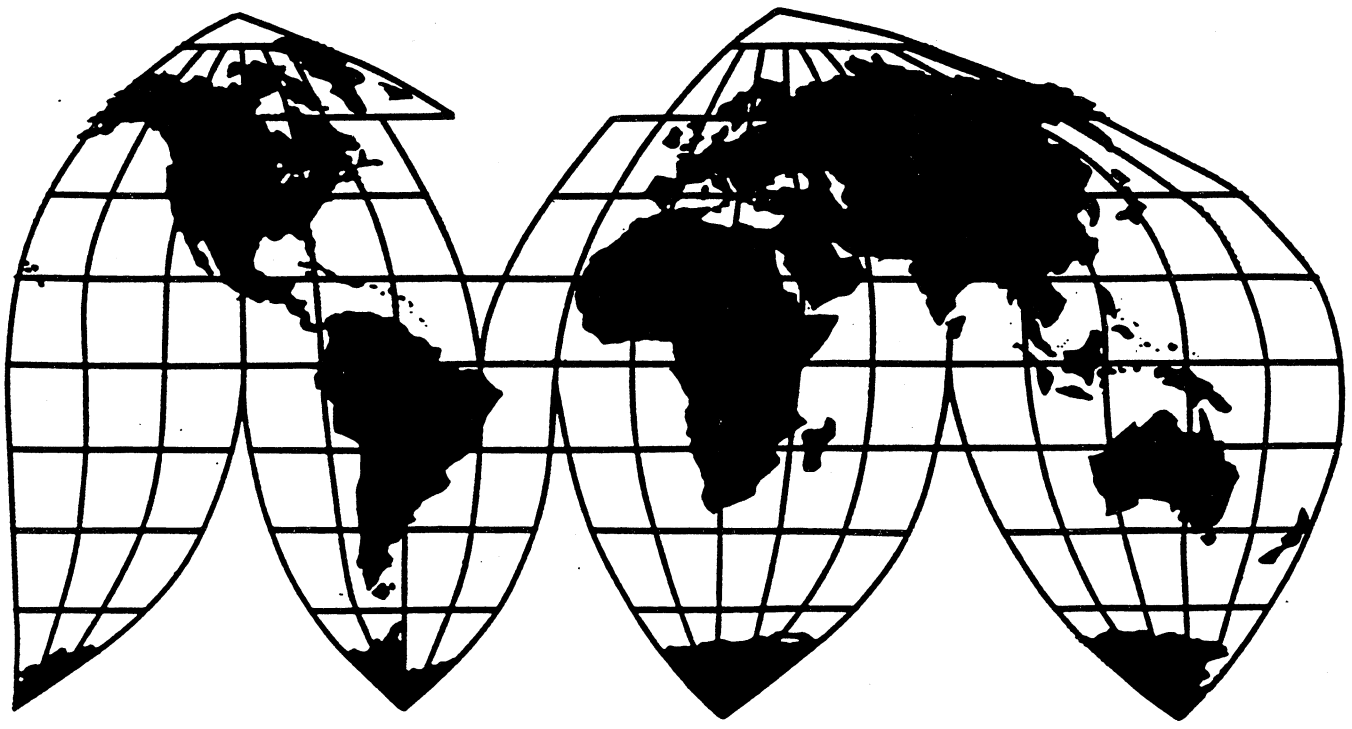
Advice Concerning the Addition of Certain Pharmaceutical Products and Chemical Intermediates to the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States

Investigation No. 332-376

Publication 3011 **January 1997**

U.S. International Trade Commission



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PREFACE

Following receipt on December 18, 1996, of a request from the United States Trade Representative (USTR) (appendix A), the Commission instituted investigation No. 332-376, *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 115 of the Uruguay Round Agreements Act (19 U.S.C. 3524) and section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)).

As requested by the USTR, the Commission in this report provides: (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 of the "zero-for-zero" initiative, including the Pharmaceutical Appendix, to the Harmonized Tariff Schedule of the United States (HTS); and (3) estimates of current U.S. imports and, where possible, 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. The Commission was asked to provide the information and advice in a report by January 17, 1997.

Copies of the notice of investigation were posted in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, 20436 and on the Commission's Internet Server (http://www.usitc.gov or ftp://ftp.usitc.gov); and the notice was published in the *Federal Register* (61 *F.R.* 68294) on December 27, 1996 (appendix B).

The information and analysis in this report are for the purpose of this report only. Nothing in this report should be construed to indicate how the Commission would find in an investigation conducted under other statutory authority covering the same or similar matters.

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CHAPTER I
BACKGROUND

Purpose and Scope of Study

On December 18, 1996, the Commission received a letter from the United States Trade Representative (USTR) asking that the Commission institute an investigation under section 115 of the Uruguay Round Agreements Act (19 U.S.C. 3524) and section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) to provide advice concerning the addition of certain pharmaceutical products and chemical intermediates to the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States (HTS). The 496 products under consideration are enumerated in the annex to the USTR's request letter (copies of the letter and annex are provided in appendix A). Inclusion of the 496 products in the Pharmaceutical Appendix[1] (and its equivalent in the tariffs of participating World Trade Organization (WTO) member nations) would make imports of the products and their derivatives into WTO countries, including the United States, eligible for duty-free treatment.[2]

More specifically, the Commission was requested to provide advice in the form of the following information: (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 of the "zero-for-zero" initiative, including the Pharmaceutical Appendix, to the Harmonized Tariff Schedule of the United States (HTS); and (3) estimates of current U.S. imports and, where possible, 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. The Commission was asked to provide the information in a report by January 17, 1997.

During the Uruguay Round, the United States sought the reciprocal elimination of duties among major countries in a wide range of sectors of key interest to U.S. firms, including pharmaceuticals. This effort was known as the "zero-for-zero" initiative.[3] As a result of the negotiations, the United States and 16 other major trading countries agreed to the reciprocal elimination of duties on approximately 7,000 pharmaceutical products and chemical intermediates (the latter to be used primarily for the production of pharmaceuticals),[4] and their derivatives. Effective January 1, 1995, U.S. imports of these products and their derivatives, as enumerated in the Pharmaceutical Appendix to the HTS, are eligible to enter free of duty under general note 13 to the tariff schedule.

As to U.S. imports, the benefits of this agreement extend to products of all WTO members, under the principle of nondiscriminatory treatment, as well as to other MFN trading partners. In the HTS, duty-free treatment is accorded to all goods of these countries that fall in chapter 30 or certain headings of chapter 29. Many of these tariff provisions also provide duty-free entry under column 2 of the HTS, but the U.S. legal obligation to accord duty-free entry under this agreement extends only to most-favored-nation (MFN)

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[1] The Pharmaceutical Appendix is an instrument of the U.S. schedule. Other countries may reflect the agreed tariff treatment differently.

[2] The derivatives are restricted to those formed by combining the pharmaceutical products with International Nonproprietary Names (INNs) listed on Table 1 of the Pharmaceutical Appendix with the prefixes and/or suffixes listed on Table 2 of the Pharmaceutical Appendix, provided that the derivatives enter under the same six-digit HTS subheading as the appropriate INN. For more information on this topic, see the discussion in Chapter II.

[3] For further information, *see* the Uruguay Round Agreements Act Statement of Administrative Action, at 45-46 (as reprinted in H. Doc. 103-316, vol. 1, at 701-02 (1994)).

[4] See letter from the USTR requesting this investigation, dated December 18, 1996.

countries. For the other goods covered by the Appendix, only MFN countries are eligible for duty-free entry of their products into the United States.

The 17 countries also agreed to conduct a review, at least once every 3 years, to identify products to be added to the list of covered products. Negotiators from several WTO members, including the United States, recently engaged in the first review and reached agreement on the addition of 496 pharmaceutical products and chemical intermediates used primarily for the production of pharmaceuticals. Of these products, 262 are pharmaceutical products with International Nonproprietary Names (INNs) and 234 are chemical intermediates.[5] According to the USTR's request letter, a coalition of pharmaceutical companies from several WTO members (which the Pharmaceutical Research and Manufacturers of America (PhRMA) coordinated) submitted to the negotiators the initial list of candidates for addition to the existing pharmaceutical agreement. Moreover, the letter states that USTR consulted with the Administration's Industry-Sector Advisory Committee-3 (ISAC-3; chemicals) throughout the negotiations and that this ISAC has endorsed the final list of products under consideration.[6]

Organization of the Report

The USTR request specifically asks for information in three areas, and in response the Commission report has been organized into three chapters. This first chapter presents a summary description of the products contained in the existing Pharmaceutical Appendix and the modifications to be made to that Appendix, as well as statistics on the producing industries. Chapter 1 ends with a brief description of the U.S. chemical and pharmaceutical industries. Chapter 2 provides an explanation of the relationship of the "zero-for-zero" initiative, including the Pharmaceutical Appendix, to the HTS. Chapter 3 provides estimates of U.S. imports and, where possible, 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.

Description of the Products Covered

The products addressed in this investigation include bulk pharmaceuticals (i.e., active ingredients in bulk form), dosage-form pharmaceuticals (i.e., formulated pharmaceuticals put up in dosage forms and/or packaged for retail sale), and certain specified, mainly organic, chemical intermediates, intended primarily for the production of pharmaceuticals.

Chemicals are used for a number of purposes: (1) as primary inputs for other products, including other chemicals; (2) as intermediate materials for other chemical and non-chemical products; and (3) as finished products (e.g., pharmaceuticals, pesticides, cosmetics, etc.) used for and by industry, agriculture,

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[5] The original Pharmaceutical Appendix contains over 6,000 INNs and approximately 350 chemical intermediates. The World Health Organization (WHO) maintains the INN database. New INNs are added to the WHO compilation regularly. These additions are published in numbered lists (e.g., List 70, List 71, etc.). The original negotiations covered INNs from lists 1-69. This current review covers products from lists 70-74.

[6] See the letter from the USTR requesting this investigation, dated December 18, 1996.

business, and individual consumers.[7] As with other industries, certain chemical industry data are collected and presented on the basis of the industry's Standard Industrial Classification (SIC) groupings.[8] SIC major group 28, entitled "Chemicals and Allied Products," which provides data at the industry level, consists of several subgroupings related to various sectors within the chemical industry. The INNs addressed in this study are classified primarily in SIC industry group 283 ("Drugs"); whereas the chemical intermediates are classified primarily in SIC industry group 286 ("Industrial Organic Chemicals").

