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
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U.S. International Trade Commission

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ABSTRACT

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

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

During the Uruguay Round trade negotiations, the United States and 21[1] 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.[2] 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.[3] 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.[4]

Description of Products Covered

Pharmaceuticals (NAICS 3254, "Pharmaceutical and Medicine Manufacturing")[5] are used to prevent, diagnose, treat, or cure diseases in humans and animals.[6] 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

[1] 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.

[2] In the United States, MFN countries are called Normal Trade Relations (NTR) countries.

[3] 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.

[4] 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.

[5] 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).*

[6] 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")[7] 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

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.[8] 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.

[7] 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).*

[8] 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.[9] 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.[10] 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.[11] 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.[12] 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)[13] 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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[9] 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.

[10] PhRMA, *Pharmaceutical Industry Profile*, 2.

[11] 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.

[12] 35 U.S.C. § 156.

[13] 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[a]	U.S. imports[b]	U.S. exports[b]	Trade balance	U.S. apparent consumption	Total employment[a,c]	Production workers[a,c]
	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.

[a]U.S. Department of Commerce, Census Bureau, *2002 Economic Census*.
[b]USITC, *Dataweb*.
[c]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

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)[14] 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[15] 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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[14] 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.

[15] 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.[16] 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.[17] 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.

[16] 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.

[17] 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

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.[18] 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.[19] 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.[20]

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,[21] the Commission requested written submissions containing estimates of levels of trade for the proposed items. Two submissions were received.[22]

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[18] 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.

[19] 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.

[20] 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.

[21] See Appendix B.

[22] 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.[23] 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	32,245	35,574
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	18,934	21,059
Total	22,929	24,846
U.S. trade balance		
2936	-221	-195
2937	685	181
2939	-627	-201
2941	-48	-32
Chapter 30	-13,312	-14,515
Total	-13,522	-14,761

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

[23] 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[a] (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[a] (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[a] (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[a] (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.

[a]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[a]	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.

[a]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.

BIBLIOGRAPHY

American Chemistry Council (ACC). *Guide to the Business of Chemistry 2005.* Arlington, VA: ACC, 2005.

Chemical & Engineering News. "Chemical Employment Falls." July 7, 2003.

Pharmaceutical Research and Manufacturers of America (PhRMA). *Pharmaceutical Industry Profile 2006.* Washington, DC: PhRMA, March 2006. http://www.phrma.org/files/2006%20Industry%20Profile.pdf (accessed June 14, 2006).

U.S. Department of Commerce. Census Bureau. *2002 Economic Census*. http://www.census.gov/econ/census02/ (accessed May 17, 2006).

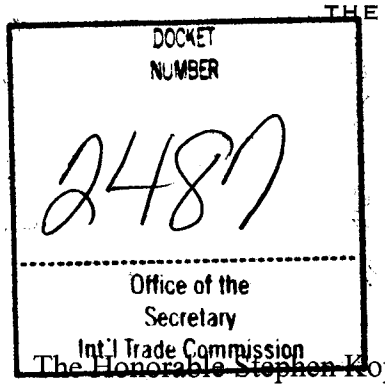
U.S. Department of Commerce. Census Bureau. *North American Industry Classification System (NAICS)*. http://www.census.gov/epcd/www/naics.html (accessed May 17, 2006).

USITC. *Interactive Tariff and Trade Dataweb (Dataweb)*. http://dataweb.usitc.gov/ (accessed various dates).

APPENDIX A
REQUEST LETTER FROM USTR AND ATTACHMENT

2487

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



MAY 19 2006

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

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
Alicaforsen	185229-68-9
Alilusem	144506-11-6
Aliskiren	173334-57-1
Alitretinoine	5300-03-8
Altinicline	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

Product	CAS No.
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
Asoprisnili 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
Becatecarin	119673-08-4

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

Product	CAS No.
Becocalcidiol	524067-21-8
Befetupitant	290296-68-3
Belatacept	706808-37-9
Belimumab	356547-88-1
Belotecan	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
Bisoctrizole	103597-45-1
Bivatuzumab	214559-60-1
Bortezomib	179324-69-7
Brivaracetam	357336-20-0
Brostallicin	203258-60-0
Bulaquine	223661-25-4
Cadrofloxacin	153808-85-6
Calcobutrol	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

Product	CAS No.
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
Crobenetine	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
Darbepoetine 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
Deferitrin	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

Product	CAS No.
Dersalazine	188913-58-8
Desloratadine	100643-71-8
Desmoteplase	145137-38-8
Desvenlafaxine	93413-62-8
Detiviciclovir	220984-26-9
Deutolperisone	474641-19-5
Dexbudesonide	51372-29-3
Dexlansoprazole	138530-94-6
Dexmethylphenidate	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
Dofequidar	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
Epafipase	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
Fampronil	134183-95-2
Fanapanel	161605-73-8
Fandosentan	221241-63-0
Farampator	211735-76-1
Farglitazar	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
Finrozole	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

Product	CAS No.
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)
Iboctadekin	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
Imiglitazar	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

Product	CAS No.
Inotuzumab ozogamicin	635715-01-4
Insulin detemir	169148-63-4
Insulin glulisine	207748-29-6
Iosimenol	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
Ispronicline	252870-53-4
Istaroxime	203737-93-3
Istradefylline	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
Meclinertant	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

