i> ,5 <i>R</i> )-5-(2,4-difluorophenyl)-5-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)tetrahydrofuran-3-yl)methoxy]phenyl}piperazin-1-yl]phenyl]-2,4-dihydro-3 <i>H</i> -1,2,4-triazol-3-one . . . . .	170985-86-1



**APPENDIX B**

***FEDERAL REGISTER NOTICE***

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**Total Estimated Burden Hours:** 5,000.

**Status:** Extension of a currently approved collection.

**Authority:** Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 35, as amended.

Dated: June 8, 2006.

**Lillian L. Deitzer,**

*Departmental Paperwork Reduction Act Officer, Office of the Chief Information Officer.*

[FR Doc. E6-9322 Filed 6-14-06; 8:45 am]

**BILLING CODE 4210-67-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[MT-060-01-1020-PG]**

#### Notice of Public Meeting; Central Montana Resource Advisory Council

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Central Montana Resource Advisory Council (RAC) will meet as indicated below.

**DATES:** The meeting will be held July 12 & 13, 2006, at the Cottonwood Inn, in Glasgow, Montana.

The July 12 session will begin at 8 a.m. and consist of a field trip to public lands in the Glasgow area.

This tour is scheduled to adjourn at 5 p.m.

The July 13 meeting will begin at 8 a.m. with a 30-minute public comment period.

This meeting is scheduled to adjourn at 3 p.m.

**SUPPLEMENTARY INFORMATION:** This 15-member council advises the Secretary of the Interior on a variety of management issues associated with public land management in Montana. At this meeting the council will discuss/act upon:

The minutes of their proceeding meeting;

A discussion of the American Prairie Foundation project;

A briefing concerning the upcoming Malta Resource Management Plan;

A review of Revised Statute—2477,

An update about the Bowdoin Gas Field;

A discussion of proposed revisions to grazing regulations;

A briefing about transportation planning; and

Administrative details.

All RAC meetings are open to the public. The public may present written comments to the RAC. Each formal RAC meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

**FOR FURTHER INFORMATION CONTACT:** June Bailey, Lewistown Field Manager, Lewistown Field Office, P.O. Box 1160, Lewistown, Montana 59457 or at 406-538-1900.

Dated: June 8, 2006.

**June Bailey,**

*Lewistown Field Manager.*

[FR Doc. E6-9340 Filed 6-14-06; 8:45 am]

**BILLING CODE 4310-\$\$-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Reclamation

#### California Bay-Delta Public Advisory Committee Public Meeting

**AGENCY:** Bureau of Reclamation, Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, the California Bay-Delta Public Advisory Committee (Committee) will meet on July 13, 2006. The agenda for the Committee meeting will include discussions with State and Federal agency representatives on the 10-Year Action Plan, Subcommittee structure, the Bay-Delta Conservation Plan and its relationship to the Delta Regional Ecosystem Restoration Plan, the Delta Vision, end of Stage 1 decisions, and recommendations on implementing agency Program Plans.

**DATES:** The meeting will be held on Thursday, July 13, 2006, from 9 a.m. to 4 p.m. If reasonable accommodation is needed due to a disability, please contact Colleen Kirtlan at (916) 445-5511 or TDD (800) 735-2929 at least 1 week prior to the meeting.

**ADDRESSES:** These meetings will be held at the John E. Moss Federal Building located at 650 Capitol Mall, 5th Floor, Sacramento, California.

**FOR FURTHER INFORMATION CONTACT:** Diane Buzzard, U.S. Bureau of Reclamation, at 916-978-5022 or Julie Alvis, California Bay-Delta Authority, at 916-445-5551.

**SUPPLEMENTARY INFORMATION:** The Committee was established to provide advice and recommendations to the Secretary of the Interior on

implementation of the CALFED Bay-Delta Program. The Committee makes recommendations on annual priorities, integration of the eleven Program elements, and overall balancing of the four Program objectives of ecosystem restoration, water quality, levee system integrity, and water supply reliability. The Program is a consortium of State and Federal agencies with the mission to develop and implement a long-term comprehensive plan that will restore ecological health and improve water management for beneficial uses of the San Francisco/Sacramento and San Joaquin Bay Delta.

Committee agendas and meeting materials will be available prior to all meetings on the California Bay-Delta Authority Web site at <http://calwater.ca.gov> and at the meetings. These meetings are open to the public. Oral comments will be accepted from members of the public at each meeting and will be limited to 3–5 minutes.

(Authority: The Committee was established pursuant to the Department of the Interior's authority to implement the Water Supply, Reliability, and Environmental Improvement Act, Pub. L. 108-361; the Fish and Wildlife Coordination Act, 16 U.S.C. 661 et seq.; the Endangered Species Act, 16 U.S.C. 1531 et seq.; and the Reclamation Act of 1902, 43 U.S.C. 391 et seq., and the acts amendatory thereof or supplementary thereto, all collectively referred to as the Federal Reclamation laws, and in particular, the Central Valley Project Improvement Act, 34 U.S.C. 3401.)

Dated: June 6, 2006.

**Allan Oto,**

*Special Projects Officer, Mid-Pacific Region, U.S. Bureau of Reclamation.*

[FR Doc. 06-5431 Filed 6-14-06; 8:45 am]

**BILLING CODE 4310-MN-M**

## INTERNATIONAL TRADE COMMISSION

**[Investigation No. 332-476]**

#### Advice Concerning the Addition of Certain Pharmaceutical Products and Chemical Intermediates to the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States

**AGENCY:** United States International Trade Commission.

**ACTION:** Institution of investigation.

**DATES:** Effective Date: June 12, 2006.

**SUMMARY:** Following receipt of a request on May 25, 2006, from the United States Trade Representative (USTR), the Commission instituted Investigation No. 332-476, *Advice Concerning the Addition of Certain Pharmaceutical*

*Products and Chemical Intermediates to the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States*, under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)).

**FOR FURTHER INFORMATION CONTACT:**

Information specific to these investigations may be obtained from Philip Stone, Project Leader (202-205-3424; [philip.stone@usitc.gov](mailto:philip.stone@usitc.gov)), Office of Industries, United States International Trade Commission, Washington, DC, 20436. For information on the legal aspects of these investigations, contact William Gearhart of the Office of the General Counsel (202-205-3091; [william.gearhart@usitc.gov](mailto:william.gearhart@usitc.gov)). General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>).

**Background:** As one part of the market access tariff results of the Uruguay Round negotiations, the United States and 21 other countries agreed to reciprocal elimination of duties on certain pharmaceutical products and chemical intermediates used primarily for the production of pharmaceuticals. In the Uruguay Round Agreement Act (URAA), Congress authorized the President to grant duty-free treatment to new pharmaceutical products and chemical intermediates. One of the requirements set out in the URAA is that the President "obtain advice regarding the proposed action" from the Commission. Pursuant to section 115 of the URAA and section 332(g) of the Tariff Act of 1930, the USTR requests that the Commission provide advice in the form of additional information on the pharmaceutical products and chemical intermediates currently under consideration. The USTR specifically requests (1) a summary description of the products contained in the existing Pharmaceutical Appendix and the modifications made to that Appendix; (2) an explanation of the relationship between the various elements in the Appendix and the Harmonized Tariff Schedule of the United States; and (3) an estimate of the current U.S. imports and, where possible, current U.S. exports of the products included in the existing Pharmaceutical Appendix and the proposed additions to the Appendix.

A list of the proposed additions to the Pharmaceutical Appendix is available on the Commission's Web site at [http://www.usitc.gov/ind\\_econ\\_ana/combined\\_tables\\_pharma\\_332.pdf](http://www.usitc.gov/ind_econ_ana/combined_tables_pharma_332.pdf). The Commission expects to provide its report to the USTR by September 1, 2006.

**Written Submissions:** The Commission does not plan to hold a

public hearing in connection with preparation of this report. However, interested parties are invited to submit written statements containing pertinent data such as levels of exports and imports for the items included in this investigation. All submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436, and should be received no later than 5:15 p.m. EDT on June 21, 2006. All written submissions must conform with the provisions of section 201.8 of the Commission's

*Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 of the rules requires that a signed original (or a copy designated as an original) and fourteen (14) copies of each document be filed. In the event that confidential treatment of the document is requested, at least four (4) additional copies must be filed, in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). The Commission's rules do not authorize filing submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the rules (see Handbook for Electronic Filing Procedures, [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/documents/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/documents/handbook_on_electronic_filing.pdf)).

Any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "nonconfidential" version, and that the confidential business information be clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available in the Office of the Secretary to the Commission for inspection by interested parties.

In his request letter, the USTR stated that he intends to make the Commission's report available to the public in its entirety, and asked that the Commission not include any confidential business or national security confidential information in the report. The report that the Commission sends to the USTR will not contain any such information. Any confidential business information received by the Commission in this investigation and used in preparing the report will not be published in a manner that would

reveal the operations of the firm supplying the information.

The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at <http://www.usitc.gov/secretary/edis.htm>. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting our TDD terminal on 202-205-1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

By order of the Commission.

Issued: June 13, 2006.

**Marilyn R. Abbott,**

*Secretary to the Commission.*

[FR Doc. E6-9455 Filed 6-14-06; 8:45 am]

**BILLING CODE 7020-02-P**

## DEPARTMENT OF JUSTICE

### Antitrust Division

#### Notice Pursuant to the National Cooperative Research and Production Act of 1993—ASTM International—Standards

Notice is hereby given that, on May 24, 2006, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), ASTM International—Standards ("ASTM") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing additions or changes to its standards development activities. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ASTM has provided an updated list of current, ongoing ASTM standards activities originating between February 2006 and May 2006, designated as Work Items. A complete listing of ASTM Work Items, along with a brief description of each, is available at <http://www.astm.org>.

On September 15, 2004, ASTM filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 10, 2004 (69 FR 65226).

The last notification was filed with the Department on February 17, 2006. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on April 12, 2006 (71 FR 18769).