Pharmaceuticals (SIC industry group 283) are used in the prevention, diagnosis, alleviation, treatment, or cure of disease in humans or animals. Bulk active ingredients are generally consumed by pharmaceutical firms and/or formulators, who then prepare finished, dosage-form products. Dosage-form products, in turn, are generally marketed or otherwise made available to the final consumer as generic or brand name prescription or nonprescription (i.e., over-the-counter) products.

Pharmaceutical products can be grouped into fairly broad therapeutic groupings depending on their end use, including anti-infective products, central nervous system (CNS) products, cardiovascular products, etc., with more specific subgroupings within each.[9] Although the 262 pharmaceutical products (i.e., INNs) under consideration fall into several of the broader therapeutic classifications, almost two thirds of the products are classified in the following groupings: cardiovascular (26 percent of the total), CNS (18 percent), and anti-infectives (18 percent). The 234 chemical intermediates under consideration are used to manufacture pharmaceuticals classified in several different therapeutic groupings.

U.S. imports of chemicals are primarily classified in chapters 28-40 of the HTS. Organic products, such as many of the bulk pharmaceutical active ingredients and chemical intermediates under consideration, are generally classified in Chapter 29, "Organic Chemicals," on the basis of their chemical structure [10] U.S. imports of pharmaceuticals are primarily classified in either chapter 29 or Chapter 30, "Pharmaceutical Products," depending on whether the product is an active ingredient in bulk form or if it is a product put up into measured dosages (i.e., dosage-form products).

Within chapter 29, as shown in the following tabulation, there are several 4-digit headings under which certain classes of bulk pharmaceutical active ingredients are grouped by use, including:

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

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[7] CMA, *U.S. Chemical Industry Statistical Handbook, 1996*, p. 7. Approximately 25 percent of the U.S. chemical industry's output in 1995 was consumed by the industry itself. (*Statistical Handbook.*, p. 25)

[8] According to the Office of Management and Budget's *Standard Industrial Classification Manual, 1987*, "The Standard Industrial Classification (SIC) is the statistical classification standard underlying all establishment-based Federal economic statistics classified by industry."

[9] Anti-infective products primarily counteract infection. Central nervous system products include, among others, analgesics and antipyretics; anticonvulsants; psychotherapeutic agents; respiratory and cerebral stimulants; and sedatives and hypnotics. Cardiovascular products, pertaining primarily to the heart and blood vessels, include, among others, cardiac drugs, antilipemic (i.e., cholesterol-lowering) products, and hypotensive agents.

[10] Those chemical intermediates under consideration that are classified as mixtures intended for consumption in the production of downstream chemical products would enter under chapter 38, "Miscellaneous Chemical Products."

The remaining bulk active ingredients are generally classified by their chemical structure in 8-digit subheadings in chapter 29 that are specifically applicable to drugs. Once these bulk active ingredients are formulated into finished, dosage-form products, however, they are generally classified in chapter 30.[11]

Brief description of the U.S. Chemical and Pharmaceutical Industries

Pharmaceutical active ingredients and finished pharmaceutical products are primarily manufactured by pharmaceutical companies. The chemical intermediates under consideration, however, are generally manufactured by chemical companies, but, depending on their relationship as a precursor to the bulk active ingredient itself (i.e., an immediate precursor versus one removed several times), could be produced by pharmaceutical companies. The U.S. chemical and pharmaceutical industries are largely multinational in operation, highly regulated, and capital and technology intensive, often utilizing state-of-the-art technology. The chemicals and allied products industry (SIC major group 28) annually accounts for approximately 2 percent of the total U.S. gross domestic product.[12] Whereas the U.S. chemical industry has production facilities distributed throughout the United States; the U.S. pharmaceutical industry is more geographically concentrated, primarily in New York, New Jersey, Pennsylvania, and California.[13]

Both industries incur large research and development (R&D) expenditures. In 1995, the chemicals and allied products industry spending on research and development increased to about $18 billion, from about $17 billion in 1994. R&D spending in the pharmaceutical industry accounted for a large share of the total, or an estimated $12 billion.[14] R&D spending in the industrial chemicals sector (including industrial organic chemicals) increased to $4.9 billion in 1995 from $4.8 billion in 1994. According to one source, the role of R&D spending in the industry is increasing in importance primarily because of changes in the composition of the industry, including "increasing diversification into high-technology fields, such as pharmaceuticals, biotechnology, and advanced materials that have applications in transportation and other industries.[15]

At the most aggregated level, data for the "chemical and allied products" industry include data on the pharmaceutical industry. For the purposes of this report, highly aggregated data on the chemical industry will be presented first, followed by more detail for the pharmaceutical industry and that portion of the chemical industry that manufactures many, if not all, of the organic chemical intermediates under consideration (see table 1). In 1995, shipments by the chemicals and allied products industry (SIC 28) were valued at approximately $368 billion. Industry employment in that year amounted to approximately 1 million employees, with production workers accounting for approximately 56 percent of the total. U.S. imports of products classified under SIC 28 were valued at about $38 billion in 1995; U.S. exports were valued at about $58 billion. In 1995, the portion of the chemical industry that manufactures pharmaceuticals and the organic chemical intermediates under consideration (i.e., SIC 283 and 286) accounted for approximately 39 percent

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[11] Chapter 30 covers other products in addition to formulated, dosage-form products (HTS heading 3004), including glands and their extracts; blood and blood products; vaccines; mixtures of pharmaceuticals (not put up in dosage form); and items such as wadding, bandages, sterile catgut, etc. However, dosage-form products accounted for almost 70 percent of total Chapter 30 imports in 1995, by value. All products in chapter 30 enter free of duty.

[12] *U.S. Chemical Industry Statistical Handbook, 1996*, p. 21.

[13] For the purposes of this study, the U.S. chemical and pharmaceutical industries are considered to include firms of foreign ownership or parents operating in the United States.

[14] Pharmaceutical Research and Manufacturers of America, *Industry Profile, 1996*, p. 9.

[15] *U.S. Chemical Industry Statistical Handbook, 1996*, p. 91.

of total U.S. apparent consumption of chemicals, 45 percent of total U.S. chemicals trade, and 39 percent of U.S. employment in the chemical industry.

Table 1.
Chemicals and pharmaceuticals: U.S. shipments, imports for consumption, exports of domestic merchandise, trade balance, apparent consumption, total employment, and production workers, 1995

Product groupings	U.S. shipments (billions of dollars)	U.S. imports (billions of dollars)	U.S. exports (billions of dollars)	U.S. trade balance (billions of dollars)	U.S. apparent consumption (billions of dollars)	Total employment (thousands)[1]	Production workers (thousands)[1]
Chemicals and Allied Products (SIC 28)	367.5	38.1	57.9	19.8	347.7	1,045	582
Drugs (SIC 283)	70.8[2]	8.6	8.0	(0.6)	71.4	260	127
Industrial Organic Chemicals (SIC 286)	68.6[2]	10.7	15.8	5.1	63.5	143	81

[1] *U.S. Chemical Industry Statistical Handbook, 1996*, p. 103.
[2] Estimated by Commission staff.

Note. -- Negative values are indicated by parentheses.

Source: Official statistics of the U.S. Department of Commerce, except as noted.

CHAPTER 2
DESCRIPTION OF THE "ZERO-FOR-ZERO"INITIATIVE AND ITS RELATIONSHIP TO THE HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

As a result of the Uruguay Round Agreements, as reflected by the United States in Schedule XX and in the HTS, duty-free treatment was granted for most, if not all, bulk and dosage-form pharmaceuticals, using a two-pronged approach. First, duties were immediately eliminated for all products classified in chapter 30 ("Pharmaceutical Products") of the HTS (primarily covering formulated pharmaceuticals in dosage form) and for those bulk active ingredients entering under HTS headings 2936, 2937, 2939, and 2941.[16]

Second, the HTS Pharmaceutical Appendix was created, enumerating the products and chemical intermediates, and their derivatives, that are eligible for duty-free entry.[17] In the HTS, the letter "K" was added to the special rates of duty subcolumn for certain 8-digit subheadings (primarily in chapters 28-39) to denote those subheadings under which many of the bulk active ingredients and/or the chemical intermediates in the Appendix could be classified (not including the headings of chapter 30 and chapter 29 headings 2936, 2937, 2939, and 2941) and to insure that they receive duty-free treatment.[18] Only MFN trading partners are eligible for these special rates.

The Pharmaceutical Appendix in the HTS consists of three tables:

Pharmaceutical Appendix Table 1 --

A list of eligible pharmaceuticals listed by their INNs. The original table 1 included INNs from World Health Organization (WHO) lists 1-69; the 262 INNs currently under consideration for addition to the Appendix are included in WHO lists 70-74. Depending on their form (i.e., bulk active ingredients or dosage-form products), the INNs can either be classified in chapter 29 or chapter 30 of the HTS. As mentioned previously, all MFN U.S. imports classified within chapter 30 and under HTS headings 2936, 2937, 2939, and 2941 automatically enter free of duty as a result of the pharmaceutical agreement initiative whether or not they are listed in the Pharmaceutical Appendix;

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[16] Except for dihydrostreptomycin and its derivatives and salts thereof.

[17] As noted above, U.S. imports of many of the INNs listed in the Pharmaceutical Appendix enter the United States under chapter 30 or under HTS headings 2936, 2937, 2939, and 2941. Even though these products would enter the United States free of duty (for some headings, from all sources, including column 2 countries), the names of such products were retained in the Appendix because of concern that these products might not be eligible for duty-free treatment if individual shipments of these products were to be classified under any HTS subheadings other than those specified as being free of duty. According to the 1997 HTS, the column 2 rate of duty applies to products imported from the following countries: Afghanistan, Cuba, Laos, North Korea, and Vietnam.