Product	CAS No.
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
Mitratapid	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
Nemifitide	173240-15-8
Neramexane	219810-59-0
Nerispirdine	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

Product	CAS No.
Omaciclovir	124265-89-0
Omalizumab	242138-07-4
Omiganan	204248-78-2
Omigapil	181296-84-4
Omocianine	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
Ospemifene	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
Padoporfin	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
Pemaglitazar	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
Ragaglitazar	222834-30-2
Ralfinamide	133865-88-0

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

Product	CAS No.
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
Rostaporfin	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
Ruplizumab	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
Satraplatin	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
Siplizumab	288392-69-8
Sipoglitazar	342026-92-0
Siramesinum	147817-50-3
Sitamaquine	57695-04-2
Sitaxentan	184036-34-8
Soblidotin	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
Stannsoporfin	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

Product	CAS No.
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
Tecalcet	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
Tenivastatin	121009-77-6
Tenofovir	147127-20-6
Teriflunomide	108605-62-5
Terutroban	165538-40-9
Tesaglitazar	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
Tetraxetan	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
Treprostinil	81846-19-7
Tretazicar	21919-05-1
Tridolgosir	72741-87-8
Triplatin tetranitrate	172903-00-3
Trodusquemine	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

Product	CAS No.
Udenafil	268203-93-6
Ulifloxacin	112984-60-8
Uliprisnil	159811-51-5
Upidosin	152735-23-4
Urtoxazumab	502496-16-4
Valategrast	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
Vepalimomab	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
Zoniporide	241800-98-6
Zosuquidar	167354-41-8
Zoticasone	678160-57-1

TABLE 2

PHARMACEUTICAL PREFIXES AND SUFFIXES PROPOSED FOR ADDITION TO THE PHARMACEUTICAL APPENDIX

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

Item
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
crosfumaril
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

Item
guacil
guanidine
hemisuccinate
heptahydrate
hexacetonide
hydrogen
2-(4-hydroxybenzoyl)benzoate
hydroxynaphthoate
iodine-131
lisetil
lisicol
lispro
lutetium
lysine
mafenatox
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

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-diyl)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-diyl)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-(Benzyloxy)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-, β-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_{1a}	142680-85-1
(25S)-25-cyclohexyl-5-demethoxy-25-de(1-methylpropyl)-22,23-dihydro-5-oxoavermectin A_{1a}	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-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-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-ethylsulfanylmethyl)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]cyclopropa[c]cyclohepten-6-yl]-1-piperazinyl}-3-(5-quinolinyloxy)-2-propanol trihydrochloride	167465-36-3
(3S)-3-{2-[(Methylsulfonyl)oxy]ethoxy}-4-(trityloxy)butyl methanesulfonate	170277-77-7
6-(Benzyloxy)-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-(methyloxy)-2-oxoethyl]-3-oxo-2,3,4,5-tetrahydro-1H-1,4-benzodiazepin-2-yl}acetic acid	193077-87-1
1-[3-(cyclopentyloxy)-4-(methyloxy)phenyl]-4-oxocyclohexanecarbonitrile	152630-47-2
Dimethyl 4-cyano-4-[3-(cyclopentyloxy)-4-(methyloxy)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(methyloxy)-5-{[3-(trifluoromethyl)phenyl]oxy}-8-quinolinamine	106635-86-3
4-Methyl-2,6-bis(methyloxy)-8-nitro-5-{[3-(trifluoromethyl)phenyl]oxy}quinoline	189746-15-4
5-Chloro-4-methyl-2,6-bis(methyloxy)-8-nitroquinoline	189746-21-2

Table 3
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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-(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)-4,5,10,3a-tetrahydro-3H,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-tetrahydronaphthylcarboxamide	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-ylpiperazinyl)ethyl]hydroquinolyl}acetamide	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 dicyclohexylamine 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]methyl}phenol	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

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Product name	CAS No.
(3αR, 4R, 5R, 6aαS)-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-(Benzyloxymethyl)-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-1,1,1a,6,10b-tetrahydrodibenzo[a,e]cyclopropa[c]cycloheptene-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