**APPENDIX C**

**WRITTEN SUBMISSIONS TO THE**

**COMMISSION**

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June 21, 2006

*Re: BRI 06-377*  
The Honorable Marilyn R. Abbott  
Secretary to the Commission  
United States International Trade Commission  
500 E. Street, S.W.  
Washington, DC 20436

Business Proprietary Information  
Deleted from Brackets [] at  
Attachment 1

**PUBLIC VERSION**

Re: Inv. No. 332-TA-476; Advice Concerning the Addition of Certain  
Pharmaceutical Products and Chemical Intermediates to the  
Pharmaceutical Appendix of the HTS

Dear Secretary Abbott:

On behalf of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and pursuant to the invitation for comments published at 71 Fed. Reg. 34,643 (June 15, 2006), we hereby submit our written statement concerning the above-referenced investigation. PhRMA and its members strongly support the current update to the pharmaceutical zero-for-zero tariff agreement, which will benefit the industry and consumers by eliminating unnecessary tariff barriers to the movement of pharmaceutical products and sole-use intermediates in international commerce.<sup>1</sup>

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JULY 21  
FBI  
#30

<sup>1</sup> PhRMA is also requesting that the following intermediate (formerly ID 119) be added back to the list of intermediates under consideration for duty elimination: HTSUS 2933.39; IUPAC Name 4-[2-(1-piperidinyl)ethoxy]phenol; CAS No. 100238-42-4. See: 69 Fed. Reg. 49940 (August 12, 2004) and [http://www.ustr.gov/assets/Trade\\_Sectors/Manufacturing/2004\\_Pharmaceutical\\_Zero\\_for\\_Zero\\_Review/as\\_set\\_upload\\_file643\\_5765.pdf?ht=](http://www.ustr.gov/assets/Trade_Sectors/Manufacturing/2004_Pharmaceutical_Zero_for_Zero_Review/as_set_upload_file643_5765.pdf?ht=). Sufficient information was provided by the submitting company to demonstrate that this submission met all requirements for inclusion in the Pharmaceutical Appendix. This item was apparently inadvertently omitted from the final list provided to the USITC and to USTR.

In these comments, PhRMA members and participants in the global coalition known as the International Committee for the Elimination of Pharmaceutical Tariffs (INTERCEPT) have attempted to estimate the potential impact on trade of the current update. However, we note that it is extremely difficult to estimate the future value of trade in most of these products, since many are still in various stages of development or the regulatory approval process, and are not yet traded in commercial volumes. Furthermore, even assuming regulatory approval is eventually granted, the volume of trade may or may not increase significantly, depending on future demand for an individual drug. Finally, the list of requested compounds may include a number of intermediates for the same end product, not all of which may eventually be traded in commercial volume, depending on the synthetic chemistry and economic rationalization of production of various intermediates at various sites.

Attachment 1 hereto contains an estimate of the 2007 import and export values for the listed products covered by this update negotiation, to the extent such information has been made available by the supplying companies. Due to the large number of products covered by this update, we are still receiving information from members concerning their trade in the subject chemicals, and will provide such information to the Commission as it becomes available.

As an alternative but clearly less desirable method of calculating potential trade impact, Attachment 2 contains data from the USITC Datweb and estimates the impact of the update based on the level of U.S. imports before and after the last update of the

Pharmaceutical Appendix in July of 1999.<sup>2</sup> Based on data obtained from the USITC Dataweb, the United States imported \$8.4 billion worth of products eligible for duty free treatment under the “K” (Pharmaceutical) Program in 1998. After the last update on July 1, 1999 imports increased to an average annual value of \$18.7 billion during the period 2000-2005, an increase of \$10.3 billion. It is difficult to calculate an actual assessed duty impact, due to changes in duty rates over the period. However, assuming a 6.5% duty rate for all items (the highest current rate for the subject HTSUS items in Chapter 29), one can calculate an average annual duty impact of \$623 million from the last update. If this number is divided by the number of compounds listed in the last update (623) and the result multiplied by the number of items in the current update (1289)<sup>3</sup>, the result suggests an annual duty impact of \$1.3 billion as a result of the current update.

We would emphasize that this is a significant overestimate and should be considered the absolute upper limit of any potential trade impact. First, it must be noted that not all of the covered products are assessed at a 6.5 percent tariff rate, as assumed above. Second, the increased imports following the 1999 update likely are not entirely attributable to the tariff elimination for the compounds covered by that update. Since the previous update had just occurred in 1997, part of the increase in imports is likely attributable to products covered by the 1997 update. Furthermore, the duty impact is likely overstated in that some of the compounds to be covered by the update are already receiving duty free treatment under foreign trade zone, boded entry procedures, or legislative duty exemptions. Also, this approach assigns equal weight to all compounds

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<sup>2</sup> See Proclamation 7207--To Extend Nondiscriminatory Treatment (Normal Trade Relations Treatment) to Products of Mongolia and To Implement an Agreement To Eliminate Tariffs on Certain Pharmaceuticals and Chemical Intermediates, 64 F.R. 36547 (July 1, 1999)

<sup>3</sup> These numbers do not include prefixes and suffixes for INN salts, esters and hydrates.

added to the appendix, despite the fact that many of these compounds will never actually be traded.

Finally, we note that we cannot estimate any potential increase in exports as a result of the current update, since similar statistical data is not available with respect to U.S. exports.

Confidential Treatment is requested for certain bracketed, business proprietary information contained in this submission in accordance with 19 C.F.R. Part 201, for the following reason: Attachment 1 contains information concerning the value of imports and exports by specific companies, revealing the operations of these individual companies. Disclosure of the foregoing confidential information would likely either impair the Commission's ability to obtain information necessary to perform its functions, or would cause substantial harm to the competitive position of the submitting companies. A certification that substantially identical information is not otherwise available to the public is attached hereto.

Please contact the undersigned should you have any questions.

Respectfully submitted,



Matthew T. McGrath  
BARNES, RICHARDSON & COLBURN  
Counsel to PhRMA

**Certification of Accuracy and Completeness**

The undersigned attorney hereby certifies that information substantially identical to the information for which confidential treatment is requested is not available to the public. The undersigned further certifies that the information contained in this submission is accurate and complete to the best of his knowledge.

*Stephen W. Brophy*  
Stephen W. Brophy  
BARNES, RICHARDSON & COLBURN  
1420 New York Ave. N.W. 7<sup>th</sup> Floor  
Washington, D.C. 20005  
(202) 628-4700

District of Columbia  
Subscribed and sworn before me  
this 21<sup>st</sup> day of June 2006.

NOTARY PUBLIC

*Holly T. Ward*

My commission expires: 30 April 2009



## **ATTACHMENT 1**

Table 1: INNS

Product	Submitter	Estimated 2007 Import Value
ID #	Submitter	Estimated 2007 Import Value
Osefiamavir	T	
Selamectin		
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771		
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**Table 3. Proposed Chemical Intermediates**