[18] It should be noted that the HTS provisions having the "K" symbol may include a broader range of products than just those listed in the Pharmaceutical Appendix. Also, depending on the HTS classifications of the 496 products under consideration, some HTS subheadings currently without a "K" symbol may need to have the symbol added to provide duty-free treatment for the additional products and their derivatives.

Pharmaceutical Appendix Table 2 --

A list of the prefixes and suffixes that could be associated with the INNs. Derivatives of the INNs are potentially represented by the addition of the prefixes and/or the suffixes listed in table 2.[19] These products would largely be classified in chapters 29, 30, and 38. Multiple permutations in derivatives are possible for most of the INNs.

However, because it is unlikely that all of the prefixes and suffixes are associated with each of the INNs, it is not possible to quantify the upper limit of the number of products that would ultimately be eligible for duty-free entry under this agreement (as long as the derivatives are classified in the same 6-digit HTS heading as the appropriate INN as required). In this review process, 81 prefixes and suffixes are being added to table 2, above and beyond the 496 INNs and chemical intermediates; and

Pharmaceutical Appendix Table 3 --

A list of chemical intermediates intended primarily for the manufacture of the pharmaceuticals. These products would generally be classified in chapters 29 and 38.

[19] As used in the pharmaceutical agreement, derivatives of chemicals are often noted by the addition of certain prefixes and suffixes denoting different chemical parts of the products' chemical structures. Although the primary chemical may be the same, addition of the chemical segments represented by different prefixes and suffixes can create different products. Adding "sodium" to the INN "Fosinopril," for example, denotes the sodium salt of the product, "Fosinopril Sodium."

CHAPTER 3
ESTIMATES OF CURRENT U.S. TRADE IN THE PRODUCTS INCLUDED IN THE EXISTING PHARMACEUTICAL APPENDIX AND THE PROPOSED ADDITIONS TO THE APPENDIX

Trade data are provided below both for the products already listed in the Pharmaceutical Appendix and for the products to be added. Trade data for the products already in the Appendix, obtained from official statistics of the U.S. Department of Commerce, are provided for 1995, the first full year the duty elimination was in effect, and for the first 10 months in 1995 and in 1996 (see table 2).[20] For U.S. imports, the data are the total of: (1) the value of imports entering under chapter 30 and HTS headings 2936, 2937, 2939, and 2941; and (2) the value of imports entering under the special duty rate as noted by the "K"symbol (i.e., bulk active ingredients and chemical intermediates in the Pharmaceutical Appendix generally classified in chapters 28-40 in HTS headings other than the four headings specified in item 1).

Estimated average annual trade data for the period 1994-99 are provided for the 496 products to be added (see table 3). The data were obtained from a PhRMA survey of 16 pharmaceutical companies, including many of the companies that belong to the industry group that proposed the additional products. These 16 companies are some of the largest pharmaceutical firms in the world, with 12 of them among the top 20 firms worldwide, in terms of sales.[21]

Many of the products under consideration are patented or licensed and, therefore, produced by only one or two companies; as such, much of the data are proprietary. At the time this report was completed, five companies had responded to PhRMA's survey. Their responses covered 62 products, or 13 percent of the total. The companies provided estimated trade data for 1994-99 for 32 products, the majority of which were intermediates. They stated in their responses that many of the remaining products for which they responded have little or no past or prospective trade. Because many of the INNs for which data were reported are believed to be patented or subject to a license, the estimated trade data provided for most of these products are likely to be complete. Many of the intermediate products, however, may not be covered by a patent or subject to a license. Therefore, it is possible that companies other than those surveyed may also import or export certain of the intermediates for which data were furnished. In view of the above and given that 11 companies have not responded to the PhRMA survey as of the date of preparation of this report, the data provided in table 3 give only a rough, lower bound estimate of the total trade associated with the 496 products under consideration.

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[20] The initiative was implemented January 1, 1995.

[21] Whereas the 234 chemical intermediates were proposed by specific companies, the 262 pharmaceutical products were those products with INNs in WHO lists 70-74. The companies associated with almost 50 percent of the latter products have not been identified.

Table 2.
Products already covered by the pharmaceutical agreement: U.S. imports, exports, and trade balance for 1995; Jan.-Oct. 1995; and Jan.-Oct. 1996

(millions of dollars)

Product groupings		1995			Jan.-Oct. 1995			Jan.-Oct. 1996		
		U.S. imports	U.S. exports	Trade balance	U.S. imports	U.S. exports	Trade balance	U.S. imports	U.S. exports	Trade balance
Trade under chapter 30 of the HTS/Schedule B[1] and HTS/Schedule B headings 2936, 2937, 2939, and 2941	2936	559	318	(240)	468	256	(212)	540	272	(268)
	2937	177	375	198	150	317	167	211	280	69
	2939	198	20	(179)	165	15	(150)	439	19	(420)
	2941	753	1,052	299	577	879	302	703	858	155
	Chapter 30	3,905	4,637	732	3,260	3,833	573	3,953	4,535	582
Pharmaceutical products and intermediates entering under the "K" symbol		3,897	([2])	([2])	3,302	([2])	([2])	4,459	([2])	([2])
Total trade for the products covered by the pharmaceutical agreement		9,489	([2])	([2])	7,922	([2])	([2])	10,305	([2])	([2])

[1] "Schedule B" refers to the *Statistical Classification of Domestic and Foreign Commodities Exported from the United States*, the export counterpart to the HTS. However, the HTS is commonly utilized for reporting exports.

[2] Not available. U.S. export data are not reported using the "K" symbol and, therefore, no comparable statistics are available for exports of these products.

Note. -- Negative values are indicated by parentheses.

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

Table 3.
Proposed additions to the Pharmaceutical Appendix: Average annual U.S. imports, exports, and trade balance, based on trade data obtained from an industry survey conducted by PhRMA, 1994-99

(millions of dollars)

Product groupings	U.S. imports	U.S. exports	Trade balance
Estimated average annual trade for the additions to the Pharmaceutical Appendix	$67	$20	($47)

Note. -- Negative values are indicated by parentheses.

Source: Estimated from trade data provided by industry sources in response to a PhRMA survey. The 5 respondent companies noted that there was neither past nor prospective trade in most of the products associated with their companies, responding for 62 products in total with trade estimates for 32 products. The data shown represent a lower bound estimate only.

Appendix A
REQUEST LETTER FROM THE USTR AND ATTACHED ANNEX

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

December 18, 1996

The Honorable Marcia E. Miller
Chairman
U.S. International Trade Commission
500 E Street, NW
Washington, D.C. 20436

Dear Chairman Miller:

Achieving improved market access through elimination of tariff barriers has been a U.S. objective that was most recently advanced in the context of the Uruguay Round negotiations and the creation of the World Trade Organization (WTO). The Administration expects to further advance that objective at the WTO Ministerial Conference being held in Singapore later this month. In that context, I am requesting the Commission's continued assistance in fulfilling the statutory requirements for implementation of tariff cuts under authority of the Uruguay Round Agreements Act (URAA).

The Commission, in the context of preparing for and implementing the results of the Uruguay Round negotiations, undertook an investigation under section 131 of the Trade Act of 1974: *Probable Economic Effect on U.S. Industries and Consumers of Modification of U.S. Tariffs* (prepared for USTR in June 1989); and an investigation under section 332 of the Tariff Act of 1930: *Potential Impact on the U.S. Economy and Industries of the GATT Uruguay Round Agreements* (prepared for the Senate Finance Committee and the House Ways and Means Committee in June 1994). These reports provided information that was one of the bases for Congress to authorize the President to proclaim tariff reductions resulting from the Uruguay Round and authorize further cuts in certain sectors.

As one part of the market access tariff results, the United States and 16 other major trading nations agreed to the reciprocal elimination of duties on approximately 7,000 pharmaceutical products and chemical intermediates used primarily for the production of pharmaceuticals. The covered products are set forth in an Appendix to the agreement and are reflected in each participant's market access schedule. Obtaining duty elimination on pharmaceuticals was part of a more comprehensive initiative on reciprocal duty elimination--the so-called zero-for-zero initiative.

Participants in the pharmaceutical "zero-for-zero" initiative agreed in the Uruguay Round to conduct a review, at least once every three years, to identify products that could be covered by the Agreement. Negotiators from several WTO members, including the United States, recently engaged in the first review, and have reached agreement on the addition of approximately 470 pharmaceutical products and chemical intermediates used primarily for the production of pharmaceuticals (a listing of covered products is attached). A coalition of pharmaceutical

companies from several WTO members (which the Pharmaceutical Research and Manufacturers of America (PhRMA)coordinated) submitted the initial list of candidates for addition to the existing Appendix to the pharmaceutical agreement. USTR consulted with ISAC-3 (chemicals) throughout the negotiations and this ISAC has endorsed the final list of items under consideration. Moreover, your staff at the Commission provided invaluable technical assistance to USTR negotiators in a number of areas, especially in regard to product nomenclature and Harmonized System issues.

In section 111(b) of the URAA, Congress explicitly authorized the President to proclaim further modifications 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 only 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) a clear and comprehensive explanation of the relationship between the various elements in the Appendix and the Harmonized Tariff Schedule of the United States (HTS); and (3) an estimate of the current U.S. imports and, where possible, current U.S. exports of the products included in the existing phamaceutical Appendix and the proposed additions to the Appendix, based on product groupings as necessary.

I recognize that data may not be available for every product, particularly in the case of new products. In such instances, I understand that the advice provided may be in a qualitative form. I request that the Commission provide its advice at the earliest possible date, but not later than January 17, 1997. After we receive the Commission's advice, the 60-day consultation and layover period may commence.

It is the intent of this office to make the Commission's report available to the 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,

Charlene Barshefsky
U.S.Trade Representative-Designate

The following list consists of the products that have been added to the World Trade Organization's list of pharmaceuticals originally negotiated under the Uruguay Round of trade negotiations. The items are listed below as they will appear in the Pharmaceutical Appendix to the Tariff Schedule In the Harmonized Tariff Schedule of the United States. Chemical Abstracts Service (CAS) registry numbers are included for ease of identification.

The list includes new International Non-proprietary Name (INN) pharmaceuticals as well as new INN prefix and suffix names and chemical intermediates for pharmaceuticals.