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Product name	CAS No.
1-[[(6R,7R)-7-[(Z)-2-(5-Amino-1,2,4-thiadiazol-3-yl)-2-(methoxyimino)acetylamino]-2-carboxylat-8-oxo-5-thia-l-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]imidazo[1,2-b]pyridazin-4-ium 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-(triphenylmethyloxyimino)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-α-9-Fluorenylmethoxycarbonyl-L-alanine	35661-39-3
N-α-Fluorenylmethoxycarbonyl-N-β-trityl-L-asparagine	132388-59-1
N-α-Fluorenylmethoxycarbonyl-L-leucine	35661-60-0
N-α-9-Fluorenylmethoxycarbonyl-L-aspartic acid β-t-butyl ester	71989-14-5
N-α-9-Fluorenylmethoxycarbonyl-L-glutamic acid γ-t-butyl ester	71989-18-9
N-α-9-Fluoroenylmethoxycarbonyl-N-γ-trityl-L-glutamine	132327-80-1
N-α-9-Fluorenylmethoxycarbonyl-L-glutamine	71989-20-3
N-α-9-Fluoroenylmethoxycarbonyl-N-im-trityl-L-histidine	109425-51-6
N-α-9-Fluorenylmethoxycarbonyl-L-isoleucine	71989-23-6
N-α-9-Fluorenylmethoxycarbonyl-N-α-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-α-glutamyl-L-α-glutamyl-O-(1,1-dimethylethyl)-L-seryl-N-trityl-L-glutaminyl-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-α-glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L- α-glutamyl-N-trityl-L-glutaminyl-L-α-glutamyl-L-leucyl-L-leucyl-L-α-glutamyl-, 1,4,6,9-tetrakis(1,1-dimethylethyl) ester	244191-94-4
L-Tryptophan, N-[(9H-fluoren-9-ylmethoxy)carbonyl]-L-α-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-α-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-α-glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L-α-glutamyl-N-trityl-L-glutaminyl-L-α-glutamyl-L-leucyl-L-leucyl-L-α-glutamyl-L-leucyl-L-α-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-α-glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L-α-glutamyl-N-trityl-L-glutaminyl-L-α-glutamyl-L-leucyl-L-leucyl-L-α-glutamyl-L-leucyl-L-α-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-α-glutamyl-L-α-glutamyl-O-(1,1-dimethylethyl)-L-seryl-N-trityl-L-glutaminyl-N-trityl-L-asparaginyl-N-trityl-L-glutaminyl-L-glutaminyl-L-α-glutamyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-N-trityl-L-asparaginyl-L-α-glutamyl-N-trityl-L-glutaminyl-L-α-glutamyl-L-leucyl-L-leucyl-L-α-glutamyl-L-leucyl-L-α-aspartyl-N6-[(1,1-dimethylethoxy)carbonyl]-L-lysyl-1-[(1,1-methylethoxy)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-, heptakis(1,1-dimethylethyl) ester	244244-26-6
N-α-Fluorenylmethoxycarbonyl-O-t-butyl-L-serine	71989-33-8
N-α-Fluorenylmethoxycarbonyl-O-t-butyl-L-threonine	71989-35-0
N-α-Fluorenylmethoxycarbonyl-N-in-t-butyloxycarbonyl-L-tryptophan	143824-78-6
N-α-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-quinolinyl)ethenyl]phenyl]-3-[2-(1-hydroxy-1-methylethyl)phenyl]-1-propanol	287930-77-2
Methyl 2-[(3S)-3-[3-[(E)-2-(7-chloro-2-quinolinyl)ethenyl]phenyl]-3-hydroxypropyl]benzoate monohydrate	287930-78-3
5-[(2,4-Dioxo-1,3-thiazolidin-5-yl)methyl]-2-(methyloxy)-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-Benzyloxycarbonylamino-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-oxoacetylamino]-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-methysulfonyl)oxy]-L-proline	120807-02-5

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Product name	CAS No.
(R)-5-(1,3,6,2-dioxazaborocan-2-yl)-1-methyl-2-tritylisoindoline	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-tritylisoindolin-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)acethyl]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-oxoazetanylacetic 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-dioxohexahydropyridazin-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-yvinyl]-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-cyanoethyldiisopropylamidophosphite	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-cyanoethyldiisopropylamidophosphite	98796-51-1
(2R,3S,5S)-5-[6-(Benzoylamino)-9H-purin-9-yl]-2-{[bis(4-methoxyphenyl)(phenyl)methoxy]methyl}tetrahydrofuranyl 2-cyanoethyldiisopropylamidophosphite	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

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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-(Benzyloxy)-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-aminobenzenesulfonamide	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-(acetyloxy)-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(acetyloxy)-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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Product name	CAS No.
tetramethyl-4-[(triethylsilyl)oxy]-, (2αR,4S,4αS,6R,9S,11S,12S,12αR,12βS)-	
Benzenepropanoic acid,.β,-(benzoylamino)-α-(1-methoxy-1-methylethoxy)-(2αR,4S,4αS,6R,9S,11S,12S,12αR,12βS)-6,12-β-bis(acetyloxy)-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-(Acetyloxy)-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(acetyloxy)-15-({(2R,3S)-3-(benzolylamino)-2-[(4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenoyloxy]-3-phenylpropan oyl}oxy)-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], pregna-4,9(11)-diene-7,21-dicarboxylic acid deriv.	95716-70-4
1-(4,5-Dinitro-10-aza-tricyclo[6.3.1.$0^{2,7}$]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-hexahydropyrano[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

Table 3
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.$0^{2,7}$]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-hydroxyoxepino[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-ylsulfanylmethyl)-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-phosphaundec-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, α-(1-methylethenyl)-7-oxo-3-(phenylmethyl)-, diphenylmethyl ester	63457-21-6
1-aminopyridazin-1-ium hexafluorophosphate	346412-97-3
1-[4-(Ethyloxy)phenyl]-2-[4-(methylsulfonyl)phenyl]ethanone	346413-00-1
2-[4-(Ethyloxy)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

Table 3
Pharmaceutical intermediates proposed for addition to the Pharmaceutical Appendix