ID #	Submitter	Estimated 2007 Import Value	Estimated 2007 Export Value	HS code	CAS-RN	Preferred name
509				2933 59	137281-39-1 4-[2-(2-amino-4-oxo-4H-dihydro-3H-pyrrrolol[2,3-d]pyrimidin-5yl)ethyl]benzoic acid	
510				3824 90	170277-77-7 (3S)-3-[2-(mesyloxy)ethoxy]-4-(trityloxy)butyl methanesulfonate, dimethylformamide solution	
511				2833 21	186462-71-5 (1R,2R,5S,6R)-2'-5'-dioxospiro[bicyclo[3.1.0]hexane-2,4'-imidazolidine]-6-carboxylic acid	
512				2922 19	42142-52-9 3-(methylamino)-1-methoxypropan-1-ol	
513				2833 39	84449-81-0 4-(2-epiperidin-1-ylethoxy)benzoyl chloride hydrochloride	
520				2834 99	102212-98-6 N'-benzoyl-2'-deoxy-5-O-(4,4'-dimethoxytrityl)cytidine, 3'-[2-cyanoethyl]disopropylphosphoramidite	
525				2934 99	93183-15-4 2'-deoxy-5'-O-(4,4'-dimethoxytrityl)-N'-isobutyltritylguanosine, 3'-[2-cyanoethyl]disopropylphosphoramidite	
526				2834 99	98796-51-1 2'-deoxy-5'-O-(4,4'-dimethoxytrityl)thymidine 3'-[2-cyanoethyl]disopropylphosphoramidite	
527				2934 99	98796-53-3 N'-benzoyl-2'-deoxy-5'-O-(4,4'-dimethoxytrityl)adenosine 3'-[2-cyanoethyl]disopropylphosphoramidite	
528				2926 90	31915-40-9 N-[1'-cyano-2-(4-hydroxyphenyl)-1-methyllethyl]acetamide	
582				2932 29	122111-01-7 [(2R)-2-(benzyloxy)-4,4-difluoro-5-oxotetrahydrofuran-2-yl)methyl] benzoate	
862				2830 90	15570-12-4 3-methoxybenzen-1-thiol	
863				2914 70	2196-99-8 2-chloro-1-(4-methoxyphenyl)ethan-1-one	
864				2930 90	40248-84-8 3-sulfanylphenol	
311				2933 99	5424-01-1 3-aminopyrazine-2-carboxylic acid	
312				2933 99	16298-03-6 methyl 3-aminopyrazine-2-carboxylate	
313				2933 59	487-21-8 pteridine-2,4(1H,3H)-dione	
314				2914 70	2350-46-1 1-[2-(3-dichloro-4-hydroxyphenyl)butan-1-one	
315				2918 90	1217-67-0 (4-buturyl-2,3-dichlorophenoxy)acetic acid	
316				2914 50	82499-20-5 (1R)-1-hydroxy-1-(3-hydroxyphenyl)acetone	
317				2925 20	249561-98-6 tris{[(2Z)-2-chloro-3-(dimethylaminol)prop-2-en-1-yldene]dimethylammonium} hexafluorophosphate(3-)	
318				2933 39	22161-55-7 5-[4-(mesyloxy)-3-(4-methylpyridin-3-yl)]-ethan-1-one	
319				2833 99	219899-83-8 3-((4S)-4-sulfanyl-L-prolineamido)benzoic acid hydrochloride	
320				2906 29	127852-28-2 (1R)-1-[3.5-bis(trifluoromethyl)phenyl]lethan-1-one	
321				3824 90	127852-28-2 (1R)-1-[3.5-bis(trifluoromethyl)phenyl]lethan-1-one, acetonitrile solution	
322				2933 99	119192-10-8 4-[1(H)-1,2,4-triazol-1-yl]methylethanolamine	
323				2933 99	160194-39-8 2-[5-[(1H)-1,2,4-triazol-1-yl)methyl]indol-3-yl]ethan-1-ol	
324				2930 90	50413-24-6 2-bromo-1-(4-mesylphenyl)ethan-1-one	
325				2834 99	30165-96-9 4-(4-chloro-1,2,5-thiadiazol-3-yl)morpholine	
326				3824 90	30165-96-9 4-(4-chloro-1,2,5-thiadiazol-3-yl)morpholine, toluene solution	
327				2934 99	194861-99-9 [(5S)-3-tert-butyl-2-phenoxy]-3-oxazolidin-5-yl)methanol	
328				2935 00	149490-61-9 N-(butane-1-sulfonyl)-O-(4-pyridin-4-ylbutyl)-L-tyrosine	
329				2834 99	171482-05-6 (2R,3S)-2-[1(R)-1-[3.5-bis(trifluoromethyl)phenyl]ethoxy]-3-(4-fluorophenyl)morpholine hydrochloride	
382				2934 99	287930-73-8 4-benzyl-3-one	
383				2934 99	287930-75-0 (2R)-4-benzyl-2-(1R)-1-[3.5-bis(trifluoromethyl)phenyl]morpholin-3-one	
384				2933 49	287930-77-2 (1S)-1-[3-(E)-2-[7-chloroguolinol-2-yl]vinyl]phenyl-3-[1-(hydroxy-1-methyllethyl)phenyl]propan-1-ol	
386				2933 49	287930-78-3 methyl 2-[3S]-3-[3(E)-2-[7-chloroguolinol-2-yl]vinyl]phenyl-3-hydroxypropylbenzoate hydrate	
387				2934 10	213282-19-8 5-[(2,4-dioxo-1,3-thiazolidin-5-yl)methyl]trifluoromethylbenzylbenzamide	
388				2933 99	252742-72-6 5-(chloromethyl)-1-[2,4-triazol-1-yl]trifluoromethylbenzylbenzamide	
581				2933 59	654617-17-9 (2R)-4-oxo-4-(3-trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4]triazolo[4,3-alpyrazin-7-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine	
835				2934 99	Phosphate [1:1] hydrate	
957				2934 99	0-0-0 potassium 5-methyl-1,3,4-oxadiazole-2-carboxylate	
958				2933 59	518048-03-8 2-[1-amino-1-(2-fluorobenzyl)carbamoyl]-1-methyl-2-[1-methyl-1-(5-methyl-1,3,4-oxadiazole-2-carboxamido)ethyl]-6-oxo-1,6-	
959				2934 99	518048-05-0 potassium 4-[N-(2-fluorobenzyl)carbamoyl]-1-methyl-2-[1-methyl-1-(5-methyl-1,3,4-oxadiazole-2-carboxamido)ethyl]-6-oxo-1,6-	
72				2933 99	2933 99 86404-63-9 1-[2,4-difluorophenyl]-2-[1H-1,2,4-triazol-1-yl]ethan-1-one	
73				2933 59	188416-20-8 3-[6-chloro-5-fluoropyrimidin-4-yl]-2-[2,4-difluorophenyl]pyrrolidin-3-yl)diphenylacetonitrile	
75				2934 99	2934 99 252317-48-9 [(3S)-1-1-[2,3-dihydro-1-benzofuran-5-yl]heptyl]nicotinic acid	
76				2935 00	247552-73-6 2-ethoxy-5-[4-ethyl]piperazine-1-sulfonyl)nicotinic acid	
78				2932 29	2932 29 142680-85-1 (25S)-25-cyclohexyl-25-deoxy-25-deoxyavermectin A <sub>8</sub>	
79				2932 29	220119-16-4 (25S)-25-cyclohexyl-25-deoxy-25-deoxyavermectin A <sub>8</sub>	
80				2933 59	137234-74-3 4-chloro-6-ethyl-5-fluoropyrimidine	
81				2933 59	188416-28-6 4-(1-bromoethyl)-6-chloro-5-fluoropyrimidine	
82				2934 99	2934 99 252317-48-9 [(3S)-1-1-[2,3-dihydro-1-benzofuran-5-yl]heptyl]nicotinic acid	
84				2922 19	115207-37-1 N-methyl-1-[4-(4-nitrophenethyl)-2-(4-nitrophenoxyl)ethyl]ethan-1-amine	
85				2922 29	115206-13-8 4-[1-(2,4-aminophenoxyethyl)imethylamino]ethyljulanine	
86				2933 99	188113-71-5 1-acetyl-3-[(2R)-1-methylpyrrolidin-2-yl)methyl]-5-[(E)-2-(phenylsulfonyl)vinyl]indole	
87				2933 99	180637-89-2 3-[(2R)-1-methylpyrrolidin-2-yl)methyl]-5-[(E)-2-(phenylsulfonyl)vinyl]indole	
88				2935 00	200575-15-1 4-[2-ethoxy-5-(4-methylpiperazine-1-sulfonyl)benzamido]-3-propylpyrazole-5-carboxamide	

# HHS CONCERN IDENTICAL

ID #	Submitter	Estimated 2007 Import Value	Estimated 2007 Export Value	HS code	CAS-RN	Preferred name
90				2934 99	78601-85-9	(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-1,3-[(2,6-dideoxy-3-O-methyl-3-C-methyl-2-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,6-trideoxy-3-(dimethylamino)-2-D-xylo-hexopyranosyl]oxy)-1-oxa-6-azacyclopentadecan-15-one
91				2933 99	32055-66-0	2-(dimethoxymethyl)quinoxaline-1,4-dioxide
93				2934 99	76646-91-8	(3S,6,6-dibromo-2-dimethylbenam-3-carboxylic acid 1,1-dioxide
242				2934 99	183434-04-0	tert-butyl (4S)-4-ethyl-4,6-dihydroxy-3,10-dioxo-3,4,8,10-tetrahydro-1H-pyran-3,4-]indolizine-7-carboxylate
243				2934 99	86639-52-3	(4S)-4-11-dieethyl-4,9-dihydroxy-1H-9H-pyranol[3,4'-6,7]indolizinol[1,2-b]quinaline-3,14(4H,12H)-dione
244				2932 29	145667-75-0	(3aR,4R,5R,6aS)-5-hydroxy-4-(3-hydroxy-5-phenylpentyl)hexahydrocyclopental[b]furan-2-one
245				2933 99	227025-33-4	1-benzyl-4H-imidazo[4,5,1]quinolin-2(1H)-one
246				2933 99	269731-34-2	(5S,6R)-1-benzyl-5-hydroxy-6-(methylamino)-5,6-dihydro-4H-imidazo[4,5,1]quinolin-2(1H)-one
247				2934 10	186538-00-1	3-[(2S,3S)-2-hydroxy-3-(3-hydroxy-2-methylbenzamido)-4-phenylbutanoyl]-5,5-dimethyl-N-(2-methylbenzyl)-1,3-thiazolidine-4-carboxamide
250				2905 59	60827-45-4	(2S)-3-chloropropane-1,2-diol
263				2933 29	178982-67-7	2-[(benzyloxy)methyl]4-isopropylimidazole
264				2933 39	178981-89-0	5-[(3,5-dichlorophenyl)sulfanyl]4-isopropyl-1-(pyridin-4-ylmethyl)imidazol-2-yl)methanol
287				2928 00	212631-79-3	2-(2-chloro-4-iodooctanilinol-N-(cyclopropylmethoxy)-3,4-difluorobenzamide
289				2934 99	233450-99-8	6-[2-(4,4-difluorobenzyl)-1-(3-benzoxazol-2-yl)]methanol
298				2934 99	227626-65-5	tert-butyl N-methyl-N-[2-(5-oxo-4,5-dihydro-1,2,4-oxadiazol-5(4H)-one
299				2934 99	227625-35-6	3-[12-(aminomethyl)cyclohexyl]methyl]1,2,4-oxadiazol-5(4H)-one
300				293336-92-9	293336-92-9	3-chloro-N-[4-chloro-2-[5-chloropyridin-2-yl]carbamoyl]-6-methoxyphenyl]4-(2-(methylamino)imidazol-1-yl)methoxythiophene-2-carboxamide
489				2933 39	319480-94-1	N-(2-fluoro-5-[[3-((E)-2-pyridin-2-ylvinyl)-1H-indazol-6-yl)amino]phenyl)-1,3-dimethylpyrazole-5-carboxamide
490				2933 39	319480-85-0	N-methyl-2-[[3-((E)-2-pyridin-2-ylvinyl)-1H-indazol-6-yl)sulfanyl]benzamide
491				2933 79	2831173-50-2	8-fluoro-2-(4-((methylaminol)methyl)phenyl)-1,3,4,5-tetrahydro-6H-azepinol[5,4-3-cd]indol-6-one
517				2934 99	98819-76-2	(2S)-2-[(S)-2-ethoxyphenoxyl]phenylmethylmorpholine
519				2915 39	60116-74-4	(1S,4R)-4-hydroxycyclopent-2-en-1-yl acetate
585				2926 90	192889-10-6	2-iodo-3,4-dimethoxy-6-nitrobenzonitrile
586				2926 90	192889-24-2	6-amino-2-iodo-3,4-dimethoxybenzonitrile
587				2935 00	210538-75-3	N-(1,2,3,4-tetrahydroisoquinolin-5-yl)methanesulfonamide hydrochloride
590				2933 19	334828-10-3	4-amino-5-ethyl-1-(2-methoxyethyl)pyrazol-3-yl-3-carboxamide
591				2935 00	334828-19-2	N-[3-carboxyl-5-ethyl-1-(2-methoxyethyl)pyrazin-3-yl]-3-ethyl-2-(2-methoxyethyl)pyrazolo[3,4-d]pyrimidine
592				2935 00	334826-98-1	5-[2-ethoxy-5-(4-ethyl)piperazine-1-sulfonyl]pyridin-3-yl-3-ethyl-2-(2-methoxyethyl)pyrazolo[3,4-d]pyrimidine
593				2935 00	334827-99-5	5-[2-ethoxy-5-(4-ethyl)piperazine-1-sulfonyl]pyridin-3-yl-3-ethyl-2-(2-methoxyethyl)pyrazolo[3,4-d]pyrimidine
594				2930 90	364323-64-8	2-[4-(methylsulfanyl)benzoic acid]phenoxylbenzylamine hydrochloride
595				2930 90	289717-37-9	N,N-dimethyl-2-[4-(methylsulfanyl)benzoic acid]benzylamine hydrochloride
596				2935 00	364321-71-1	3-[dimethylaminolmethyl]-4-[(4-(methylsulfanyl)benzyl)-4-(4-(methylsulfanyl)benzyl)-1-sulfonamide L-tartarate (1:1)
597				2935 00	364323-49-9	3-[dimethylaminolmethyl]-4-[(4-(methylsulfanyl)benzyl)-1-carboxyhexane-1-carboxyamido-3-phenylpropanoate
598				2924 29	316348-76-4	4,4-difluoro-N-(1S)-3-hydroxy-1-phenylpropylcyclohexane-1-carboxamide
599				2924 29	376348-77-5	4,4-difluoro-N-(1S)-3-oxo-1-phenylpropylcyclohexane-1-carboxamide
600				2924 29	376348-78-6	4,4-difluoro-N-(1S)-3-oxo-1-phenylpropylcyclohexane-1-carboxamide
649				2933 39	423165-13-3	8-benzyl-3-exo-[3-isopropyl-5-methyl-4H-1,2,4-triazol-4-yl]-8-azabicyclo[3.2.1]octane
659				2934 99	183433-66-1	[6-chloro-4-(2-ethyl-1,3-dioxolan-2-yl)-2-methoxy]pyridin-3-yl)methanol
660				2932 29	957716-70-4	7-[methoxymethoxy]3-oxo-1-phenylpropylcyclohexane-1-carbolactone
661				2933 39	230615-59-5	7,8-dinitro-3-(trifluoroacetyl)-2,3,4,5-tetrahydro-1H-1,5-methano-3-benzazepine
673				2926 90	474645-97-1	(3R)-3-aminopantanenitrile methanesulfonate
674				2933 39	474645-93-7	methyl 12-ethyl-6-(trifluoromethyl)-1,2,3,4-tetrahydroquinolin-4-yl)carbamate
676				2933 39	180915-95-1	1-[2-(4-bromo-6-methoxy-3-phenyl)phenoxy]ethyl)pyrrolidine
677				2933 39	180915-94-0	1-[2-(4-methoxy-3,4-dihydro-1-naphthyl)phenoxy]ethyl)pyrrolidine
686				2916 20	122695-97-8	4,4-difluorocyclohexane-1-carboxylic acid
687				2924 29	325715-13-7	N-(3-acetylphenyl)-N-methylacetamide
688				2934 99	96219-87-3	(3-aminopyrazol-4-yl)(2-thienyl)methanone
690				2933 39	230615-52-8	2,3,4,5-tetrahydro-3-benzene-1,5-methano-3-sulfone hydrochloride
692				2933 79	162142-14-5	1-cyclopentyl-3-ethyl-1,4,5,6-tetrahydro-7H-pyrazolo[3,4-c]pyridin-7-one
693				2933 79	303752-13-8	4,4-difluorocyclohexane-1-carboxylic acid
696				2924 29	667937-05-5	3-[4-(trifluoromethyl)anilinol]pentanamide
697				2934 99	192049-49-3	4-nitrobenzyl 2-((1R,5R)-3-benzyl-7-oxo-4-methylbenzene-1-sulfonate
700				2932 19	87392-07-2	(2S)-tetrahydrodofuran-2-carboxylic acid