Table 1

New INNs to be added

The following new INNs along with their CAS numbers are to be added:

Product	CAS Number
ABCIXIMAB	143653-53-6
ABITESARTAN	137882-98-5
ACITAZANOLAST	114607-46-4
ADATANSERIN	127266-56-2
ADEFOVIR	106941-25-7
ADELMIDROL	1675-66-7
AFELIMOMAB	156227-98-4
AFOVIRSEN	151356-08-0
AGLEPRISTONE	124478-60-0
ALMAGODRATE	
ALNESPIRONE	138298-79-0
ALNIDITAN	152317-89-0
ANAKINRA	143090-92-0
ANASTROZOLE	120511-73-1
ANTITHROMBIN III, HUMAN	9000-94-6
APAXIFYLLINE	151581-23-6
APTIGANEL	137159-92-3
ARTEFLENE	123407-36-3
ATEXAKIN ALFA	143631-61-2
ATIBEPRONE	153420-96-3
ATORVASTATIN	134523-00-5
AZALANSTAT	143393-27-5
AZIMILIDE	149908-53-2
BALAZIPONE	137109-71-8
BALOFLOXACIN	127294-70-6
BASIFUNGIN	127785-64-2
BATIMASTAT	130370-60-4
BERUPIPAM	150490-85-0
BERVASTATIN	132017-01-7
BESIPIRDINE	119257-34-0
BETASIZOFIRAN	39464-87-4
BICALUTAMIDE	90357-06-5
BISNAFIDE	144849-63-8
BIVALIRUDIN	128270-60-0

BOSENTAN	147536-97-8
CANDESARTAN	139481-59-7
CANDOCURONIUM IODIDE	54278-85-2
CAPECITABINE	154361-50-9
CAPROMAB	151763-64-3
CARTASTEINE	149079-51-6
CEFLUPRENAM	116853-25-9
CEFOSELIS	122841-10-5
CERTOPARIN SODIUM	
CIDOFOVIR	113852-37-2
CILMOSTIM	148637-05-2
CINALUKAST	128312-51-6
CIPAMFYLLINE	132210-43-6
CISATRACURIUM BESILATE	96946-42-8
COLESTILAN	95522-45-5
CROMOGLICATE LISETIL	110816-79-0
CROSPOVIDONE	9003-39-8
DACLIXIMAB	152923-56-3
DAPABUTAN	6582-31-6
DARIFENACIN	133099-04-4
DARSIDOMINE	137500-42-6
DELAVIRDINE	136817-59-9
DELEQUAMINE	119905-05-4
DENOTIVIR	51287-57-1
DESIRUDIN	120993-53-5
DETUMOMAB	145832-33-3
DEXECADOTRIL	112573-72-5
DEXKETOPROFEN	22161-81-5
DEXPEMEDOLAC	114030-44-3
DIMADECTIN	156131-91-8
DOMITROBAN	112966-96-8
DORNASE ALFA	143831-71-4
EBALZOTAN	149494-37-1
EFEGATRAN	105806-65-3
EFLETIRIZINE	150756-35-7
ELISARTAN	158682-68-9
ELOPIPRAZOLE	115464-77-2
EMIDELTIDE	62568-57-4
ENLIMOMAB	142864-19-5
EPOETIN EPSILON	154725-65-2
EPOETIN OMEGA	148363-16-0
EPRINOMECTIN	123997-26-2
EPROSARTAN	133040-01-4
EPTACOG ALFA (ACTIVATED)	102786-52-7
ERBULOZOLE	
ERSENTILIDE	125279-79-0
EXAMORELIN	140703-51-1
FENLEUTON	141579-54-6
FIBRIN, BOVINE	
FIBRIN, HUMAN	
FODIPIR	118248-91-2
FOLLITROPIN ALFA	9002-68-0

FOZIVUDINE TIDOXIL	141790-23-0
FRADAFIBAN	148396-36-5
FULADECTIN	
GADOVERSETAMIDE	131069-91-5
GADOXETIC ACID	135326-11-3
GALDANSETRON	116684-92-5
GECLOSPORIN	74436-00-3
GLENVASTATIN	122254-45-9
GORALATIDE	120081-14-3
IBANDRONIC ACID	114084-78-5
ICOMETASONE ENBUTATE	103466-73-5
IDRAMANTONE	20098-14-0
IFETROBAN	143443-90-7
IGANIDIPINE	119687-33-1
ILEPCIMIDE	82857-82-7
ILOMASTAT	142880-36-2
ILONIDAP	135202-79-8
IMIDAPRILAT	89371-44-8
IMIGLUCERASE	154248-97-2
IMITRODAST	114686-12-3
INCADRONIC ACID	124351-85-5
INOGATRAN	155415-08-0
INOLIMOMAB	152981-31-2
INSULIN LISPRO	133107-64-9
INTERFERON ALFA	9008-11-1
INTERFERON BETA	9008-11-1
INTERFERON GAMMA	9008-11-1
IOLOPRIDE (123 I)	113716-48-6
IPENOXAZONE	104454-71-9
IPIDACRINE	62732-44-9
IRALUKAST	151581-24-7
IRBESARTAN	138402-11-6
ITAMELINE	121750-57-0
LAFLUNIMUS	147076-36-6
LAFUTIDINE	118288-08-7
LAMIFIBAN	144412-49-7
LANPERISONE	116287-14-0
LANPROSTON	105674-77-9
LAURCETIUM BROMIDE	1794-75-8
LEDISMASE	149394-67-2
LENAPENEM	149951-16-6
LENERCEPT	156679-34-4
LEPIRUDIN	138068-37-8
LETROZOLE	112809-51-5
LEVORMELOXIFENE	78994-23-7
LEVOSEMOTIADIL	116476-16-5
LEXACALCITOL	131875-08-6
LEXIPAFANT	139133-26-9
LIREQUINIL	143943-73-1
LISOFYLLINE	100324-81-0
LOBUCAVIR	127759-89-1
LOVIRIDE	147362-57-0

LUBELUZOLE	144665-07-6
LUTROPIN ALFA	152923-57-4
MANGAFODIPIR	155319-91-8
MAPINASTINE	140945-32-0
MAZAPERTINE	134208-17-6
MIBEFRADIL	116644-53-2
MINOLTEPARIN SODIUM	
MIPITROBAN	136122-46-8
MIRISETRON	135905-89-4
MOBENAKIN	124146-64-1
MOFAROTENE	125533-88-2
MONTELUKAST	158966-92-8
MONTEPLASE	156616-23-8
MOROCTOCOG ALFA	
MUPLESTIM	148641-02-5
MUROMONAB-CD3	
NACOLOMAB TAFENATOX	150631-27-9
NADROPARIN CALCIUM	
NAPITANE	148152-63-0
NAPSAGATRAN	154397-77-0
NATEPLASE	159445-63-3
NEMORUBICIN	108852-90-0
NETIVUDINE	84558-93-0
NICANARTINE	150443-71-3
NICOTREDOLE	29876-14-0
NUPAFANT	139133-27-0
OCINAPLON	96604-21-6
OCTOCOG ALFA	139076-62-3
ODULIMOMAB	159445-64-4
OLOPATADINE	113806-05-6
OLPADRONIC ACID	63132-39-8
OLPRINONE	106730-54-5
ONTAZOLAST	147432-77-7
ORIENTIPARCIN	159445-62-2
OXECLOSPORIN	135548-15-1
PAMICOGREL	101001-34-7
PANAMESINE	139225-22-2
PARNAPARIN SODIUM	
PAZINACLONE	103255-66-9
PAZUFLOXACIN	127045-41-4
PEGORGOTEIN	155773-57-2
PENTOSAN POLYSULFATE SODIUM	
PEROSPIRONE	150915-41-6
PICLAMILAST	144035-83-6
PIMILPROST	139403-31-9
PLUSONERMIN	
POBILUKAST	107023-41-6
POLIXETONIUM CHLORIDE	31512-74-0
POLYSORBATE 1	9017-37-2
POLYSORBATE 8	9009-51-2
POLYSORBATE 20	9005-64-5
POLYSORBATE 21	9005-64-5

POLYSORBATE 40	9005-66-7
POLYSORBATE 60	9005-67-8
POLYSORBATE 61	9005-67-8
POLYSORBATE 65	9005-71-4
POLYSORBATE 80	9005-65-6
POLYSORBATE 81	9005-65-6
POLYSORBATE 85	9005-70-3
POLYSORBATE 120	1543262-61-5
POMISARTAN	144702-17-0
PREMAFLOXACIN	143383-65-7
PRILIXIMAB	147191-91-1
PROPAGERMANIUM	
PRULIFLOXACIN	123447-62-1
QUIFLAPON	136668-42-3
RACECADOTRIL	81110-73-8
RAMATROBAN	116649-85-5
RAMOSETRON	132036-88-5
RASAGILINE	136236-51-6
REGAVIRUMAB	153101-26-9
REPAGERMANIUM	
REVIPARIN SODIUM	
RICASETRON	117086-68-7
RIPISARTAN	148504-51-2
ROCEPAFANT	132418-36-1
ROFLEPONIDE	144459-70-1
RUFINAMIDE	106308-44-5
RUZADOLANE	115762-17-9
SALNACEDIN	87573-01-1
SAMIXOGREL	133276-80-9
SANFETRINEM	156769-21-0
SAPRISARTAN	146623-69-0
SEPRILOSE	133692-55-4
SERATRODAST	112665-43-7
SETIPAFANT	132418-35-0
SPIROGLUMIDE	137795-35-8
SPRODIAMIDE	138721-73-0
STACOFYLLINE	98833-92-2
SULFADIAZINE SODIUM	547-32-0
SULODEXIDE	57821-29-1
SUSALIMOD	149556-49-0
TAGORIZINE	118420-47-6
TALSACLIDINE	147025-53-4
TAMIBAROTENE	94497-51-5
TASOSARTAN	145733-36-4
TAZAROTENE	118292-40-3
TAZOFELONE	136433-51-7
TECHNETIUM (99M TC) FURIFOSMIN	142481-95-6
TELINAVIR	143224-34-4
TELMISARTAN	144701-48-4
TEVERELIX	144743-92-0
THYMALFASIN	62304-98-7
TINZAPARIN SODIUM	