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-naphthalenyloxy)-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-IH-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-(Benzyloxy)-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
Ethynylcyclopropane	6746-94-7
(αR,βS)-β-methyl-α-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-{[(3R,5R)-5-(2,4-difluorophenyl)-5-(1H-1,2,4-triazol-1-ylmethyl)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-{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-[(3*R*)-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-T-C-C-C-G-C-G), tridecasodium salt	362543-73-5
DNA d(P-thio) (G-A-T-C-C-G-C-G-G-G-A-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-butyryl]-5,5-dimethyl-thiazolidine-4-carboxylic acid allylamide	478410-84-3
(2S,3S)-3-Amino-2-hydroxy-4-phenyl-butyric acid	62023-62-5
Benzenethiol, 3-methoxy-	15570-12-4
Ethanone, 2-chloro-1-(4-methoxyphenyl)-	2196-99-8
Phenol, 3-mercapto-	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, α-phenyl-	19395-39-2
(6aR)-5,6,6a,7-tetrahydro-6-methyl-4H-dibenzo[de,g]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-1H,3'H-[2,5']bibenzoimidazolyl	152628-02-9
(6R)-5,6-Dihydro-4-hydroxy-6-(1-(2-phenyl)ethyl)-6-propyl-2H-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-(trifluoromethy) phenyl) dihydrochloride	57061-71-9
N-(4-(Methylamino)-3-nitrobenzoyl)-N-2-pyridinyl-ß-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)-4a,6,11, 11a-tetrahydro-pyrido(2,3-b)(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-[(6S)-2-Amino-4-oxo-3,4,5,6,7,8-hexahydropyrido[2,3-d]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(4H)-one hydrochloride	227626-75-7
3,4'-Dichloro-2'-[(5-chloro-2-pyridyl)carbamoyl]-6'-methoxy-4-[(2-methylamino-1H-imidazol-1-yl)methyl]thiophene-2-carboxanilide trifluoroacetate	229340-73-2
(R)-5-(2-Aminopropyl)-2-methoxybenzenesulfonamide	112101-81-2
2-Methyl-3-[(2S)-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]-3H,15H-oxepino[3',4':6,7]indolizino[1,2-b]quinoline-3,15-dione monohydrochloride	220997-99-9
2-chloro-6,7-difluoro-3-quinolinemethanol	209909-03-5
(S)-α-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-[(1S,2S)-2-(benzyloxy)-1-ethylpropyl]-4-{4-[4-(4-{[(3R,5R)-5-(2,4-difluorophenyl)-5-(1H-1,2,4-triazol-1-ylmethyl)tetrahydrofuran-3-yl]methoxy}phenyl)piperazin-1-yl]phenyl}-2,4-dihydro-3H-1,2,4-triazol-3-one	170985-86-1

APPENDIX B
FEDERAL REGISTER NOTICE

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 INFORMATON 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,Rreliability, 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*), 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*). 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*. 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*).

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: CBI 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

2006 JUN 21 PM 4:30

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.[1]

[1] 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/asset_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.[2] 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)[3], 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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[2] *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)

[3] 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
BARNES, RICHARDSON & COLBURN
1420 New York Ave. N.W. 7th Floor
Washington, D.C. 20005
(202) 628-4700

District of Columbia
Subscribed and sworn before me
this 21st day of June 2006.