# INVENTORY INVENTORY

ID #	Submitter	Estimated 2007 Import Value	Estimated 2007 Export Value	HS code	CAS-RN	Preferred name
702				2934 99	655233-39-9	4-nitrobenzyl (7R)-7-amino-3-[(2S)-tetrahydrofuran-2-yl]-3,4-didehydorocepham-4-carboxylate hydrochloride
728				2933 99	71056-57-0	ethyl 1-methyl-5-nitroindole-2-carboxylate
729				2933 99	481659-93-2	ethyl 1-methyl-5-[4-(trifluoromethyl)biphenyl-2-carboxamido]indole-2-carboxylate
730				2933 99	481659-96-5	potassium 1-methyl-5-[4-(trifluoromethyl)biphenyl-2-carboxamido]indole-2-carboxylate
731				2924 29	481659-97-6	tert-butyl [(1S)-2-(benzyl(methylamino)ethyl)-5-[(Z)-(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethylpyrrole-3-carboxamide L-
776				2933 79	341031-54-7	N-[2-(diethylamino)ethyl]-5-[(Z)-(5-fluoro-2-oxo-1,2-dihydro-3H-indol-3-ylidene)methyl]-2,4-dimethylpyrrole-3-carboxamide L- malate (1:1)
803				2926 90	604784-44-3	tert-butylammonium [(Z)-3-cyan-5-methylhex-3-enatoe N-(2S)-aminoinomethyl-2-hydroxyphenoxyl-3,5-difluoro-6-(3-(1-methyl-4,5-dihydropyrimidazol-2-yl)phenoxy)pyridin-4-yl]N-
840				2933 39	213839-64-6	methylglycine dihydrochloride
841				2934 99	253450-12-3	6-[(2-(4-benzyl(piperidin-1-yl)ethyl)sulfanyl)-1,3-benzoxazol-2(3H)-one
842				2933 39	280129-82-0	4-(2-[(benzyloxy)methyl]imidazo[1-2-y]methyl)pyridine oxalate (1:2)
857				2922 49	223445-75-8	[(3S,4S)-1-(aminomethyl)-3,4-dimethylcyclopentenyl]acetic acid
859				2934 10	478410-84-3	(4R)-N-allyl-3-[(2S,3S)-2-hydroxy-3-(3-hydroxy-2-methoxybenzamido)-4-phenylbutanoyl]-5,5-dimethylthiazolidine-4-carboxamide
860				2922 50	62023-62-5	(2S,3S)-3-amino-2-hydroxy-4-phenylbutanoic acid
961				2934 99	635724-55-9	(2S)-2-[(S)-2-ethoxyphenoxy]phenylsuccinate
278A				2934 99	177587-08-5	N-[2-((6S)-2-amino-4-oxo-3,4,5,6,7,8-hexahydroxypyridin[2,3-d]pyrimidin-6-yl)ethyl]-4-methylthiophene-2-carboxylic acid
299A				2934 99	227626-75-7	3-[(2-(aminomethyl)cyclohexyl)methyl]-1,2,4-oxadiazol-5(4H)-one hydrochloride
300A				2934 99	229340-73-2	3-chloro-N-(4-chloro-2-(5-chloropyridin-2-yl)carbamoyl)-6-methoxyphenyl)-4-[(2-(methylenimino)imidazol-1-yl)methyl]thiophene-2-carboxamide trifluoroacetate
3				2909 30	165254-21-7	1,2-bis[2-(2-(2-methoxyethoxyethoxyethoxyethoxy)-4,5-dinitrobenzene
4				2933 99	149365-59-3	bis[4-(3,4-dieethylpyrrole-2,5-diy)bis(methylene)]bis[4-(3-methoxy-3-oxopropyl)-3-methylpyrrole-2-carboxaldehyde]
5				2933 99	149365-62-8	5,5'-[(3,4-dieethylpyrrole-2,5-diy)bis(methylene)]bis[4-(3-hydroxycyclohex-1-ene-1-carboxylic acid
760				2918 19	138-59-0	(3R,4S,5R)-3,4,5-trihydroxycyclohex-1-ene-1-carboxylic acid
762				2932 19	37076-71-4	1,2,3-tri-O-acetyl-5-deoxy-D-riofuranose
409				3824 90	38345-66-3	(2S,3R)-4-(dimethylamino)-3-methyl-1,2-diphenylbutan-2-ol, toluene solution
875				2933 39	19395-39-2	2-phenyl-2-piperidin-2-ylacetamide



## **ATTACHMENT 2**

**U.S. IMPORTS FOR CONSUMPTION**  
**Import Program: (K) Pharmaceuticals**

<b>Year</b>	<b>Customs Value (US\$)</b>	<b>Duties at 6.5%</b>
1998	8,419,042,807	547,237,782
2000	17,677,369,831	1,149,029,039
2001	19,097,662,270	1,241,348,048
2002	18,937,323,018	1,230,925,996
2003	19,118,743,524	1,242,718,329
2004	19,182,439,292	1,246,858,554
2005	18,755,445,614	1,219,103,965
Avg. 2000-2005	18,794,830,592	1,221,663,988
Difference	10,375,787,785	674,426,206
Estimated Impact 1999 Update	674,426,206	
Products in 1999 Update	637	
Duties per product	1,058,754	
Products in New Update	1289	
Estimated Impact Current Update	1,364,733,720	

Source: USITC Dataweb

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June 21, 2006

Marilyn Abbott, Secretary  
United States International Trade Commission  
500 E Street, S.W.  
Washington, DC 20436

332-476

2006 JUN 21 PM 4:23

**RE: Advice Concerning the Addition of Certain Pharmaceutical Products and  
Chemical Intermediates to the Pharmaceutical Appendix to the Harmonized  
Tariff Schedule of the United States, 71 Fed. Reg. 34643 (June 15, 2006);  
Written comments on behalf of Novus International, Inc.**

Dear Secretary:

We are submitting this letter, and the enclosed trade data, on behalf of Novus International, Inc. in response to the June 15<sup>th</sup> Federal Register notice requesting information on certain pharmaceutical products that are being considered for inclusion in the Pharmaceutical Appendix to the Harmonized Tariff Schedule. (See 71 FR 34643) Novus International, Inc. is a U.S. manufacturer of *desmeninol* located in St. Louis, Missouri.

In September 2004, Novus International, Inc. submitted a request to the Office of the U.S. Trade Representative asking that a particular pharmaceutical product, *desmeninol*, be included in Table 1 of the Pharmaceutical Appendices providing for zero tariff treatment. (See Attachment A, September 17, 2004 letter on behalf of Novus International)

As discussed in our previous letter, the WTO plurilateral Pharmaceutical Agreement provides that pharmaceutical compounds listed on Table 1 of the Pharmaceutical Appendices that have an “international non-proprietary name” (INN) will be afforded zero tariff treatment by all signatories to that agreement. The relevant language of the WTO plurilateral Pharmaceutical Agreement is set forth below:

1. With respect to pharmaceutical products (as defined below), [the signatories] will eliminate customs duties and all other duties and charges...on **ALL** items in the following categories:...