TIROFIBAN	144494-65-5
TOBORINONE	143343-83-3
TOLAFENTRINE	139308-65-9
TRADECAMIDE	132787-19-0
TROVAFLOXACIN	147059-72-1
TROVIRDINE	149488-17-5
VEDAPROFEN	71109-09-6
VERSETAMIDE	129009-83-2
VORICONAZOLE	137234-62-9
VOTUMUMAB	148189-70-2
XANOMELINE	131986-45-3
ZAFIRLUKAST	107753-78-6
ZALEPLON	151319-34-5
ZANAMIVIR	139110-80-8
ZANKIREN	138742-43-5
ZIFROSILONE	132236-18-1
ZIPRASIDONE	146939-27-7
ZOLASARTAN	145781-32-4
ZOLEDRONIC ACID	118072-93-8
ZUCAPSAICIN	25775-90-0

Table 2 Modifications

Additions

The following chemical or INN prefixes and suffixes (also called INN modifiers or INNMs) are to be added in alphabetical order:

ACETURATE
N-ACETYLGLYCINATE
ACISTRATE
ACOXIL
AMSONATE
BENZATHINE
BEZOMIL
BUCICLATE
BUNAPSILATE
BUTEPRATE
BUTYL ESTER
CARBESILATE
P-CHLOROBENZENESULFONATE
P-CHLOROBENZENESULPHONATE
CICLOTATE
CIPIONATE
CLOSILATE
CLOSYLATE
CROBEFATE
CROMACATE
CROMESILATE
CYCLOPENTANEPROPIONATE
CYCLOTATE
CYPIONATE
DAPROPATE
DEANIL
DECIL
DIBUDINATE
DIBUNATE
DIETHANOLAMINE
DIGOLIL
N,N-DIMETHYL-ß-ALANINE
DIOLAMINE
DOCOSIL
DOFOSFATE
EDAMINE
EDISYLATE
EPOLAMINE
ERBUMINE
ETABONATE
ETHANOLAMINE
ETHYLENEDIAMINE
FARNESIL
FENDIZOATE

FOSTEDATE
HIBENZATE
HYBENZATE
HYCLATE
o-(4-HYDROXYBENZOYL)BENZOATE
ISOCAPROATE
LAURIL
LAURILSULFATE
LAURYLSULPHATE
MEGALLATE
METEMBONATE
4-METHYLBICYCLO[2.2.2]OCT-2-ENE-1-CARBOXYLATE
MOFETIL
OCTIL
OLAMINE
OXOGLURATE
PENDETIDE
PIVOXETIL
PROXETIL
1-PYRROLIDINEETHANOL
SODIUM LAURIL SULFATE
SODIUM LAURIL SULPHATE
SODIUM LAURYL SULFATE
SODIUM LAURYL SULPHATE
STEAGLATE
TENOATE
TEPROSILATE
TETRADECYL HYDROGEN PHOSPHATE
TOFESILATE
TRICLOFENATE
TRIETHANOLAMINE
TRIFLUTATE
TROLAMINE
TROMETAMOL
TROMETHAMINE
TROXUNDATE
XINOFOATE

Table 3 modifications

The following products are to be added to Table 3. They include finished chemical products that are to be used as pharmaceuticals as well as chemical intermediates that will be used to produce pharmaceuticals. Products are listed along with Chemical Abstracts Service (CAS) registry numbers for ease of identification.

Name	CAS Number
(alpha-D-glucopyranosylthio)gold	12192-57-3
1-chloro-2-(chlorodiphenylmethyl)benzene	42074-68-0
alpha,4-dibromo-2-fluorotoluene	76283-09-5
2-[(1S,2R)-6-fluoro-2-hydroxy-1-isopropyl-1,2,3,4-tetrahydro-2-naphthyl]ethyl p-toluenesulfonate	104265-58-9
2,3,5-trimethylhydroquinone	700-13-0
4-[2-(cyclopropylmethoxy)ethyl]phenol	63659-16-5
11-alpha-hydroxypregn-4-ene-3,20-dione	80-75-1
5,6-dimethoxyindan-1-one	2107-69-9
9-beta,11-beta-epoxy-17,21-dihydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione	24916-90-3
21-chloro-9-beta,11-beta-epoxy-17-hydroxy-16-alpha-methylpregna-1,4-diene-3,20-dione	83881-08-7
20-oxopregna-5,16-dien-3-beta-yl acetate	979-02-2
pentyl chloroformate	638-41-5
trans-4-(p-chlorophenyl)cyclohexanecarboxylic acid	49708-81-8
(E)-oct-4-ene-1,8-dioic acid	48059-97-8
triethyl 3-bromopropane-1,1,1-tricarboxylate	71170-82-6
indan-5-yl hydrogen phenylmalonate	27932-00-9
dibenzoyl-L-tartaric acid	2743-38-6
ethyl DL-mandelate	4358-88-7
{(1R,3R,5S)-3,5-dihydroxy-2-[(E)-(3S)-3-hydroxyoct-1-enyl]cyclopentyl}acetic acid	56188-04-6
3-chloroformyl-o-tolyl acetate	167678-46-8
(R)-2-(3-benzoylphenyl)propionic acid	56105-81-8
(RS)-2-(3-benzoylphenyl)propionic acid	22161-86-0
ethyl 7-chloro-2-oxoheptanoate	78834-75-0
3-[(3aS,4S,7aS)-7a-methyl-1,5-dioxooctahydro-1H-inden-4-yl]propionic acid	1944-63-4
methyl 2-(3-nitrobenzylidene)-3-oxobutyrate	39562-17-9
(RS)-2-(6-methoxy-2-naphthyl)propionic acid	26159-31-9
methyl (2R,3S)-2,3-epoxy-3-(4-methoxyphenyl)propionate	105560-93-8
methyl 7-[(3RS)-3-hydroxy-5-oxocyclopent-1-enyl]heptanoate	40098-26-8
(2-chloroethyl)diisopropylamine hydrochloride	4261-68-1
N,N'-dibenzylethylenediammonium di(acetate)	122-75-8
(1S,2R)-1-aminoindan-2-ol	126456-43-7
4'-[2-(dimethylamino)ethoxy]-2-phenylbutyrophenone	68047-07-4
2-amino-5-chloro-2'-fluorobenzophenone	784-38-3
(S)-5-amino-2-(dibenzylamino)-1,6-diphenylhex-4-en-3-one	156732-13-7
5-amino-2,4,6-triiodoisophthaloyl dichloride	37441-29-5
benzyl L-alaninate--p-toluenesulfonic acid (1:1)	42854-62-6
(-)-alpha-(chloroformyl)benzylammonium chloride	39878-87-0
2-(N-methylbenzylamino)ethyl 3-aminobut-2-enoate	54527-73-0
methyl (4-nitrophenyl)-L-alaninate	81677-60-3
3-(4-nitrophenyl)-L-alanine	949-99-5
(2S)-2-amino-3-hydroxy-N-pentylpropionamide--oxalic acid (1:1)	153758-31-7
L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysyl-L-leucyl-L-leucyl-L-leucyl-L-leucyl-L-lysine	138531-07-4
3'-acetyl-4'-hydroxybutyranilide	40188-45-2
N-(benzyloxycarbonyl)-L-valine	1149-26-4
(2S,3S)-3-(tert-butoxycarbonylamino)-2-hydroxy-4-phenylbutyric acid	116661-86-0
tert-butyl [(1S,3S,4S)-4-amino-1-benzyl-3-hydroxy-5-phenylpentyl]carbamate	144163-85-9
tert-butyl [(1S,2S)-1-benzyl-2,3-dihydroxypropyl]carbamate	149451-80-9
tert-butyl {(S)-alpha-[(S)-oxiranyl]phenethyl}carbamate	98737-29-2
2-chloro-N-[2-(2-chlorobenzoyl)-4-nitrophenyl]acetamide	0-00-0
2-[alpha-(4-fluorobenzoyl)benzyl]-4-methyl-3-oxovaleranilide	125971-96-2
methyl (2R,3S)-3-benzamido-2-hydroxy-3-phenylpropionate	32981-85-4
meso-N-benzyl-3-nitrocyclopropane-1,2-dicarboximide	151860-15-0