NOTARY PUBLIC

My commission expires: 30 April 2009

ATTACHMENT 1

Esimated 2007 U.S. Import and Export Value

Table 1: INNS

Product	Submitter	Esimated 2007 Import Value
Oseltamavir	[	]
Selamectin		

Table 3. Proposed Chemical Intermediates

ID #	Submitter	Esimated 2007 Import Value	Esimated 2007 Export Value	HS code	CAS-RN	Preferred name
30	[			2934 99	199327-61-2	7-methoxy-6-(3-morpholinopropoxy)quinazolin-4(3H)-one
31				2933 99	181827-47-4	[N-(methoxycarbonyl)-L-valyl]-L-proline
33				2928 00	253605-31-1	N-hydroxy-2-methylpropan-2-amine acetate (salt) or tert-butylhydroxylamine acetate (salt)
35				2933 99	171964-73-1	[N-(4-methoxybenzoyl)-L-valyl]-N-[(1S)-3,3,3-trifluoro-1-isopropyl-2-oxopropyl]-L-prolinamide
36				2933 49	172649-40-0	3-[(4S)-5-oxo-2-(trifluoromethyl)-1,4,5,6,7,8-hexahydroquinolin-4-yl]benzonitrile
37				2932 99	124655-09-0	tert-butyl [(4R,6S)-6-(hydroxymethyl)-2,2-dimethyl-1,3-dioxan-4-yl]acetate
38				2933 59	160009-37-0	methyl 4-(4-fluorophenyl)-6-isopropyl-2-(N-methylmethanesulfonamido)]pyrimidine-5-carboxylate
39				2933 59	140373-09-7	4-[[(3-{[(2,2-dimethylpropanoyl)oxy]methyl}-2,7-dimethyl-4-oxo-3,4-dihydroquinazolin-6-yl)methyl](prop-2-yn-1-yl)amino}-2-fluorobenzoic acid
224				2935 00	289042-12-2	(4R,6S)-6-((E)-2-{4-(4-fluorophenyl)-6-isopropyl-2-[mesyl(methyl)amino]pyrimidin-5-yl}vinyl)-2,2-dimethyl-1,3-dioxan-4-yl 3,3-dimethylbutanoate
436				2920 90	163133-43-5	4-(nitrooxy)butyl (2S)-2-(6-methoxy-2-naphthyl)propanoate
457				2933 79	105318-28-3	((2S,3S)-2-{(1R)-2-[(4-chlorophenyl)sulfanyl]-1-methyl-2-oxoethyl}-3-((1R)-1-hydroxyethyl)-4-oxoazetidin-1-yl)acetic acid
691				2935 00	186497-07-4	N-(3-methoxy-5-methylpyrazin-2-yl)-2-[4-(1,3,4-oxadiazol-2-yl)phenyl]pyridine-3-sulfonamide
340				2934 99	197897-11-3	1-[((7R)-7-amino-4-carboxy-3,4-didehydrocepham-3-yl)methyl]-1H-imidazo[1,2-b]pyridazin-4-ium iodide
342				2934 99	92096-37-2	diphenylmethyl (7R)-3-(mesyloxy)-7-(phenylacetamido)-3,4-didehydrocepham-4-carboxylate
343				2934 99	127111-98-2	diphenylmethyl (7R)-7-amino-3-(mesyloxy)-3,4-didehydrocepham-4-carboxylate hydrochloride
344				2934 99	140128-37-6	diphenylmethyl (7R)-7-(2-{2-[(tert-butoxycarbonyl)amino]-1,3-thiazol-4-yl}-2- [(trityloxy)imino]acetamido)-3-({[(1H-1,2,3-triazol-4-yl)sulfanyl]methyl}sulfanyl)-3,4-didehydrocepham-4-carboxylate
398				2924 29	22871-58-5	3-amino-5-[(2-hydroxyethyl)carbamoyl]-2,4,6-triiodobenzoic acid
447				2934 99	135790-89-5	[(2,2-dimethylpropanoyl)oxy]methyl (7R)-7-[(2Z)-2-(2-{(2S)-2-[(tert-butoxycarbonyl)amino]propanamido}-1,3-thiazol-4-yl)-2-(methoxyimino)acetamido]-3,4-didehydrocepham-4-carboxylate
448				2934 99	36923-17-8	(7R)-7-amino-3,4-didehydrocepham-4-carboxylic acid
451				2934 99	11389-01-3	diphenylmethyl (2S,5R)-6,6-dibromo-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate 4-oxide
455				2933 59	119532-26-2	1-(2,3-dichlorophenyl)piperazine
651				2934 10	136401-69-9	(Z)-5-{4-[2-(5-ethylpyridin-2-yl)ethoxy]benzylidene}-1,3-thiazolidine-2,4-dione
765				2933 39	25333-42-0	(3R)-quinuclidin-3-ol
767				2934 99	13636-02-7	(RS)-3-(dimethylamino)-1-(2-thienyl)propan-1-ol
769				2934 99	663603-70-1	(2Z)-3-(methylamino)-1-(2-thienyl)prop-2-en-1-one
770				2934 99	116539-55-0	(1S)-3-(methylamino)-1-(2-thienyl)propan-1-ol
771				2934 99	164015-32-1	N-methyl-3-(1-naphthyloxy)-2-(2-thienyl)propan-1-amine phosphate
120				2933 99	113963-68-1	3,4-di(indol-3-yl)-1-methylpyrrole-2,5-dione
123				2933 59	167465-36-3	(2R)-1-[4-((1aR,10bS)-1,1-difluoro-1,1a,6,10b-tetrahydrodibenzo[a,e]cyclopropa[c][7]annulen-6-yl)piperazin-1-yl]-3-[(quinolin-5-yl)oxy]propan-2-ol trihydrochloride
124				2909 49	170277-77-7	(3S)-3-[2-(mesyloxy)ethoxy]-4-(trityloxy)butyl methanesulfonate
125				2934 99	182133-09-1	6-(benzyloxy)-3-bromo-2-(4-methoxyphenyl)-1-benzothiophene 1-oxide
127				2932 99	196303-01-2	(7S)-7-methyl-5-(4-nitrophenyl)-7,8-dihydro-5H-[1,3]dioxolo[4,5-g]isochromene
131				3002 10	42617-41-4	Blood-coagulation factor XIVa
132				3824 90	84449-81-0	4-[2-(piperidin-1-yl)ethoxy]benzoyl chloride hydrochloride, 1,2-dichloroethane solution
226				2922 19	114247-09-5	(3R)-N-methyl-3-phenyl-3-[4-(trifluoromethyl)phenoxy]propan-1-amine hydrochloride
227				2933 99	14907-27-8	methyl D-tryptophanate hydrochloride
230				2933 99	172733-42-5	sodium [(1-benzyl-2-ethyl-3-oxamoylindol-4-yl)oxy]acetate
231				2922 49	209216-09-1	2-aminobicyclo[3.1.0]hexane-2,6-dicarboxylic acid hydrate
308				2906 29	167155-76-2	1,1-difluoro-1,1a,6,10b-tetrahydrodibenzo[a,e]cyclopropa[c][7]annulen-6-ol
309				2924 19	186193-10-2	(2S)-2-{[3-(tert-butoxycarbonyl)-2,2-dimethylpropanoyl]oxy}-4-methylpentanoic acid
310				2934 99	204990-60-3	(3S,10R,13Z,16S)-10-(3-chloro-4-methoxybenzyl)-3-isobutyl-6,6-dimethyl-16-[(1S)-1-((2R,3R)-3-phenyloxiran-2-yl)ethyl]-1,4-dioxa-8,11-diazacyclohexadec-13-ene-2,5,9,12-tetrone
408				2934 99	287737-72-8	(2S)-hydroxy(phenyl)acetic acid — (1S)-3-(dimethylamino)-1-(2-thienyl)propan-1-ol (1:1) (salt)
508			]	2918 30	134176-18-4	ethyl 2-oxobicyclo[3.1.0]hexane-6-carboxylate