Member International Society of Primerus Law Firms

Secretary  
U.S. International Trade Commission  
RE: Written Comments on behalf of Novus International

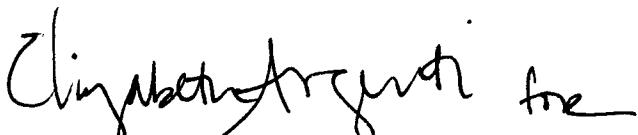
June 21, 2006  
Page 2

- (iii) pharmaceutical active ingredients designated in [Table] 1 and that bear an "international non-proprietary name," (INN) from the World Health Organization;

As we also noted in our September 2004 submission, 2-Hydroxy-4-(methylthio)butyric acid, a chemical name listed on Table 3 of the Pharmaceutical Appendices, has been given an INN designation of *desmeninol*. Therefore, we respectfully request that *desmeninol* be added to Table 1 and afforded zero tariff treatment pursuant to the WTO plurilateral Pharmaceutical Agreement.

Additionally, in response to a request by Philip Stone of the USITC, we submit the enclosed trade data relating to U.S. imports and exports of *desmeninol*. (See Attachment B, U.S. trade data by quantity and value) These data cover the period of 2001 through April 2006. If you have any questions, or require additional information, please contact our office.

Respectfully submitted,



Alan M. Dunn  
Counsel to Novus International, Inc.

Attachments

cc: Alice Sterkel, General Counsel, Novus International, Inc.  
Philip Stone, USITC, *via facsimile*

# Attachment A

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September 17, 2004

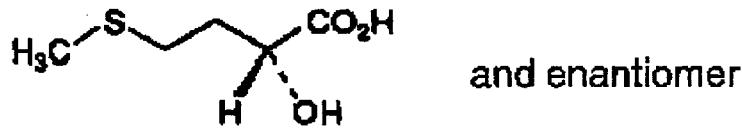
Trade Policy Staff Committee  
Office of the U.S. Trade Representative  
600 17<sup>th</sup> Street, N.W.  
Washington, D.C. 20508

**RE: Expansion of the List of Pharmaceutical Products Receiving Zero Duties;  
Written Comments of Novus International Inc.**

HS Code: 2930.90 CAS Number: 583-91-5 (or 120-91-2) Chemical Name: Desmeninol (*Desmeninolum*)

Molecular Structure:

(±)-2-hydroxy-4-(methylthio)butyric acid  
C<sub>5</sub>H<sub>10</sub>O<sub>3</sub>S                    120-91-2                    amino acid analogue



## SUMMARY

On August 12, 2004, the Office of the United States Trade Representative (USTR) published a request for comments on expanding the coverage of the Uruguay Round's zero-for-zero results on pharmaceuticals in preparation for negotiations that will occur in 2004 at the World Trade Organization (WTO). See *Trade Policy Staff Committee; Public Comments for Multilateral Negotiations in the World Trade Organization on Expansion of the List of Pharmaceutical Products Receiving Zero Duties*, 69 Fed. Reg. 49940 (USTR, Aug. 12, 2004).



Member International Society of Primerus Law Firms

In response to USTR's request for comments, we are writing on behalf of Novus International, Inc., to request that its product "*desmeninol*," on list 70 of the World Health Organization's (WHO) list of International Nonproprietary Names for Pharmaceutical Substances (INN), be included in Table 1 of the Pharmaceutical Appendices of all signatory countries to the zero-for-zero pharmaceutical arrangement established during the Uruguay Round.<sup>1</sup> Table 1 lists by INN all of the pharmaceuticals that are eligible for zero duty treatment. Currently, *desmeninol* is listed only by its chemical name on Table 3 of the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States (HTSUS) as "2-Hydroxy-4-(methylthio)butyric acid" with CAS number 583-91-5. See Attachment 2. *Desmeninol* is, in fact, the INN given to "2-Hydroxy-4-(methylthio)butyric acid." The addition of *desmeninol* to Table 1 of the Pharmaceutical Appendix in the tariff schedules of all signatories to the zero-for-zero pharmaceutical arrangement would prevent confusion as to the proper tariff treatment upon importation from the U.S. into the signatory countries, a problem that has occurred in the past.

## BACKGROUND

Novus International, Inc., located at 530 Maryville Centre Drive, St. Louis, Missouri 63141, is a U.S. manufacturer of *desmeninol* under the brand name Alimet. Alimet is a form of synthetic methionine that is used as an animal feed supplement to provide an essential amino acid necessary for the nutritional well being of farm raised animals. Novus manufactures *desmeninol* for use in pharmaceutical applications as well. See Attachment 3 (noting the use of "2-Hydroxy-4-(methylthio)butyric acid" in the pharmaceutical Ketostril and other pharmaceutical applications). *Desmeninol* is manufactured in Novus' facility located in Chocolate Bayou, Texas, from which over 60 percent of the Alimet produced is exported.

Since its introduction in 1979, Alimet has grown to become the preferred source of liquid synthetic methionine worldwide. By the year 2000, Novus estimates that liquid synthetic methionine had replaced its competition, d, l-methionine, a dry powder form of synthetic

<sup>1</sup> The 30 signatories include: the EU-25 (Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom), Canada, Japan, Norway, Switzerland, and the United States. See Attachment 1 plus the 10 new members of the EU.

methionine, as the most used synthetic methionine product in the world. Novus is one of the world leaders with respect to methionine supplementation.

## COMMENTS

### I. The WTO Pharmaceutical Arrangement Allows Pharmaceuticals with an INN to be Listed in Table 1

The WTO zero-for-zero pharmaceutical arrangement states in part:

1. With respect to pharmaceutical products (as defined below), [the signatories] will eliminate customs duties and all other duties and charges . . . on ALL items in the following categories: . . .
  - (iii) pharmaceutical active ingredients designated in [Table] 1 and that bear an "international non-proprietary name," (INN) from the World Health Organization;

*See Attachment 1 (emphasis in original).*

During the negotiation stage of the zero-for-zero pharmaceutical arrangement during the Uruguay Round "2-Hydroxy-4-(methylthio)butyric acid" did not yet have a registered INN. Shortly after the completion of the negotiating round, however, the German pharmaceutical firm "Frensenius Pharmazeutika," was able to obtain an INN for "2-Hydroxy-4-(methylthio)butyric acid" which they use in a drug called "Ketostril" that is given to patients with impaired kidney functions to ease the stress upon the kidney. The INN given to "2-Hydroxy-4-(methylthio)butyric acid" was *desmeninol*. *See* Attachment 4.

As is evident in Attachment 4, the Chemical Abstract Service's (CAS) listing for *desmeninol* is 120-91-2. Table 3 of the Pharmaceutical Annex to the HTSUS, however, lists the CAS number for the identical product, "2-Hydroxy-4-(methylthio)butyric acid", as 583-91-5. Attachment 5 clearly shows that *desmeninol* is recognized under both CAS listings 120-91-2 and 583-91-5.<sup>2</sup> Because *desmeninol* is recognized under both CAS numbers, it is important that it be listed on both Table 3 and Table 1 of all the signatories' tariff schedules in order to prevent

---

<sup>2</sup> The American Chemical Society Registry indicates that CAS 120-91-2 was superceded by CAS 583-91-5. See Attachment 5. The National Library of Medicine website indicates that desmeninol has been assigned both registry numbers. *See* <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp?/chemidlite.jsp> (either 120-91-2 or 583-91-5 can be entered into the search engine in order to find *desmeninol*).

confusion as to whether it is subject to preferential tariff treatment upon importation. Moreover, because *desmeninol* is the issued INN name for a recognized pharmaceutical product, it should be listed on Table 1 pursuant to the provision of the zero-for-zero pharmaceutical arrangement quoted above.

**II. USTR Should Negotiate Actively to Expand Application of the Pharmaceutical Products Receiving Zero Tariffs to all WTO Members During the Doha Round**

Although *desmeninol* already is eligible for a zero duty treatment in all signatory countries to the zero-for-zero pharmaceutical arrangement, it is in the interests of the United States to negotiate an expansion of the arrangement to all WTO Members during the Doha Round negotiations. Achieving zero-for-zero treatment in all WTO Member countries for pharmaceuticals, including *desmeninol*, would undoubtedly result in enhanced international competitiveness for Novus, and would directly benefit U.S. industry and workers. The U.S. has already supported this position in its proposal for a tariff-free world. *See* Attachment 6.

Novus International, Inc. supports this U.S. negotiating position and hereby states its support specifically for USTR efforts to expand the pharmaceutical zero-for-zero in the context of the Doha WTO negotiations.

\* \* \*

If you have any questions regarding this submission, please contact the undersigned.

Respectfully submitted,

Alan M. Dunn  
Eric P. Salonen  
Stewart and Stewart  
Counsel to Novus International, Inc.

Enclosures: Attachments 1 - 6



**ATTACHMENT 1**

**GENERAL AGREEMENT  
ON TARIFFS AND TRADE**

**RESTRICTED**  
**L/7430**  
**25 March 1994**  
**Limited Distribution**

(94-0547)

Original: English

**TRADE IN PHARMACEUTICAL PRODUCTS**

The following communication concerning trade in pharmaceutical products has been received from the delegations listed below:

**RECORD OF DISCUSSION**

In the course of the Uruguay Round negotiations, representatives of the following governments discussed the treatment of pharmaceutical products and came to the following conclusions:

Australia  
Austria  
Canada  
Czech Republic  
European Communities  
Finland  
Japan  
Norway  
Slovak Republic  
Sweden  
Switzerland  
United States

Each government will eliminate customs duties on pharmaceutical products, as defined below, recognizing the objective of tariff elimination should not be frustrated by trade restrictive or trade distorting measures. Other governments are encouraged to do the same.