ethyl (S)-3-(4-aminophenyl)-2-phthalimidopropionate hydrochloride	97338-03-9
ethyl (S)-3-{4-[bis(2-chloroethyl)amino]phenyl}-2-phthalimidopropionate hydrochloride	94213-26-0
(Z)-(2-cyanovinyl)trimethylammonium p-toluenesulfonate	58311-73-2
ethyl (1-cyanocyclohexyl)acetate	133481-10-4
4-(2,2,3,3-tetrafluoropropoxy)cinnamonitrile	123632-23-5
(Z)-[cyano(2,3-dichlorophenyl)methylene]carbazamidine	94213-23-7
benzyl (1R,2S)-3-chloro-2-hydroxy-1-(phenylthiomethyl)propylcarbamate	159878-02-1
N-(benzyloxycarbonyl)-S-phenyl-L-cysteine	159453-24-4
ethyl N-{2-[(acetylthio)methyl]-3-(o-tolyl)-1-oxopropyl}-L-methionate	136511-43-8
ammonium (Z)-2-methoxyimino-2-(2-furyl)acetate	97148-39-5
alpha-acetyl-gamma-butyrolactone	517-23-7
4'-demethylepipodophyllotoxin	6559-91-7
(3aR,4bS,4R,4aS,5aS)-4-(5,5-dimethyl-1,3-dioxolan-2-yl)hexahydrocyclopropa-[3,4]cyclopenta[1,2-b]furan-2(3H)-one	39521-49-8
(3aR,4R,5R,6aS)-4-formyl-2-oxohexahydro-2H-cyclopenta[b]furan-5-yl benzoate	39746-01-5
3-oxopregn-4-ene-21,17-alpha-carbolactone	976-70-5
2-acetamido-2-deoxy-beta-D-glucopyranose	7512-17-6
trans-6-amino-2,2-dimethyl-1,3-dioxepan-5-ol	79944-37-9
tert-butyl [(4R,6R)-6-(cyanomethyl)-2,2-dimethyl-1,3-dioxolan-4-yl]acetate	125971-94-0
10-deacetylbaccatin III	32981-86-5
3-beta-hydroxy-5-alpha-spirostan-12-one	467-55-0
3,4-(methylenedioxy)phenol	533-31-3
magnesium bis[(2,3-dihydro-1,5-dimethyl-3-oxo-2-phenyl-1H-pyrazol-4-yl)methylamino]-methanesulfonate	6150-97-6
3-aminopyrazole-4-carboxamide hemisulfate	27511-79-1
5-chloro-1-methyl-4-nitroimidazole	4897-25-0
(RS)-2-[(1-benzyl-4-piperidyl)methyl]-5,6-dimethoxyindan-1-one	142057-79-2
2-[(1-benzyl-4-piperidyl)methylene]-5,6-dimethoxyindan-1-one	120014-07-5
benzyl(2-pyridyl)amine	6935-27-9
6-bromo-2-pyridyl p-tolyl ketone	87848-95-1
N-(tert-butyl)-3-methylpyridine-2-carboxamide	32998-95-1
1-[2-(4-carboxyphenoxy)ethyl]piperidinium chloride	84449-80-9
4-carboxy-4-phenylpiperidinium p-toluenesulfonate	83949-32-0
8-chloro-6,11-dihydro-11-(1-methyl-4-piperidylidene)-5H-benzo[5,6]cyclohepta-[1,2-b]pyridine	38092-89-6
3-[2-(3-chlorophenyl)ethyl]pyridine-2-carbonitrile	31255-57-9
3-[2-(3-chlorophenyl)ethyl]-2-pyridyl 1-methyl-4-piperidyl ketone hydrochloride	107256-31-5
2-chloro-3-pyridylamine	6298-19-7
2,2-diphenyl-4-piperidinovaleronitrile	5424-11-3
1-[2-(4-methoxyphenyl)ethyl]-4-piperidylamine dihydrochloride	108555-25-5
5-(1-methyl-4-piperidyl)-5H-dibenzo[a,d]cyclohepten-5-ol hydrochloride	4046-24-6
1-methyl-1,2,5,6-tetrahydropyridine-3-carbaldehyde (E)-O-methyloxime hydrochloride	139886-04-7
1-(2-pyridyl)-3-(pyrrolidin-1-yl)-1-(p-tolyl)propan-1-ol	70708-28-0
quinuclidin-3-ol	1619-34-7
benzyl (1S,2S)-3-[(3S,4aS,8aS)-3-tert-butylcarbamoylperhydro-2-isoquinolyl]-2-hydroxy-1-(phenylthiomethyl)propylcarbamate	159878-04-3
7-[3-(tert-butoxycarbonylamino)pyrrolidin-1-yl]-8-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid	105956-96-5
(3S,4aS,8aS)-N-(tert-butyl)-2-[(2S,3S)-2-hydroxy-3-(3-hydroxy-2-methylbenzamido)-4-(phenylthio)butyl]perhydroisoquinoline-3-carboxamide	159989-64-7
(3S,4aS,8aS)-N-(tert-butyl)-2-[(2S,3S)-2-hydroxy-3-(3-hydroxy-2-methylbenzamido)-4-(phenylthio)butyl]perhydroisoquinoline-3-carboxamide--methanesulfonic acid (1:1)	159989-65-8
7-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydroquinoline-3-carboxylic acid	86393-33-1
3-[(E)-2-(7-chloro-2-quinolyl)vinyl]benzaldehyde	120578-03-2
1-cyclopropyl-6,7-difluoro-8-methoxy-4-oxo-1,4-dihydroquinoline-3-carboxylic acid	112811-72-0
ethyl 1-cyclopropyl-6,7-difluoro-4-oxo-1,4-dihydroquinoline-3-carboxylate	98349-25-8
(9S,13S,14S)-3-methoxymorphinan hydrochloride	1087-69-0
pentamethylene bis{3-[1-(3,4-dimethoxybenzyl)-6,7-dimethoxy-1,2,3,4-tetrahydro-2-isoquinolyl]propionate}--oxalic acid (1:2)	64228-78-0
2-[(2-acetamido-6-oxo-6,9-dihydro-1H-purin-9-yl)methoxy]ethyl acetate	75128-73-3
N-(9-acetyl-6-oxo-6,9-dihydro-1H-purin-2-yl)acetamide	3056-33-5
2-amino-6-chloropurine	10310-21-1
2-[(2-amino-6-oxo-1,6-dihydro-9H-purin-9-yl)methoxy]ethyl N-(benzyloxycarbonyl)-L-valinate	124832-31-1
(2R,4S)-2-benzyl-5-[2-(tert-butylcarbamoyl)-4-(3-pyridylmethyl)piperazin-1-yl]-4-hydroxy-N-[(1S,2R)-2-hydroxyindan-1-yl]valeramide	150378-17-9

(2R,4S)-2-benzyl-5-[2-(tert-butylcarbamoyl)-4-(3-pyridylmethyl)piperazin-1-yl]-4-hydroxy-N-[(1S,2R)-2-hydroxyindan-1-yl]valeramide sulfate	157810-81-6
(3S)-1-(tert-butoxycarbonyl)-3-(tert-butylcarbamoyl)piperazine	150323-35-6
1-(2-chlorophenyl)piperazine hydrochloride	41202-32-8
1-(3-chlorophenyl)piperazine hydrochloride	13078-15-4
cytosine	71-30-7
1,3-dichloro-6,7,8,9,10,12-hexahydroazepino[2,1-b]quinazoline hydrochloride	149062-75-9
1-(2,3-dichlorophenyl)piperazine hydrochloride	41202-77-1
2-ethoxy-5-fluoropyrimidin-4(1H)-one	56177-80-1
ethyl (7-chloro-2,4-dioxo-1,2,3,4-tetrahydroquinazolin-1-yl)acetate	112733-45-6
4-ethyl-2,3-dioxopiperazine-1-carbonyl chloride	59703-00-3
1-(4-fluorophenyl)piperazine dihydrochloride	64090-19-3
isopropyl[2-(piperazin-1-yl)-3-pyridyl]amine	147539-21-7
1-(2-methoxyphenyl)piperazine	35386-24-4
1-(2-methoxyphenyl)piperazine hydrochloride	5464-78-8
(7RS,9aRS)-perhydropyrido[1,2-a]pyrazin-7-ylmethanol	145012-50-6
1-phenylpiperazinium chloride	2210-93-7
4-(piperazin-1-yl)-2,6-bis(pyrrolidin-1-yl)pyrimidine	111641-17-9
purin-6(1H)-one	68-94-0
1-(o-tolyl)piperazine hydrochloride	70849-60-4
tetrahydro-2-methyl-3-thioxo-1,2,4-triazine-5,6-dione	58909-39-0
(3S,4R)-3-[(R)-1-(tert-butyldimethylsilyloxy)ethyl]-4-[(1R,3S)-3-methoxy-2-oxocyclohexyl]azetidin-2-one	135297-22-2
1-{[(cyclohexyloxy)carbonyl]oxy}ethyl 1-(1-hydroxyethyl)-5-methoxy-2-oxo-1,2,5,6,7,8,8a,8b-octahydroazeto[2,1-a]isoindole-4-carboxylate	141646-08-4
(3R,4S)-3-hydroxy-4-phenylazetidin-2-one	132127-34-5
p-nitrobenzyl (2R,5R,6S)-6-[(R)-1-hydroxyethyl]-3,7-dioxo-1-azabicyclo[3.2.0]heptane-2-carboxylate	75363-99-4
potassium 1-(1-hydroxyethyl)-5-methoxy-2-oxo-1,2,5,6,7,8,8a,8b-octahydroazeto-[2,1-a]isoindole-4-carboxylate	141316-45-2
N-[(R)-2-({(R)-2-[(2-adamantyloxycarbonyl)amino]-3-(1H-indol-3-yl)-2-methyl-1-oxopropyl}amino)-1-phenylethyl]succinamic acid--1-deoxy-1-methylamino-D-glucitol (1:1)	130404-91-0
3-[(S)-3-(L-alanylamino)pyrrolidin-1-yl]-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid hydrochloride	122536-48-5
7-{(S)-3-[(S)-2-(tert-butoxycarbonylamino)-1-oxopropylamino]pyrrolidin-1-yl}-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid	122536-91-8
tert-butyl meso-3-azabicyclo[3.1.0]hex-6-ylcarbamate	134575-17-0
tert-butyl {(S)-1-methyl-2-oxo-2-[(S)-pyrrolidin-3-ylamino]ethyl}carbamate	122536-66-7
tert-butyl [(RS)-pyrrolidin-3-yl]carbamate	140629-77-2
7-chloro-1-cyclopropyl-6-fluoro-4-oxo-1,4-dihydro-1,8-naphthyridine-3-carboxylic acid	100361-18-0
[7-chloro-5-(2-fluorophenyl)-2,3-dihydro-1H-1,4-benzodiazepin-2-yl]methylamine	59467-64-0
[7-chloro-5-(2-fluorophenyl)-2,3-dihydro-1H-1,4-benzodiazepin-2-ylmethyl]ammonium bis(maleate)	59469-29-3
8-chloro-6-(2-fluorophenyl)-1-methyl-3a,4-dihydro-3H-imidazo[1,5-a][1,4]benzodiazepine	59467-69-5
7-chloro-5-(2-fluorophenyl)-3-methyl-2-(nitromethylene)-2,3-dihydro-1H-1,4-benzodiazepine 4-oxide	59469-63-5
7-chloro-5-(2-fluorophenyl)-2-(nitromethylene)-2,3-dihydro-1H-1,4-benzodiazepine	59467-63-9
5-chloro-2-[3-(hydroxymethyl)-5-methyl-4H-1,2,4-triazol-4-yl]benzophenone	38150-27-5
5-chloro-2-(3-methyl-4H-1,2,4-triazol-4-yl)benzophenone	36916-19-5
2',5-dichloro-2-[3-(hydroxymethyl)-5-methyl-4H-1,2,4-triazol-4-yl]benzophenone	54196-62-2
2',5-dichloro-2-(3-methyl-4H-1,2,4-triazol-4-yl)benzophenone	54196-61-1
(E)-(+)-2-(2,4-difluorophenyl)-1-{3-[4-(2,2,3,3-tetrafluoropropoxy)styryl]-1H-1,2,4-triazol-1-yl}-3-(1H-1,2,4-triazol-1-yl)propan-2-ol	141113-28-2
(R)-2-(2,4-difluorophenyl)-3-(1H-1,2,4-triazol-1-yl)propane-1,2-diol	141113-41-9
dimethyl{2-[5-(1H-1,2,4-triazol-1-ylmethyl)indol-3-yl]ethyl}amine	144034-80-0
ethyl [3-(cyanomethyl)-4-oxo-3,4-dihydrophthalazin-1-yl]acetate	122665-86-5
2-(7-ethyl-1H-indol-3-yl)ethanol	41340-36-7
5-ethyl-4-(2-phenoxyethyl)-4H-1,2,4-triazol-3(2H)-one	95885-13-5
ethyl 1H-tetrazole-5-carboxylate, sodium salt	96107-94-7
trans-4-hydroxy-1-(4-nitrobenzyloxycarbonyl)-L-proline	96034-57-0
2-iodo-4-(1H-1,2,4-triazol-1-ylmethyl)aniline	160194-26-3
isopropyl 2,3-dihydro-1H-pyrrolizine-1-carboxylate	66635-71-0
methyl 1H-1,2,4-triazole-3-carboxylate	4928-88-5
1,4,7,10-tetraazacyclododecane-1,4,7-triacetic acid sulfate	0-00-0