ID #	Submitter	Esimated 2007 Import Value	Esimated 2007 Export Value	HS code	CAS-RN	Preferred name
509				2933 59	137281-39-1	4-[2-(2-amino-4-oxo-4,7-dihydro-3H-pyrrolo[2,3-d]pyrimidin-5-yl)ethyl]benzoic acid
510				3824 90	170277-77-7	(3S)-3-[2-(mesyloxy)ethoxy]-4-(trityloxy)butyl methanesulfonate, dimethylformamide solution
511				2933 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-phenylpropan-1-ol
513				2933 39	84449-81-0	4-(2-piperidin-1-ylethoxy)benzoyl chloride hydrochloride
520				2934 99	102212-98-6	N^4-benzoyl-2'-deoxy-5'-O-(4,4'-dimethoxytrityl)cytidine 3'-(2-cyanoethyl diisopropylphosphoramidite)
525				2934 99	93183-15-4	2'-deoxy-5'-O-(4,4'-dimethoxytrityl)-N^2-isobutyrylguanosine 3'-(2-cyanoethyl diisopropylphosphoramidite)
526				2934 99	98796-51-1	2'-deoxy-5'-O-(4,4'-dimethoxytrityl)thymidine 3'-(2-cyanoethyl diisopropylphosphoramidite)
527				2934 99	98796-53-3	N^6-benzoyl-2'-deoxy-5'-O-(4,4'-dimethoxytrityl)adenosine 3'-(2-cyanoethyl diisopropylphosphoramidite)
528				2926 90	31915-40-9	N-[1-cyano-2-(4-hydroxyphenyl)-1-methylethyl]acetamide
582				2932 29	122111-01-7	[(2R)-2-(benzoyloxy)-4,4-difluoro-5-oxotetrahydrofuran-2-yl]methyl benzoate
862				2930 90	15570-12-4	3-methoxybenzene-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-butyryl-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-(dimethylamino)prop-2-en-1-ylidene]dimethylammonium} hexafluorophosphate(3-)
318				2933 39	221615-75-4	2-(4-mesylphenyl)-1-(6-methylpyridin-3-yl)- ethan-1-one
319				2933 99	219909-83-8	3-((4S)-4-sulfanyl-L-prolinamidol)benzoic acid hydrochloride
320				2906 29	127852-28-2	(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethan-1-ol
321				3824 90	127852-28-2	(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethan-1-ol, acetonitrile solution
322				2933 99	119192-10-8	4-[(1H-1,2,4-triazol-1-yl)methyl]aniline
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				2934 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-phenyl-1,3-oxazolidin-5-yl)methanol
328				2935 00	149490-61-9	N-(butane-1-sulfonyl)-O-(4-pyridin-4-ylbutyl)-L-tyrosine
329				2935 00	149490-60-8	N-(butane-1-sulfonyl)-L-tyrosine
382				2934 99	171482-05-6	(2R,3S)-2-{(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethoxy}-3-(4-fluorophenyl)morpholine hydrochloride
383				2934 99	287930-73-8	4-benzyl-2-hydroxymorpholin-3-one
384				2934 99	287930-75-0	(2R)-4-benzyl-2-{(1R)-1-[3,5-bis(trifluoromethyl)phenyl]ethoxy}morpholin-3-one
386				2933 49	287930-77-2	(1S)-1-{3-[(E)-2-(7-chloroquinolin-2-yl)vinyl]phenyl}-3-[2-(1-hydroxy-1-methylethyl)phenyl]propan-1-ol
387				2933 49	287930-78-3	methyl 2-((3S)-3-{3-[(E)-2-(7-chloroquinolin-2-yl)vinyl]phenyl}-3-hydroxypropyl)benzoate hydrate
388				2934 10	213252-19-8	5-[(2,4-dioxo-1,3-thiazolidin-5-yl)methyl]-2-methoxy-N-[4-(trifluoromethyl)benzyl]benzamide
581				2933 99	252742-72-6	5-(chloromethyl)-1,2-dihydro-3H-1,2,4-triazol-3-one
835				2933 59	654671-77-9	(2R)-4-oxo-4-[3-(trifluoromethyl)-5,6,7,8-tetrahydro[1,2,4]triazolo[4,3-a]pyrazin-7-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine phosphate (1:1) hydrate
957				2934 99	0-00-0	potassium 5-methyl-1,3,4-oxadiazole-2-carboxylate
958				2933 59	518048-03-8	2-(1-amino-1-methylethyl)-N-(4-fluorobenzyl)-5-hydroxy-1-methyl-6-oxo-1,6-dihydropyrimidine-4-carboxamide
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-dihydropyrimidine-5-olate
72				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)-1-(1H-1,2,4-triazol-1-yl)butan-2-ol hydrochloride
75				2935 00	247582-73-6	2-ethoxy-5-(4-ethylpiperazine-1-sulfonyl)nicotinic acid
78				2932 29	142680-85-1	(25S)-25-cyclohexyl-25-de(sec-butyl)-5-O-demethyl-22,23-dihydroavermectin A_{1a}
79				2932 29	220119-16-4	(25S)-cyclohexyl-25-de(sec-butyl)- 5-demethoxy-5-oxo-22,23-dihydroavermectin A_{1a}
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	252317-48-9	{(3S)-1-[1-(2,3-dihydro-1-benzofuran-5-yl)ethyl]pyrrolidin-3-yl}diphenylacetonitrile
84				2922 19	115287-37-1	N-methyl-N-(4-nitrophenethyl)-2-(4-nitrophenoxy) ethan-1-amine
85				2922 29	115256-13-8	4-(1-{[2-(4-aminophenoxy)ethyl]methylamino}ethyl)aniline
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]-1-methyl-3-propylpyrazole-5-carboxamide