1. With respect to pharmaceutical products (as defined below), they will eliminate customs duties and all other duties and charges, as defined within the meaning of Article II.1 (b) of the General Agreement on Tariffs and Trade (1994), on ALL items in the following categories:

- (i) items classified (or classifiable) in Harmonized System Chapter 30;
- (ii) items classified (or classifiable) in HS headings 2936, 2937, 2939, and 2941, with the exception of dihydrostreptomycin and salts, esters, and hydrates thereof;
- (iii) pharmaceutical active ingredients as designated in Annex I and that bear an "international non-proprietary name," (INN) from the World Health Organization;

- (iv) salts, esters, and hydrates of pharmaceutical products which are described by the combination of an INN active ingredient contained in Annex I with a prefix or suffix as designated in Annex II to this record, as long as such salt, ester, or hydrate is classified in the same HS 6-digit heading as the INN active ingredient;
- (v) salts, esters, and hydrates of INN active ingredients that are separately contained in Annex III to this record and that are not classified in the same HS 6-digit heading as the INN active ingredient;
- (vi) additional products used for the production and manufacture of finished pharmaceuticals as designated in Annex IV to this record.

In addition, to ensure transparency, each government will incorporate these measures into that government's schedule to the General Agreement on Tariffs and Trade (1994), and, in addition, at either its national tariff line level or the Harmonized System 6-digit level in either its national tariff or any other published versions of the tariff schedule, whichever is ordinarily used by importers and exporters.

Each government will fully implement the duty elimination on the date of entry into force of the World Trade Organization (WTO) agreement, for that government.

In incorporating the results described above, duty elimination can be achieved either by creating sub-headings at the national tariff line level, or attaching an Annex to the national tariff listing all products concerned or by a combination of the above methods, whereby duty-free treatment is provided for at national tariff line level for certain products.

In cases where it is not possible to designate an entire national tariff line for duty-free treatment, **EACH GOVERNMENT** will list the pharmaceutical products covered in an Annex to its national tariff, with a full concordance to the products listed in Annexes I, III, and IV at either the national tariff line level or the Harmonized System 6-digit level. Where some or all of the products are incorporated in such an Annex, each government will include appropriate footnotes (or other means of cross-referencing at the national tariff line level or the Harmonized System 6-digit level) either in the national tariff or in any other published version of the national tariff to indicate that bound duty-free treatment is provided for the products listed in the Annex.

2. In implementing these measures, each government's national customs authorities may require importers to provide one or more of the following types of information to certify that the imported chemical is included in this record:

- (i) Harmonized System 6-digit heading of the chemical;
- (ii) Chemical Description;
- (iii) International Non-proprietary Name (INN);
- (iv) Chemical Abstracts Service (CAS) Registry Number (RN);
- (v) Prefix or suffix of the salt/ester/hydrate (if applicable).

3. Representatives of the governments listed above will meet under the auspices of the Council for Trade in Goods of the WTO -- normally at least once every three years -- to review the product

coverage with a view to including, by consensus, additional pharmaceutical products for tariff elimination. They agreed to encourage autonomous elimination of duties prior to agreement to eliminate duties on a permanent and reciprocal basis, in accordance with their national procedures.

4. The positive list of products covered by these annexes has been deposited with the GATT Secretariat.

\*Paracetamol, ibuprofen, dihydrostreptomycin, monosodium glutamate, and levomenthol have been excluded from the coverage of this record of discussion.

**GENERAL AGREEMENT  
ON TARIFFS AND TRADE**

**RESTRICTED**  
**L/7430/Add.1**  
**25 March 1994**  
**Limited Distribution**

**(94-0548)**

**Original: English**

**TRADE IN PHARMACEUTICAL PRODUCTS**

**RECORD OF DISCUSSION**

**Communication from the Czech Republic**

The following communication has been received from the delegation of the Czech Republic.

I have the honour to refer to document L/7430, dated 25 March 1994, containing the record of discussion of the representatives of the governments concerned on the treatment of pharmaceutical products.

In connection with that record of discussion I wish to confirm that the Czech Republic will eliminate its customs duties on pharmaceutical products over ten years and in accordance with the terms set forth in the Schedule of the Czech Republic to be annexed to the Marrakesh Protocol.

I am kindly requesting you to bring this communication to the attention of the Uruguay Round participants, possibly as an addendum to the above-mentioned document L/7430.

**GENERAL AGREEMENT  
ON TARIFFS AND TRADE**

**RESTRICTED**  
**L/7430/Add.2**  
**25 March 1994**  
**Limited Distribution**

(94-0565)

Original: English

**TRADE IN PHARMACEUTICAL PRODUCTS**

**RECORD OF DISCUSSION**

**Communication from the Slovak Republic**

The following communication has been received from the delegation of the Slovak Republic.

I wish to refer to GATT document L/7430 dated 25 March 1994, containing the record of discussion of the representatives of the governments concerned on the treatment of pharmaceutical products.

In connection with that record of discussion I wish to confirm that the Slovak Republic will eliminate its customs duties on pharmaceutical products over ten years and pursuant to the terms set forth in the Schedule of the Slovak Republic to be annexed to the Marrakesh Protocol.

I would request you to circulate this communication to the Uruguay Round participants as an addendum to the above-mentioned document L/7430.

**GENERAL AGREEMENT  
ON TARIFFS AND TRADE**

**RESTRICTED**  
**L/7430/Add.3**  
**30 June 1994**  
**Limited Distribution**

(94-1377)

Original: English

**TRADE IN PHARMACEUTICAL PRODUCTS**

**Record of Discussion**

**Communication from Australia**

The following communication has been received from the delegation of Australia.

I have the honour to refer to document L/7430, dated 25 March 1994, containing the record of discussion of the representatives of the governments concerned on the treatment of pharmaceutical products.

In connection with that record of discussion, Australia did not agree to being included in the list of countries which "came to the conclusions" set out in that document. The document was submitted to the Secretariat for issue to CPs prior to our delegation having the opportunity to receive final instructions on our participation. Subsequent to circulation of L/7430 we wish to confirm that we do not wish to be a participant to the agreement set out therein and Australia should be deleted from the list of such. We were an interested participant in the informal plurilateral discussions which produced the "Record of Discussions" but had always reserved our final position on participating in the outcome on technical classifications. In any case, Australia's intention was clear at that time because the L/ document was not referenced in our Final Schedule of Uruguay Round Concessions and Commitments.

Notwithstanding that we did not wish to participate in the outcome covered by that document, Australia has made a trade weighted cut of 87 percent and will bind 93 percent of tariff lines at zero for pharmaceuticals through its Uruguay Round Schedule.

I am kindly requesting you to bring this communication to the attention of the Uruguay Round participants, as an addendum to the above-mentioned document L/7430.



## **ATTACHMENT 2**

**Harmonized Tariff Schedule of the United States (2004) -- Supplement 1**  
 Annotated for Statistical Reporting Purposes

PHARMACEUTICAL APPENDIX TO THE TARIFF SCHEDULE

68

Table 3. (con.)

<u>Product Name</u>	<u>CAS Number</u>
4-O- $\beta$ -D-Galactopyranosyl-D-gluconic acid	96-82-2
( $\alpha$ -D-Glucopyranosylthio)gold	12192-57-3
5-Glyoxyloylsalicylamide hydrate	141862-47-7
2-Guanidinothiazol-4-ylmethyl carbamimidothioate dihydrochloride	88046-01-9
Hemocyanins, megathura crenulata, reaction products with 1-O-[2-acetamido-2-deoxy- $\beta$ -D-galactopyranosyl-(1,4)-O-(N-acetyl- $\alpha$ -neuraminosyl)- (2,3)-O- $\beta$ -D-galactopyranosyl-(1,4)- $\beta$ -D-glucopyranose	195993-11-4
1,1,1,3,3-Hexafluoropropan-2-ol	920-66-1
$\alpha$ , $\alpha$ , $\alpha$ , $\alpha'$ , $\alpha'$ -Hexafluoro-2,5-xylidine	328-93-8
1,6-Hexanediamine, polymer with 1,10-dibromodecane	162430-94-6
Hexestrol dibutyrate (INNM)	36557-18-3
Hexestrol dipropionate (INNM)	59386-02-6
3-(4-Hexyloxy-1,2,5-thiadiazol-3-yl)-1-methylpyridinium iodide	131988-19-7
(3S,4S)-3-Hexyl-4-[(R)-2-(hydroxytridecyl)]oxetan-2-one	104872-06-2
N-(4-Hydrazinobenzy1)methanesulfonamide hydrochloride	81880-96-8
4-Hydrazonobenzenesulfonamide hydrochloride	17852-52-7
$\alpha$ -Hydroxy- $\beta$ , $\beta$ -dimethyl- $\gamma$ -butyrolactone	599-04-2
DL- $\alpha$ -Hydroxy- $\beta$ , $\beta$ -dimethyl- $\gamma$ -butyrolactone	79-50-5
17 $\alpha$ -Hydroxy-3,20-dioxopregna-4,9(11)-diene-21-yl acetate	7753-60-8
N-(2-Hydroxyethyl)lactamide	5422-34-4
1-[(1S,2S)-2-Hydroxy-2-(4-hydroxyphenyl)-1-methylethyl]-4-phenylpiperidin-4-ol methanesulfonate trihydrate	189894-57-3
4-Hydroxyindole	2380-94-1
11 $\alpha$ -Hydroxy-7 $\alpha$ -(methoxycarbonyl)-3-oxopregn-4-ene-21,17 $\alpha$ -carbolactone	192704-56-6
(2S,3S)-3-hydroxy-2-(4-methoxyphenyl)-2,3-dihydro-1,5-benzothiazepin-4(5H)-one	42399-49-5
4-[1-Hydroxy-2-(methylamino)ethyl]phenol-L-tartaric acid (2:1)	16589-24-5
17 $\alpha$ -Hydroxy-16 $\alpha$ -methyl-3,20-dioxopregna-1,4-dien-21-yl acetate	24510-54-1
17 $\alpha$ -Hydroxy-16 $\beta$ -methyl-3,20-dioxopregna-1,4-dien-21-yl acetate	24510-55-2
17 $\alpha$ -Hydroxy-16 $\beta$ -methyl-3,20-dioxopregna-1,4,9(11)-trien-21-yl acetate	910-99-6
17-Hydroxy-16 $\alpha$ -methyl-3,20-dioxopregna-1,4,9(11)-trien-21-yl acetate	10106-41-9
2-Hydroxy-2-methyl-4'-nitro-3'-(trifluoromethyl)propionanilide	52806-53-8
2-Hydroxy-4-(methylthio)butyric acid	583-91-5
6-Hydroxynicotinic acid	5006-66-6
trans-4-Hydroxy-1-(4-nitrobenzoyloxycarbonyl)-L-proline	96034-57-0
11 $\alpha$ -Hydroxy-3-oxopregna-4,6-diene-21,17 $\alpha$ -carbolactone	73726-56-4
(3R,4S)-3-Hydroxy-4-phenylazetidin-2-one	132127-34-5
D-2-(4-Hydroxyphenyl)glycine	22818-40-2
11 $\alpha$ -Hydroxypregn-4-ene-3,20-dione	80-75-1
3 $\beta$ -Hydroxy-5 $\alpha$ -spirostan-12-one	467-55-0
5-Hydroxy-1,2,3,4-tetrahydro-1-naphthone	28315-93-7
2-imino-1,3-thiazol-4-one	556-90-1
Indan-5-yl hydrogen phenylmalonate	27932-00-9
Inosine 5'-disodium phosphate	4691-65-0
Intermediate concentrate obtained from a genetically-modified Escherichia coli fermentation medium, containing human granulocyte-macrophage colony-stimulating factor; for use in the manufacture of medicaments of HS No. 3002	
Intermediate concentrate obtained from a genetically-modified Escherichia coli fermentation medium, containing human interferon $\alpha$ -2b; for use in the manufacture of medicaments of HS No. 3002	