1,4,7,10-tetraazoniacyclododecane bis(sulfate)	112193-77-8
1H-1,2,4-triazole-3-carboxamide	3641-08-5
1H-1,2,4-triazole-3-carboxylic acid	4928-87-4
1,2,4-triazolo[4,3-a]pyridin-3(2H)-one	6969-71-7
2-[4-(2-amino-4-oxo-4,5-dihydrothiazol-5-ylmethyl)phenoxymethyl]-2,5,7,8-tetramethylchroman-6-yl acetate	171485-87-3
(Z)-2-(2-aminothiazol-4-yl)-2-methoxyiminoacetic acid	65872-41-5
(Z)-2-[2-(chloroacetamido)thiazol-4-yl]-2-(methoxyimino)acetic acid	64486-18-6
1-{4-[(2-cyanoethyl)thiomethyl]thiazol-2-yl}guanidine	76823-93-3
{5-[(Z)-3,5-di(tert-butyl)-4-hydroxybenzylidene]-4-oxo-4,5-dihydrothiazol-2-yl}-ammonium methanesulfonate	139340-56-0
ethyl (Z)-2-(2-aminothiazol-4-yl)-2-(methoxyimino)acetate	64485-88-7
ethyl 2-(hydroxyimino)-2-[2-(tritylamino)thiazol-4-yl]acetate hydrochloride	66339-00-2
2-guanidinothiazol-4-ylmethyl carbamimidothioate dihydrochloride	88046-01-9
N-[2-isopropylthiazol-4-ylmethyl(methyl)carbamoyl]-L-valine	154212-61-0
(Z)-2-methoxyimino-2-[2-(tritylamino)thiazol-4-yl]acetic acid	66215-71-2
4-nitrophenyl thiazol-5-ylmethyl carbonate hydrochloride	154212-59-6
thiazol-5-ylmethanol	38585-74-9
thiazol-5-ylmethyl (1S,2S,4S)-1-benzyl-2-hydroxy-4-{(2S)-2-[3-(2-isopropylthiazol-4-ylmethyl)-3-methylureido]-3-methylbutyramido}-5-phenylpentylcarbamate	155213-67-5
1-(1,2-benzisothiazol-3-yl)piperazine hydrochloride	87691-88-1
S-(benzothiazol-2-yl) (Z)-2-(2-aminothiazol-4-yl)-2-methoxyiminothioacetate	80756-85-0
adenosine	58-61-7
(S)-4-(4-aminobenzyl)oxazolidin-2-one	152305-23-2
5-[(2-aminoethyl)amino]-2-(2-diethylaminoethyl)-2H-[1]benzothiopyrano-[4,3,2-cd-]indazol-8-ol	119221-49-7
2-(2-amino-5-nitro-6-oxo-1,6-dihydropyrimidin-4-yl)-3-(3-thienyl)propiononitrile	115787-67-2
7-amino-3-[1-(sulfomethyl)-1H-tetrazol-5-ylthiomethyl]-3-cephem-4-carboxylic acid, sodium salt	71420-85-4
2-amino-7-thenyl-1,7-dihydro-4H-pyrrolo[2,3-d]pyrimidin-4-one hydrochloride	117829-20-6
3'-azido-3'-deoxy-5'-O-tritylthymidine	29706-84-1
benzhydryl 3-hydroxy-7-(phenylacetamido)cepham-4-carboxylate	51762-51-7
5-[(benzofuran-2-ylcarbonyl)amino]indole-2-carboxylic acid	110314-42-6
3-(4-chloro-1,2,5-thiadiazol-3-yl)pyridine	131986-28-2
omega-conotoxin M VIIA	107452-89-1
2-cyano-3-morpholinoacrylamide	25229-97-4
2-{2-[4-(dibenzo[b,f][1,4]thiazepin-11-yl)piperazin-1-yl]ethoxy}ethanol	111974-69-7
2-(dichloromethyl)-4,5-dihydro-5-(4-mesylphenyl)oxazol-4-ylmethanol	126429-09-2
(4R,5R)-2-(dichloromethyl)-4,5-dihydro-5-(4-mesylphenyl)oxazol-4-ylmethanol	126813-11-4
2',3'-dideoxyadenosine	4097-22-7
N-{5-[(1,4-dihydro-2-methyl-4-oxoquinazolin-6-ylmethyl)methylamino]-2-thenoyl}-L-glutamic acid	112887-68-0
(4S,6S)-5,6-dihydro-6-methyl-4H-thieno[2,3-b]thiopyran-4-ol 7,7-dioxide	147086-81-5
(S)-4-{[3-(2-dimethylaminoethyl)-1H-indol-5-yl]methyl}oxazolidin-2-one	139264-17-8
(S)-N,N-dimethyl-[3-(2-thienyl)-3-(1-naphthyloxy)propyl]amine--phosphoric acid (1:1)	161005-84-1
(S)-4-ethyl-4-hydroxy-7,8-dihydro-1H-pyrano[3,4-f]indolizine-3,6,10(4H)-trione	110351-94-5
6-[3-fluoro-5-(4-methoxytetrahydropyran-4-yl)phenoxymethyl]-1-methyl-2-quinolone	140841-32-3
1-(1-{3-[2-(4-fluorophenyl)-1,3-dioxolan-2-yl]propyl}-4-piperidyl)-2,3-dihydro-1H-benzimidazole-2-thione	94732-98-6
(4R,6R)-6-{2-[2-(4-fluorophenyl)-5-isopropyl-3-phenyl-4-(phenylcarbamoyl)pyrrol-1-yl]ethyl}-4-hydroxytetrahydro-2H-pyran-2-one	125995-03-1
3-(4-hexyloxy-1,2,5-thiadiazol-3-yl)-1-methylpyridinium iodide	131988-19-7
(2S,3S)-3-hydroxy-2-(4-methoxyphenyl)-2,3-dihydro-1,5-benzothiazepin-4(5H)-one	42399-49-5
3-isopropoxy-5-methoxy-N-(1H-tetrazol-5-yl)benzo[b]thiophene-2-carboxamide	104795-66-6
3-isopropoxy-5-methoxy-N-(1H-tetrazol-5-yl)benzo[b]thiophene-2-carboxamide--1H-imidazole (1:1)	104795-67-7
3-isopropoxy-5-methoxy-N-(1H-tetrazol-5-yl)benzo[b]thiophene-2-carboxamide, sodium salt	104795-68-8
(1R,2S,5R)-menthyl (2R,5S)-5-(4-amino-2-oxo-1,2-dihydropyrimidin-1-yl)-1,3-oxathiolane-2-carboxylate	147027-10-9
(1R,2S,5R)-menthyl (2R,5R)-5-hydroxy-1,3-oxathiolane-2-carboxylate	147126-62-3
3'-O-mesyl-5'-O-tritylthymidine	104218-44-2
6-methoxy-2-(4-methoxyphenyl)benzo[b]thiophene	63675-74-1
5-methyl-2-(2-nitroanilino)thiophene-3-carbonitrile	138564-59-7
3-methyl-7-(phenylacetamido)-3-cephem-4-carboxylic acid	27255-72-7
(1R,2S,3S,6R)-[(S)-1-phenylethyl]-3,6-epoxytetrahydrophthalimide	0-00-0

1-piperonylpiperazine	32231-06-4
5'-O-tritylthymidine	55612-11-8
(4-amino-3-iodophenyl)-N-methylmethanesulfonamide	151140-66-8
5-[(R)-(2-aminopropyl)]-2-methoxybenzenesulfonamide	112101-81-2
N-(5,6-dihydro-6-methyl-2-sulfamoyl-4H-thieno[2,3-b]thiopyran-4-yl)acetamide 7,7-dioxide	120298-38-6
5-methanesulfonamidoindole-2-carboxylic acid	150975-95-4
sodium 4-[2-(5-methylpyrazine-2-carboxamido)ethyl]benzenesulfonamide	84522-34-9
(RS)-tetrahydropapaverine hydrochloride	66820-84-6
1,2,3,5-tetraacetyl-beta-D-ribofuranose	13035-61-5
1,3-bis(4-nitrophenyl)urea--4,6-dimethylpyrimidin-2-ol (1:1)	330-95-0
(R)-6,7-dimethoxy-2-methyl-1-(3,4,5-trimethoxybenzyl)-1,2,3,4-tetrahydroisoquinoline--dibenzoyl-L-tartaric acid (1:1)	104832-01-1
ethyl 7-chloro-2-oxoheptanoate, in the form of a solution in toluene	0-00-0
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	0-00-0
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	0-00-0
Intermediate concentrates obtained from a Micromonospora inyoensis fermentation medium used for the manufacture of the antibiotics sisomicin (INN) and netilmicin (INN)	0-00-0
Intermediate concentrates obtained from a Micromonospora purpurea fermentation medium used for the manufacture of the antibiotics gentamicin sulfate (INNM) and isepamicin (INN)	0-00-0
1,6-hexanediamine, polymer with 1,10-dibromodecane	162430-94-6
danaparoid sodium	83513-48-8