ID #	Submitter	Esimated 2007 Import Value	Esimated 2007 Export Value	HS code	CAS-RN	Preferred name
90				2934 99	76801-85-9	(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-dideoxy-3-C-methyl-3-O-methyl-±-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,8,10,12,14-hexamethyl-11-{[3,4,6-trideoxy-3-(dimethylamino)-²-D-xylo-hexopyranosyl]oxy}-1-oxa-6-azacyclopentadeçan-15-one
91				2933 99	32065-66-0	2-(dimethoxymethyl)quinoxaline 1,4-dioxide
93				2934 99	76646-91-8	(3S)-6,6-dibromo-2,2-dimethylpenam-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-pyrano[3,4-f]indolizine-7-carboxylate
243				2934 99	86639-52-3	(4S)-4,11-diethyl-4,9-dihydroxy-1H,12H-pyrano[3',4':6,7]indolizino[1,2-b]quinoline-3,14(4H,12H)-dione
244				2932 29	145667-75-0	(3aR,4R,5R,6aS)-5-hydroxy-4-((3R)-3-hydroxy-5-phenylpentyl)hexahydrocyclopenta[b]furan-2-one
245				2933 99	227025-33-4	1-benzyl-4H-imidazo[4,5,1-ij]quinolin-2(1H)-one
246				2933 99	269731-84-2	(5R,6R)-1-benzyl-5-hydroxy-6-(methylamino)-5,6-dihydro-4H-imidazo[4,5,1-ij]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-iodoanilino)-N-(cyclopropylmethoxy)-3,4-difluorobenzamide
289				2934 99	253450-09-8	6-({2-[4-(4-fluorobenzyl)piperidin-1-yl]ethyl}sulfinyl)-1,3-benzoxazol-2(3H)-one
298				2934 99	227626-65-5	tert-butyl N-methyl-N-{2-[(5-oxo-4,5-dihydro-1,2,4-oxadiazol-3-yl)methyl]cyclohexyl}carbamate
299				2934 99	227625-35-6	3-{[2-(aminomethyl)cyclohexyl]methyl}-1,2,4-oxadiazol-5(4H)-one
300				2934 99	229336-92-9	3-chloro-N-{4-chloro-2-[(5-chloropyridin-2-yl)carbamoyl]-6-methoxyphenyl}-4-{[2-(methylamino)imidazol-1-yl]methyl}thiophene-2-carboxamide
489				2933 39	319460-94-1	N-(2-fluoro-5-{[3-((E)-2-pyridin-2-ylvinyl)-1H-indazol-6-yl]amino}phenyl)-1,3-dimethylpyrazole-5-carboxamide
490				2933 39	319460-85-0	N-methyl-2-{[3-((E)-2-pyridin-2-ylvinyl)-1H-indazol-6-yl]sulfanyl}benzamide
491				2933 79	283173-50-2	8-fluoro-2-{4-[(methylamino)methyl]phenyl}-1,3,4,5-tetrahydro-6H-azepino[5,4,3-cd]indol-6-one
517				2934 99	98819-76-2	(2S)-2-[(S)-(2-ethoxyphenoxy)phenylmethyl]morpholine
519				2915 39	60176-77-4	(1S,4R)-4-hydroxycyclopent-2-en-1-yl acetate
585				2926 90	192869-10-6	2-iodo-3,4-dimethoxy-6-nitrobenzonitrile
586				2926 90	192869-24-2	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)pyrazole-3-carboxamide
591				2935 00	334828-19-2	N-[3-carbamoyl-5-ethyl-1-(2-methoxyethyl)pyrazol-4-yl]-2-ethoxy-5-[(4-ethylpiperazin-1-yl)sulfonyl]nicotinamide
592				2935 00	334826-98-1	5-[2-ethoxy-5-(4-ethylpiperazine-1-sulfonyl)pyridin-3-yl]-3-ethyl-2-(2-methoxyethyl)-2,3,4,5,6,7-hexahydropyrazolo[4,3-d]pyrimidin-7-one
593				2935 00	334827-99-5	5-[2-ethoxy-5-(4-ethylpiperazine-1-sulfonyl)pyridin-3-yl]-3-ethyl-2-(2-methoxyethyl)-2,3,4,5,6,7-hexahydropyrazolo[4,3-d]pyrimidin-7-one 4-methylbenzene-1-sulfonate
594				2930 90	364323-64-8	2-[4-(methylsulfanyl)phenoxy]benzaldehyde
595				2930 90	289717-37-9	N,N-dimethyl-2-[4-(methylsulfanyl)phenoxy]benzylamine hydrochloride
596				2935 00	364321-71-1	3-[(dimethylamino)methyl]-4-[4-(methylsulfanyl)phenoxy]benzene-1-sulfonamide
597				2935 00	364323-49-9	3-[(dimethylamino)methyl]-4-[4-(methylsulfanyl)phenoxy]benzene-1-sulfonamide L-tartarate (1:1)
598				2924 29	376348-76-4	ethyl (3S)-3-(4,4-difluorocyclohexane-1-carboxamido)-3-phenylpropanoate
599				2924 29	376348-77-5	4,4-difluoro-N-((1S)-3-hydroxy-1-phenylpropyl)cyclohexane-1-carboxamide
600				2924 29	376348-78-6	4,4-difluoro-N-((1S)-3-oxo-1-phenylpropyl)cyclohexane-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-methoxypyridin-3-yl]methanol
660				2932 29	95716-70-4	7±-(methoxycarbonyl)-3-oxo-17±-pregna-4,9(11)-diene-21,17-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-aminopentanenitrile methanesulfonate
674				2933 49	474645-93-7	methyl [2-ethyl-6-(trifluoromethyl)-1,2,3,4-tetrahydroquinolin-4-yl]carbamate
676				2933 99	180915-95-1	1-{2-[4-(2-bromo-6-methoxy-3,4-dihydro-1-naphthyl)phenoxy]ethyl}pyrrolidine
677				2933 99	180915-94-0	1-{2-[4-(6-methoxy-3,4-dihydro-1-naphthyl)phenoxy]ethyl}pyrrolidine
686				2916 20	122665-97-8	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-1H-1,5-methano-3-benzazepine 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	1-cyclopentyl-3-ethyl-6-(4-methoxybenzyl)-1,4,5,6-tetrahydro-7H-pyrazolo[3,4-c]pyridin-7-one 4-methylbenzene-1-sulfonate
696				2924 29	667937-05-5	3-[4-(trifluoromethyl)anilino]pentanamide
697				2934 99	192049-49-3	4-nitrobenzyl 2-((1R,5R)-3-benzyl-7-oxo-4-thia-2,6-diazabicyclo[3.2.0]hept-2-en-6-yl)-3-methylbut-2-enoate
700				2932 19	87392-07-2	(2S)-tetrahydrofuran-2-carboxylic acid

