

June 2, 1998

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC 20436

MEMORANDUM TO THE COMMITTEE ON WAYS AND MEANS OF THE UNITED STATES
HOUSE OF REPRESENTATIVES ON PROPOSED TARIFF LEGISLATION¹

Bill no., sponsor, and sponsor's state: H.R. 3477 (105th Congress), Representative Matsui (CA).

Companion bill: None.

Title as introduced: To suspend temporarily the duty on a certain drug substance used in the formulation of HIV Antiviral Drug.

Summary of bill:²

The bill would temporarily suspend the duty on U.S. imports of chloromethyl pivalate entered, or withdrawn from warehouse for consumption, on or before December 31, 1999.

Effective date: The 15th day after enactment.

Retroactive effect: None.

Statement of purpose:

The sponsor made no statement in the *Congressional Record* when introducing this bill. However, according to a representative of Gilead Sciences, Inc., the proponent, the elimination of duties on the subject product will allow the company to offer a unique and highly specialized antiviral drug at a lower cost to the consumer.³

Product description and uses:

Chloromethyl pivalate: This synthetic organic chemical is used in the production of a drug, Adefovir Dipivoxil, that is undergoing clinical trials to receive FDA approval for treating HIV/AIDS or Hepatitis B.

¹ Industry analyst: Elizabeth Howlett (205-3365); attorney: Leo Webb (205-2599).

² See appendix A for definitions of tariff and trade agreement terms.

³ April 16, 1998 fax from Barnes, Richardson & Colburn, legal counsel for Gilead Sciences, Inc. (see appendix C).

Tariff treatment:⁴

<u>Product</u>	<u>HTS subheading</u>	<u>Col. 1-general rate of duty</u>
Chloromethyl pivalate.....	2915.90.50	3.8% ad valorem.

Structure of domestic industry (including competing products):

Chloromethyl pivalate: During 1995-97, there were no known domestic producers of commercial quantities of this chemical. However, there are several domestically produced drugs that are currently used for treating HIV/AIDS or Hepatitis B and would therefore be in competition with Adefovir Dipivoxil, the drug made with the subject chemical, once it has been approved by the FDA.

Private-sector views:

Most pharmaceutical chemicals, including finished products, active ingredients, and intermediates used solely in the production of drug products, are afforded duty-free entry to the United States under the WTO Pharmaceutical Agreement. The subject chemical as well as the drug it is used to produce, Adefovir Dipivoxil, are currently being considered for inclusion on the list of approved items covered by this agreement, known as the Pharmaceutical Appendix; however, a decision is not expected to become effective until mid-1999. According to industry sources,⁵ the list of proposed additions to the Pharmaceutical Appendix has been circulated among at least twenty domestic pharmaceutical companies for their review, and at this time there has been no objection to the proposed elimination of duties on this item.

U.S. consumption:

Chloromethyl pivalate:	<u>1995</u>	<u>1996</u>	<u>1997</u>
	-----(\$million)-----		
U.S. production.....	(¹)	(¹)	(¹)
U.S. imports.....	(¹)	(¹)	(¹)
U.S. exports.....	(¹)	(¹)	(¹)
Apparent U.S. consumption.....	(¹)	(¹)	(¹)

¹Not available.

Principal import sources: Japan, the European Union, and Canada.

Principal export markets: Not available.

⁴See appendix B for column 1-special and column 2 duty rates.

⁵ Conversations with a representative of the Pharmaceutical Researchers and Manufacturers of America (PhRMA) on April 15, 1998 and April 21, 1998.

Effect on customs revenue:⁶

Future (1998-99) effect:

The projected average annual revenue loss is anticipated to be less than \$8,000 during the period covered by this bill.⁷

Retroactive effect: None.

Technical comments:

None.

⁶Actual revenue loss may be understated if a significant increase in imports occurs during the duty suspension period.

⁷This estimate may be overstated because it is based on the assumption that none would enter from Canada under NAFTA, which provides for duty-free treatment of all products classified in HTS subheading 2915.90.50.

APPENDIX A

TARIFF AND TRADE AGREEMENT TERMS

In the **Harmonized Tariff Schedule of the United States** (HTS), chapters 1 through 97 cover all goods in trade and incorporate in the tariff nomenclature the internationally adopted Harmonized Commodity Description and Coding System through the 6-digit level of product description. Subordinate 8-digit product subdivisions, either enacted by Congress or proclaimed by the President, allow more narrowly applicable duty rates; 10-digit administrative statistical reporting numbers provide data of national interest. Chapters 98 and 99 contain special U.S. classifications and temporary rate provisions, respectively. The HTS replaced the **Tariff Schedules of the United States** (TSUS) effective January 1, 1989.

Duty rates in the **general** subcolumn of HTS column 1 are most-favored-nation (MFN) rates, many of which have been eliminated or are being reduced as concessions resulting from the Uruguay Round of Multilateral Trade Negotiations. Column 1-general duty rates apply to all countries except those enumerated in HTS general note 3(b) (Afghanistan, Cuba, Laos, North Korea, and Vietnam), which are subject to the statutory rates set forth in **column 2**. Specified goods from designated MFN-eligible countries may be eligible for reduced rates of duty or for duty-free entry under one or more preferential tariff programs. Such tariff treatment is set forth in the **special** subcolumn of HTS rate of duty column 1 or in the general notes. If eligibility for special tariff rates is not claimed or established, goods are dutiable at column 1-general rates. The HTS does not enumerate those countries as to which a total or partial embargo has been declared.