Appendix B
FEDERAL REGISTER NOTICE

investigations. The Commission will issue a final phase notice of scheduling which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules upon notice from the Department of Commerce (Commerce) of an affirmative preliminary determination in an investigation under section 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of an affirmative final determination in an investigation under section 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On November 5, 1996, a petition was filed with the Commission and the Department of Commerce by Geneva Steel Co., Provo, UT, and Gulf States Steel, Inc., Gadsden, AL, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV imports of cut-to-length carbon steel plate from China, Russia, South Africa, and Ukraine. Accordingly, effective November 5, 1996, the Commission instituted antidumping investigations Nos. 731–TA–753–756 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of November 13, 1996 (61 FR 58216). The conference was held in Washington, DC, on November 26, 1996, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on December 20, 1996. The views of the Commission are contained in USITC Publication 3009 (December 1996), entitled *Cut-to-length Carbon Steel Plate from China, Russia, South Africa, and Ukraine: Investigations Nos. 731–TA–753–756 (Preliminary).*

Issued: December 20, 1996.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 96–33013 Filed 12–26–96; 8:45 am]

BILLING CODE 7020–02–P

[Investigation 332–376]

Advice Concerning the Addition of Certain Pharmaceutical Products and Chemical Intermediates to the Pharmaceutical Appendix to the HTS

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation.

EFFECTIVE DATE: December 20, 1996.

SUMMARY: Following receipt on December 18, 1996, of a request from the United States Trade Representative, the Commission instituted investigation No. 332–376, 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 115 of the Uruguay Round Agreements Act (19 U.S.C. 3524) and section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)).

As requested by the USTR, the Commission will 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 of the "zero-for-zero" initiative, including the Pharmaceutical Appendix, to the HTS; and (3) estimates of current U.S. imports and, where possible, 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. The Commission will submit its report to the USTR by January 17, 1997.

FOR FURTHER INFORMATION CONTACT: Information on general aspects of the study may be obtained from Elizabeth Nesbitt, Office of Industries (202–205–3355) or, on legal aspects, from William Gearhart, Office of the General Counsel (202–205–3091). The media should contact Margaret O'Laughlin, Office of Public Affairs (202–205–1819). Hearing impaired individuals are advised that information on this matter can be obtained by contacting the TDD terminal on (202–205–1810). A copy of the **Federal Register** notice announcing the institution of this investigation and the annex listing the products under consideration can be downloaded from the Commission's Internet server (http://www.usitc.gov or ftp://ftp.usitc.gov) or may be obtained by contacting the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW, Washington, DC 20436, or at 202–205–1802.

BACKGROUND: During the Uruguay Round, the United States and 16 other major trading countries agreed to the reciprocal elimination of duties on approximately 7,000 pharmaceutical products and chemical intermediates (the latter are to be used primarily for the production of pharmaceuticals), and their derivatives, resulting in the "zero-for-zero" initiative in pharmaceuticals. Effective January 1, 1995, U.S. imports of these products, as enumerated in the Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States (HTS), now enter free of duty under general note 13 to the tariff schedule. The 17 countries also agreed to conduct a review, at least once every 3 years, to identify products to be added to the Pharmaceutical Appendix. Negotiators from several countries, including the United States, have recently been engaged in the first review and have reached agreement on the addition of 496 pharmaceutical products and chemical intermediates. Addition to the list would provide duty-free treatment to these products and their derivatives.

According to the request letter from the USTR, a coalition of pharmaceutical companies from several WTO members (which the Pharmaceutical Research and Manufacturers of America (PhRMA) coordinated) submitted the initial list of candidates for addition to the existing Appendix to the pharmaceutical agreement. Moreover, the letter states that USTR consulted with the Administration's Industry Sector Advisory Committee-3 (ISAC–3; chemicals) throughout the negotiations and that this ISAC has endorsed the final list of items under consideration.

Section 111(b) of the Uruguay Round Agreements Act (the Act) authorizes the President, subject to the consultation and layover requirements of section 115 of the Act, to proclaim duty-free treatment under the "zero-for-zero" initiative for additional pharmaceutical products to be added, such as those now under consideration. One of the requirements set out in section 115 is that the President obtain advice regarding the proposed action from the United States International Trade Commission.

Issued: December 20, 1996.

By order of the Commission.
Donna R. Koehnke,
Secretary.
[FR Doc. 96–33014 Filed 12–26–96; 8:45 am]
BILLING CODE 7020–02–P

[Investigation No. 332–360]

International Harmonization of Customs Rules of Origin

AGENCY: United States International Trade Commission.

ACTION: Request for public comment on draft proposals for chapters 50–63 (Textiles).

EFFECTIVE DATE: December 20, 1996.

FOR FURTHER INFORMATION CONTACT: Eugene A. Rosengarden, Director, Office of Tariff Affairs and Trade Agreements (O/TA&TA) (202–205–2595), or Jan Summers (202–205–2605).

Parties having an interest in particular products or HTS chapters and desiring to be included on a mailing list to receive available documents pertaining thereto should advise Diane Whitfield by phone (202–205–2610) or by mail at the Commission, 500 E St SW, Room 404, Washington, D.C. 20436. Hearing impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. The media should contact Margaret O'Laughlin, Director, Office of Public Affairs (202–205- 1819).

BACKGROUND: Following receipt of a letter from the United States Trade Representative (USTR) on January 25, 1995, the Commission instituted Investigation No. 332–360, International Harmonization of Customs Rules of Origin, under section 332(g) of the Tariff Act of 1930 (60 FR 19605, April 19, 1995).

The investigation is intended to provide the basis for Commission participation in work pertaining to the Uruguay Round Agreement on Rules of Origin (ARO), under the General Agreement on Tariffs and Trade (GATT) 1994 and adopted along with the Agreement Establishing the World Trade Organization (WTO).

The ARO is designed to harmonize and clarify nonpreferential rules of origin for goods in trade on the basis of the substantial transformation test; achieve discipline in the rules' administration; and provide a framework for notification, review, consultation, and dispute settlement. These harmonized rules are intended to make country-of-origin determinations impartial, predictable, transparent, consistent, and neutral, and to avoid restrictive or distortive effects on international trade. The ARO provides that technical work to those ends will be undertaken by the Customs Cooperation Council (CCC) (now informally known as the World Customs Organization or WCO), which must report on specified matters relating to such rules for further action by parties to the ARO. Eventually, the WTO Ministerial Conference is to "establish the results of the harmonization work program in an annex as an integral part" of the ARO.

In order to carry out the work, the ARO calls for the establishment of a Committee on Rules of Origin of the WTO and a Technical Committee on Rules of Origin (TCRO) of the WCO. These Committees bear the primary responsibility for developing rules that achieve the objectives of the ARO.

A major component of the work program is the harmonization of origin rules for the purpose of providing more certainty in the conduct of world trade. To this end, the agreement contemplates a 3-year WCO program, which was formally initiated in July, 1995. Under the ARO, the TCRO is to undertake (1) to develop harmonized definitions of goods considered wholly obtained in one country, and of minimal processes or operations deemed not to confer origin, (2) to consider the use of change in Harmonized System classification as a means of reflecting substantial transformation, and (3) for those products or sectors where a change of tariff classification does not allow for the reflection of substantial transformation, to develop supplementary or exclusive origin criteria based on value, manufacturing or processing operations or on other standards.

The draft rules for chapters 50–63 of the Harmonized System that are being made available for public comment cover goods that are not considered to be wholly made in a single country. The rules rely largely on the change of heading as a basis for ascribing origin. Copies of the proposed revised rules will be available from the Office of the Secretary at the Commission, from the Commission's Internet web server (http://www.usitc.gov), or by submitting a request on the Office of Tariff Affairs and Trade Agreements voice messaging system, 202–205–2592. Due to their length, the rules will not be available by FAX. These proposals are intended to serve as the basis for the U.S. proposal to the Technical Committee on Rules of Origin of the WCO. The proposals are based on the principles of application enacted by Congress in Section 334 of the Uruguay Round Agreements Act (19 U.S.C. 3592) with respect to country of origin determinations for textile goods but may not necessarily reflect or restate existing Customs treatment in all cases for all current nonpreferential purposes. Based upon a decision of the Trade Policy Staff Committee, the proposals are intended for future harmonization for the nonpreferential purposes indicated in the ARO for application on a global basis. The proposals may undergo change as proposals from other government administrations and the private sector are received and considered.

Under the circumstances, the proposals should not be cited as authority for the application of current domestic law.

If eventually adopted by the TCRO for submission to the Committee on Rules of Origin of the World Trade Organization, these proposals would comprise an important element of the ARO work program to develop harmonized, non-preferential country of origin rules, as discussed in the Commission's earlier notice. Thus, in view of the importance of these rules, the Commission seeks to ascertain the views of interested parties concerning the extent to which the proposed rules reflect the standard of substantial transformation provided in the Agreement.

Forthcoming Commission notices will advise the public on the progress of the TCRO's work and will contain any harmonized definitions or rules that have been provisionally or finally adopted.

WRITTEN SUBMISSIONS: Interested persons are invited to submit written statements concerning this phase of the Commission's investigation. Written statements should be submitted as quickly as possible, and follow-up statements are permitted; but all statements must be received at the Commission by the close of business on February 7, 1997 in order to be considered. Information supplied to the Customs Service in statements filed pursuant to notices of that agency has been given to us and need not be separately provided to the Commission. Again, the Commission notes that it is particularly interested in receiving input from the private sector on the effects of the various proposed rules and definitions on U.S. exports. Commercial or financial information which a submitter desires the Commission to treat as confidential must be submitted on separate sheets of paper, each marked "Confidential Business Information" at the top. All submissions requesting confidential treatment must conform with the requirements of