## **ATTACHMENT 3**

ATTACHMENT

(from INN application)

The principal therapeutic use of DL-2-hydroxy-4-(methylthio)butanoic acid (hydroxy analog of methionine) is as an orally or parenterally effective source of the essential amino acid L-Methionine (L-2-amino-4-(methylthio)butanoic acid). Hydroxy analog of methionine differs from L-Methionine at the position of the second carbon: as is indicated by the scientific names of the compounds, the second carbon of the hydroxy analog of methionine bears a hydroxy group while that of L-methionine bears an amino group. The biochemical pathway for the conversion of hydroxy analog of methionine to L-methionine (i.e., replacement of the hydroxyl group with an amino group) has been described (Dibner and Knight, 1984) as a two step pathway in which the first step is the oxidation of the alpha carbon to 2-oxo-4-(methylthio)butanoic acid and the second step is a transamination of the alpha carbon to produce L-Methionine. The two enzymes which catalyze the oxidation of hydroxy analog of methionine (L-a-hydroxy acid oxidase, EC 1.1.3.15 and D-a-hydroxy acid dehydrogenase, EC 1.1.99.6) have been studied in numerous vertebrates, including rabbit, hog, rat and chicken, and are broadly specific for a-hydroxy acids, including lactic acid and glycolic acid (Tubbs and Greville, 1961; Robinson et al., 1962; Langer, 1965; Cammack, 1969; Langer et al., 1971).

The dose of the hydroxy analog of methionine is determined by the nutritional requirement for L-methionine or other amino acids, as it is of course by the dose of other amino acid sources with which it is combined.

In Ketostril, the hydroxy analog of methionine is combined with analogs of other amino acids, specifically, keto-analogues. It is given for prevention of essential amino acid deficiency in cases of chronic progressive renal failure. Amino acids, by increasing the body's metabolism of protein, permits protein restriction which, in turn, can slow progression of renal disease (with the exception of polycystic disease of the adult type).

Relevant both to this question and the question on the back of the application form concerning dates of clinical trials, from June 1981 to June 1985, 22 patients with advanced chronic renal failure were treated with Ketosteril (1/tablet/5 gm/day) combined with a protein supply of 0.4 g/kg/day. At the beginning of treatment, their mean plasma creatinine was 762 +/- 135 mumol/l and their creatinine clearance, 8.4 +/- 3.1 ml/min/1.73 m<sup>2</sup>. By the end of November, 1985, among the 20 assessable patients, 4 had been on the methionine/keto analogs for 8 to 52 months, 9 had to be dialyzed after 4 to 20 months, 5 had died and 2 had abandoned treatment. A mean 28% decrease in plasma urea level and daily urinary urea output was observed after 1 month of treatment, and a sustained reduction in plasma creatinine was observed in 12 patients. Mean renal survival was 15.6 +/- 12 months (median: 12 months), and was longer in patients whose plasma creatinine was lower than 700 mumol/l at the beginning of treatment. The ketoanalogues were well tolerated, and no denutrition occurred. The study confirmed the usefulness of this therapeutic approach to uremic patients and suggest that the best results would be obtained if Ketosteril were introduced before end-stage renal failure. P. Jungers, P. Chauveau, B. Lebkiri, C. Ciancioni, N.K. Man, J. Crossnier; Press Med. 1987 June 6; 16(21): 1039-43.

In providing nutritionally essential amino acids during the management of renal insufficiency, the preferred sources are nitrogen-free (i.e., the amino group is missing from the compound), in order to minimize the burden of ammonia on the kidney. Hydroxy analog of methionine is among the nitrogen-free sources of L-Methionine which are, for that reason, particularly well suited for use in instances of renal insufficiency. (Batshaw et al., 1976; Mitch and Walser, 1977). The biochemical pathway of DL-methionine (another source of L-methionine which appears as an alternative INN national name under "methioninum"), by contrast, results in free ammonia as a byproduct of an intermediate reaction in the body (its conversion into the keto intermediate (2-oxy-4-(methylthio)butanoic acid)). This ammonia must be excreted by the kidney.

In studies of uremic patients receiving oral hydroxy analog of methionine as a source of L-methionine, a dose of 2.01 g hydroxy analog of methionine per day was used (W. Mitch and M. Walser, 1977. Nitrogen balance of uremic patients receiving branched-chair ketoacids and the hydroxy-analogue of methionine as substitutes for the respective amino acids. Clinical Nephrology, 8: 341-344).

In a subsequent study by the same group, three doses of hydroxy analog of methionine were used: 0, 2 and 5 g/day. Using the first diet, plasma methionine levels fell significantly below normal following 4 weeks and remained below normal until the study was terminated after 13 weeks, indicating the need for a dietary source of methionine (Abras, E., M. Walser and W.E. Mitch, 1981). Mixed salts of basic amino acids with branched chain ketoacids as the basis for new supplements designed to improve nutrition in chronic renal failure. In: Metabolism and Clinical Implications of Branched Chain Amino Ketoacids, Walser, M. and J.R. Williamson, eds. Elsevier/North Holland, New York, p. 593-598). With a dose of 5 g/day, plasma methionine levels were 94% of normal after 5-6 weeks, and were not significantly different from levels observed feeding the hydroxy analog of methionine at 2 g/day (M. Walser, W.E. Mitch and E. Abras, 1983. Supplements containing amino acids and ketoacids in the treatment of chronic uremia. Kidney International, 24:, Suppl. 16: S285-S289). The authors concluded that a dose of hydroxy analog of methionine of 2 g/day was sufficient to maintain plasma L-methionine levels in uremic patients.

A United States Patent (4762854-A) reports the hydroxy analog of methionine efficacious as a urinary acidifier in the treatment of renal calculi in humans and laboratory animals. Among other United States patents describing pharmaceutical uses of the hydroxy analog of methionine is one in which the hydroxy analog of methionine was used as a treatment (in combination with manganese) for hypoglycemia (W08503870-A) and one in which it was used in the treatment of memory disorders in elderly humans (W08503869-A). As far as can be determined, commercially produced hydroxy analog of methionine is not used in any of these applications.



## **ATTACHMENT 4**

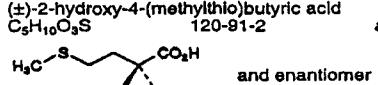
# International Nonproprietary Names for Pharmaceutical Substances (INN)

Notice is hereby given that, in accordance with article 3 of the Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances, the following names are under consideration by the World Health Organization as Proposed International Nonproprietary Names. The inclusion of a name in the lists of Proposed International Nonproprietary Names does not imply any recommendation of the use of the substance in medicine or pharmacy.

Comments on, or formal objections to, the proposed names may be forwarded by any person to the INN Programme of the World Health Organization within four months of the date of their publication in *WHO Drug Information*, i.e., for List 70 Proposed INN not later than 30 June 1994.

## Proposed International Nonproprietary Names: List 70

*Lists of proposed (1–65) and recommended (1–31) international nonproprietary names can be found in Cumulative List No. 8, 1992.*

<i>Proposed International Nonproprietary Name (Latin, English)</i>	<i>Chemical Name or Description; Molecular and Graphic formulae Chemical Abstracts Service (CAS) registry number Action and Use*</i>
desmeninolum desmeninol	( $\pm$ )-2-hydroxy-4-(methylthio)butyric acid $C_5H_{10}O_3S$ 120-91-2  amino acid analogue and enantiomer

*\*Action and Use: The statements in italics indicating the action and use are based largely on information supplied by the manufacturer. The information is meant to provide an indication of the potential use of new substances at the time they are accorded Proposed International Nonproprietary Names. WHO is not in a position either to uphold these statements or to comment on the efficacy of the action claimed. Because of their provisional nature, these descriptors will be neither revised nor included in the Cumulative Lists of INNs.*

1

## **ATTACHMENT 5**

## AMERICAN CHEMICAL SOCIETY REGISTRY

Explore by Substance Identifier started at: Fri Sep 17, 2004 at 9:50 AM

Explored by Substance Identifier in REGISTRY.

REGISTRY Answers  
1 for 583-91-5

Copyrights:

CAPLUS: Copyright 2004 ACS (The UK patent material in this product/service is UK Crown copyright and is made available with permission. (C) Crown Copyright. The French (FR) patent material in this product/service is made available from Institut National de la Propriete Industrielle (INPI).)

REGISTRY: Copyright 2004 ACS (Some records contain information from GenBank(R). See also: Benson D.A., Karsch-Mizrachi I., Lipman D.J., Ostell J., Rapp B.A., Wheeler D.L. Genbank. Nucl. Acids Res. 28(1):15-18 (2000). Property values tagged with IC are from the ZIC/VINITI data file provided by InfoChem.)

CASREACT: Copyright 2004 ACS (In addition to reactions indexed by CAS, CASREACT contains reactions derived from the following sources: ZIC/VINITI database (1974-1991) provided by InfoChem, INPI data prior to 1986, and Biotransformations database compiled under the direction of Professor Dr. Klaus Kieslich.)