The **Generalized System of Preferences** (GSP) affords nonreciprocal tariff preferences to developing countries to aid their economic development and to diversify and expand their production and exports. The U.S. GSP, enacted in title V of the Trade Act of 1974 for 10 years and extended several times thereafter, applies to merchandise imported on or after January 1, 1976 and before the close of June 30, 1998. Indicated by the symbol "A", "A*", or "A+" in the special subcolumn, the GSP provides duty-free entry to eligible articles the product of and imported directly from designated beneficiary developing countries, as set forth in general note 4 to the HTS.

The **Caribbean Basin Economic Recovery Act** (CBERA) affords nonreciprocal tariff preferences to developing countries in the Caribbean Basin area to aid their economic development and to diversify and expand their production and exports. The CBERA, enacted in title II of Public Law 98-67, implemented by Presidential Proclamation 5133 of November 30, 1983, and amended by the Customs and Trade Act of 1990, applies to merchandise entered, or withdrawn from warehouse for consumption, on or after January 1, 1984. Indicated by the symbol "E" or "E*" in the special subcolumn, the CBERA provides duty-free entry to eligible articles, and reduced-duty treatment to certain other articles, which are the product of and imported directly from designated countries, as set forth in general note 7 to the HTS.

Free rates of duty in the special subcolumn followed by the symbol "IL" are applicable to products of Israel under the **United States-Israel Free Trade Area Implementation Act** of 1985 (IFTA), as provided in general note 8 to the HTS.

Preferential nonreciprocal duty-free or reduced-duty treatment in the special subcolumn followed by the symbol "J" or "J*" in parentheses is afforded to eligible articles the product of designated beneficiary countries under the **Andean Trade Preference Act** (ATPA), enacted as title II of Public Law 102-182 and implemented by Presidential Proclamation 6455 of July 2, 1992 (effective July 22, 1992), as set forth in general note 11 to the HTS.

Preferential or free rates of duty in the special subcolumn followed by the symbol "CA" are applicable to eligible goods of Canada, and rates followed by the symbol "MX" are applicable to eligible goods of Mexico, under the **North American Free Trade Agreement**, as provided in general note 12 to the HTS and implemented effective January 1, 1994 by Presidential Proclamation 6641 of December 15, 1993. Goods must originate in the NAFTA region under rules set forth

in general note 12(t) and meet other requirements of the note and applicable regulations.

Other special tariff treatment applies to particular **products of insular possessions** (general note 3(a)(iv)), **products of the West Bank and Gaza Strip** (general note 3(a)(v)), goods covered by the **Automotive Products Trade Act** (APTA) (general note 5) and the **Agreement on Trade in Civil Aircraft** (ATCA) (general note 6), **articles imported from freely associated states** (general note 10), **pharmaceutical products** (general note 13), and **intermediate chemicals for dyes** (general note 14).

The **General Agreement on Tariffs and Trade 1994** (GATT 1994), pursuant to the Agreement Establishing the World Trade Organization, is based upon the earlier GATT 1947 (61 Stat. (pt. 5) A58; 8 UST (pt. 2) 1786) as the primary multilateral system of disciplines and principles governing international trade. Signatories' obligations under both the 1994 and 1947 agreements focus upon most-favored-nation treatment, the maintenance of scheduled concession rates of duty, and national treatment for imported products; the GATT also provides the legal framework for customs valuation standards, "escape clause" (emergency) actions, antidumping and countervailing duties, dispute settlement, and other measures. The results of the Uruguay Round of multilateral tariff negotiations are set forth by way of separate schedules of concessions for each participating contracting party, with the U.S. schedule designated as Schedule XX.

Pursuant to the **Agreement on Textiles and Clothing** (ATC) of the GATT 1994, member countries are phasing out restrictions on imports under the prior "Arrangement Regarding International Trade in Textiles" (known as the **Multifiber Arrangement** (MFA)). Under the MFA, which was a departure from GATT 1947 provisions, importing and exporting countries negotiated bilateral agreements limiting textile and apparel shipments, and importing countries could take unilateral action in the absence or violation of an agreement. Quantitative limits had been established on imported textiles and apparel of cotton, other vegetable fibers, wool, man-made fibers or silk blends in an effort to prevent or limit market disruption in the importing countries. The ATC establishes notification and safeguard procedures, along with other rules concerning the customs treatment of textile and apparel shipments, and calls for the eventual complete integration of this sector into the GATT 1994 over a ten-year period, or by Jan. 1, 2005.

Rev. 8/12/97

APPENDIX B

**SELECTED PORTIONS OF THE
HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES**

(Appendix not included in the electronic version of this report.)

APPENDIX C

OTHER ATTACHMENTS

(Appendix not included in the electronic version of this report.)

105TH CONGRESS
2D SESSION

H. R. 3477

To suspend temporarily the duty on a certain drug substance used in the formulation of HIV Antiviral Drug.

IN THE HOUSE OF REPRESENTATIVES

MARCH 17, 1998

Mr. MATSUI introduced the following bill; which was referred to the Committee on Ways and Means

A BILL

To suspend temporarily the duty on a certain drug substance used in the formulation of HIV Antiviral Drug.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. TEMPORARY DUTY SUSPENSION.**

4 (a) IN GENERAL.—Subchapter II of chapter 99 of
5 the Harmonized Tariff Schedule of the United States is
6 amended by inserting in numerical sequence the following
7 new heading:

“	9902.33.10	Chloromethyl Pivalate (CAS No. 18997-19-8) (Provided for in subheading 2915.90.50)	Free	No change	No change	On or before 12/31/99	”.
---	------------	---------------------------------------------------------------------------------------------------------	------	-----------	-----------	--------------------------	----

1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) applies with respect to goods entered, or
3 withdrawn from warehouse for consumption, on or after
4 the date that is 15 days after the date of the enactment
5 of this Act.

○