CHEMLIST, CHEMCATS: Copyright 2004 ACS

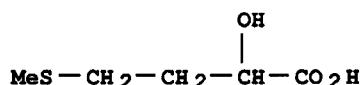
~418 References

Commercial Sources

Regulated Chemicals Listing

Reaction Information

Registry Number: 583-91-5



Formula: C<sub>5</sub>H<sub>10</sub>O<sub>3</sub>S

CA Index Name: Butanoic acid, 2-hydroxy-4-(methylthio)- (9Cl)

**Other Names:** Butyric acid, 2-hydroxy-4-(methylthio)- (6CI,8CI);  
 (+)-2-Hydroxy-4-(methylthio)butyric acid;  
 α-Hydroxy-γ-(methylmercapto)butyric acid;  
 α-Hydroxy-γ-(methylthio)butyric acid; α-Hydroxy-4-(methylthio)butyric acid; γ-(Methylmercapto)-α-hydroxybutyric acid;  
 γ-(Methylthio)-α-hydroxybutyric acid;  
 2-Hydroxy-4-(methylmercapto)butyric acid;  
 2-Hydroxy-4-(methylthio)butanoic acid;  
 2-Hydroxy-4-(methylthio)butyric acid; Alimet;  
 DL-α-Hydroxy-γ-methylmercaptobutyric acid;  
 DL-2-Hydroxy-4-(methylmercapto)butanoic acid;  
 DL-2-Hydroxy-4-(methylmercapto)butyric acid;  
 DL-2-Hydroxy-4-(methylthio)butanoic acid;  
 DL-2-Hydroxy-4-(methylthio)butyric acid; Desmenidol; Hydan L; MHA acid; MHA-FA

-- Properties --

<b>Property</b>	<b>Calculated Value</b>	<b>Condition</b>	<b>Note</b>
Bioconc. Factor	1.09	pH 1	(1) ACD
Bioconc. Factor	1	pH 4	(1) ACD
Bioconc. Factor	1	pH 7	(1) ACD
Bioconc. Factor	1	pH 8	(1) ACD
Bioconc. Factor	1	pH 10	(1) ACD
Boiling Point	316.5±27.0 °C	Press: 760.0 Torr	(1) ACD
Enthalpy of Vap.	64.67±6.0 kJ/mol		(1) ACD
Flash Point	145.2±42.7 °C		(1) ACD
H acceptors	3		(1) ACD
H donors	2		(1) ACD
Koc	37.0	pH 1	(1) ACD
Koc	11.8	pH 4	(1) ACD
Koc	1	pH 7	(1) ACD
Koc	1	pH 8	(1) ACD
Koc	1	pH 10	(1) ACD
logD	0.35	pH 1	(1) ACD
logD	-0.15	pH 4	(1) ACD
logD	-2.91	pH 7	(1) ACD
logD	-3.55	pH 8	(1) ACD
logD	-3.74	pH 10	(1) ACD
logP	0.353±0.399		(1) ACD
Molar Solubility	Soluble	pH 1	(1) ACD
Molar Solubility	Soluble	pH 4	(1) ACD
Molar Solubility	Very Soluble	pH 7	(1) ACD
Molar Solubility	Very Soluble	pH 8	(1) ACD
Molar Solubility	Very Soluble	pH 10	(1) ACD
Molecular Weight	150.20		(1) ACD
pKa	3.67±0.20	Most Acidic	(1) ACD
Vapor Pressure	3.45E-5 Torr	Temp: 25.0 °C	(1) ACD

Notes:

(1) Calculated using Advanced Chemistry Development (ACD/Labs) Software Solaris V4.67 (© 1994-2004 ACD/Labs)

**-- Resources --**

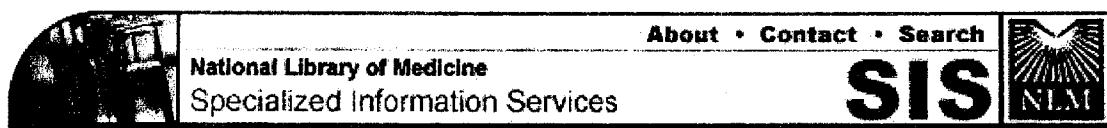
**References:** ~418

**STN Files:** CAPLUS, AGRICOLA, ANABSTR, BEILSTEIN, BIOBUSINESS,  
BIOSIS, BIOTECHNO, CA, CAOLD, CASREACT, CBNB, CEN,  
CHEMCATS, CHEMINFORMRX, CHEMLIST, CIN, CSCHEM, DDFU,  
DRUGU, EMBASE, HSDB, IFICDB, IFIPAT, IFIUDB, MEDLINE, MRCK,  
PROMT, RTECS, SPECINFO, TOXCENTER, USAN, USPAT2,  
USPATFULL, VETU

(Additional Information is available through STN International. Contact your information specialist,  
a local CAS representative, or the CAS Help Desk for Assistance)

**Deleted Registry Number(s):** 120-91-2, 96661-25-5, 110518-19-9

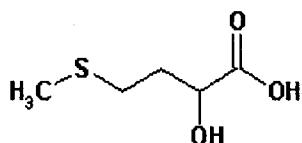
**Database:** REGISTRY (Copyright 2004 ACS)



## ChemIDplus Record

[Tox. & Env. Health](#)   [TOXNET](#)   [Return to Results Page](#)

### Desmeninol [INN] RN: 583-91-5



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#### CAS Registry Number

[1](#) 583-91-5

#### Other Registry Number

[1](#) 110518-19-9

[1](#) 120-91-2

[1](#) 96661-25-5

#### Related Registry Number

[1](#) 14676-91-6 (calcium salt)

[1](#) 14676-91-6 (unspecified calcium salt)

[1](#) 23597-90-2 (mono-hydrochloride salt)

[1](#) 4857-44-7 (calcium[2:1] salt)

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#### System Generated Number

[1](#) 000583915

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[National Institutes of Health, Department of Health & Human Services](#)

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Customer Service: [tehp@teh.nlm.nih.gov](mailto:tehp@teh.nlm.nih.gov).

Last modified on October 1, 2003.



**ATTACHMENT 6**



# Trade Facts

From the Office of the United States Trade Representative  
Washington, DC 20508

[www.ustr.gov](http://www.ustr.gov)

## U.S. Proposes A Tariff-Free World - Modalities

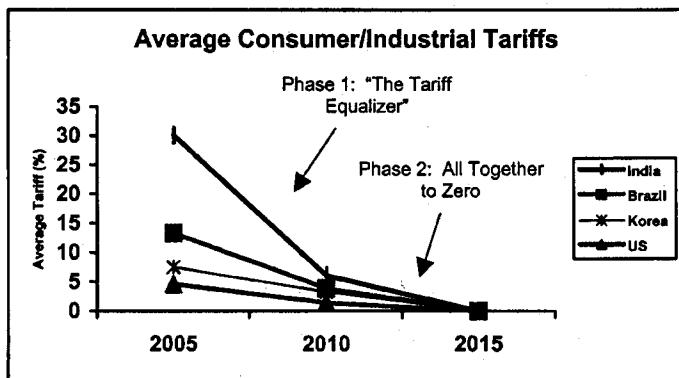
### Phase One, 2005-2010 – Cut and Harmonize

1. Eliminate low tariffs of 5% or less by 2010.
2. Eliminate tariffs in highly-traded goods as soon as possible, but no later than 2010.  
*Expand participation in Uruguay Round "zero-for-zero" sectors, and seek new sectoral initiatives. Sectors should include, but are not limited to:*

Agricultural equipment	Medical Equipment
Bicycle parts	Non-Ferrous Metals
Chemicals and allied products including photo film & soda ash	Paper
Civil aircraft	Pharmaceuticals
Construction Equipment	Scientific Equipment
Environmental technologies	Steel
Fish and Fish Products	Toys
Furniture	Wood products
Information Technology and Electronics Products	(Distilled spirits, beer, & oilseeds covered under negotiations on agricultural tariffs.)

3. Harmonize remaining tariffs to less than 8%.

- Cut highest tariffs fastest
- The formula:  $T_1 = (T_0 * 8) / (T_0 + 8)$  [T<sub>1</sub> = new tariff; T<sub>0</sub> = current tariff]



### Phase Two, 2010-2015: Equal Annual Cuts to Zero

1. With tariffs harmonized, countries make equal annual cuts to zero.

A parallel process will seek to identify and eliminate non-tariff trade barriers.

# Attachment B

**HTS - 2930904600: DL-HYDROXY ANALOGUE OF DL-METHIONINE**  
**First Unit of Quantity by First Unit of Quantity**  
**For ALL Countries**

**U.S. Imports For Consumption**

**Annual + Year-To-Date Data from Jan - Apr**

Quantity Description	2001	2002	2003	2004	2005	2005 YTD	2006 YTD	Percent Change YTD2005 - YTD2006
	<i>In 1,000</i>							
kilograms	920	341	21	6,580	15,416	3,571	2,614	-26.80%

**HTS - 2930904600: DL-HYDROXY ANALOGUE OF DL-METHIONINE**  
**Customs Value by Customs Value**  
**For ALL Countries**

**U.S. Imports For Consumption**

**Annual + Year-To-Date Data from Jan - Apr**

TOTAL	2001	2002	2003	2004	2005	2006	Percent Change YTD2005 - YTD2006
	YTD	YTD	YTD	YTD	YTD	YTD	
\$	1,583	903	562	7,600	20,872	4,446	4,559 2.50%

**2930904550: OTHER ORGANO-SULFUR ACID COMPOUNDS**  
**First Unit of Quantity by First Unit of Quantity**  
**For ALL Countries**

**U.S. Total Exports**

**Annual + Year-To-Date Data from Jan - Apr**

Quantity Description	2001	2002	2003	2004	2005	2005 YTD	2006 YTD	Percent Change YTD2005 - YTD2006
	<i>In 1,000</i>							
kilograms	115,230	110,968	124,212	123,110	97,204	32,512	29,337	-9.80%

**2930904550: OTHER ORGANO-SULFUR ACID COMPOUNDS**  
**FAS Value by FAS Value**  
**For ALL Countries**

**U.S. Total Exports**

**Annual + Year-To-Date Data from Jan - Apr**

	2001	2002	2003	2004	2005	2006 YTD	Percent Change YTD2005 - YTD2006
<b>TOTAL</b>	\$ 182,674	194,162	199,975	185,521	135,431	51,146	42,128 -17.60%