ID #	Submitter	Esimated 2007 Import Value	Esimated 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-didehydrocepham-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(methyl)amino]-2-oxo-1-phenylethyl}carbamate hydrochloride
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-cyano-5-methylhex-3-enoate
840				2933 39	213839-64-6	N-{2-[5-(aminoiminomethyl)-2-hydroxyphenoxy]-3,5-difluoro-6-[3-(1-methyl-4,5-dihydroimidazol-2-yl)phenoxy]pyridin-4-yl]-N-methyglycine dihydrochloride
841				2934 99	253450-12-3	6-[[2-(4-benzylpiperidin-1-yl)ethyl]sulfinyl}-1,3-benzoxazol-2(3H)-one
842				2933 39	280129-82-0	4-({2-[(benzyloxy)methyl]-4-isopropylimidazol-1-yl}methyl)pyridine oxalate (1:2)
857				2922 49	223445-75-8	[(3S,4S)-1-(aminomethyl)-3,4-dimethylcyclopentyl]acetic acid
859				2934 10	478410-84-3	(4R)-N-allyl-3-[(2S,3S)-2-hydroxy-3-(3-hydroxy-2-methylbenzamido)-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)phenylmethyl]morpholine succinate
278A				2934 99	177587-08-5	N-{5-[2-((6S)-2-amino-4-oxo-3,4,5,6,7,8-hexahydropyrido[2,3-d]pyrimidin-6-yl)ethyl]-4-methylthiophene-2-carbonyl}-L-glutamic 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-(methylamino)imidazol-1-yl]methyl}thiophene-2-carboxamide trifluoroacetate
3				2909 30	165254-21-7	1,2-bis{2-[2-(2-methoxyethoxy)ethoxy]ethoxy}-4,5-dinitrobenzene
4				2933 99	149365-59-3	dibenzyl 5,5'-[(3,4-diethylpyrrole-2,5-diyl)bis(methylene)]bis[4-(3-methoxy-3-oxopropyl)-3-methylpyrrole-2-carboxylate]
5				2933 99	149365-62-8	5,5'-[(3,4-diethylpyrrole-2,5-diyl)bis(methylene)]bis[4-(3-hydroxypropyl)-3-methylpyrrole-2-carbaldehyde]
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-ribofuranose
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

Year	Customs Value (US$)	Duties at 6.5%
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

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 15th 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:...

(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

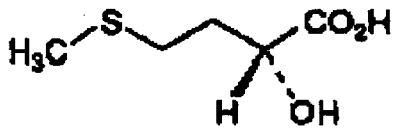
Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

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
$C_5H_{10}O_3S$ 120-91-2 *amino acid analogue*



and enantiomer

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).

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.[1] 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

---

[1] 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. <u>The WTO Pharmaceutical Arrangement Allows Pharmaceuticals with an INN to be Listed in Table 1</u>

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.[2] 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

[2] 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

Table 3. (con.)

Product Name	CAS Number
4-O-ß-D-Galactopyranosyl-D-gluconic acid	96-82-2
(α-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-[O-2-acetamido-2-deoxy-ß-D-galactopyranosyl-(1,4)-O-(N-acetyl-α-neuraminosyl)-(2,3)-O-ß-D-galactopyranosyl-(1,4)-ß-D-glucopyranose	195993-11-4
1,1,1,3,3,3-Hexafluoropropan-2-ol	920-66-1
α,α,α,α',α',α'-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-Hydrazinobenzyl)methanesulfonamide hydrochloride	81880-96-8
4-Hydrazonobenzenesulfonamide hydrochloride	17852-52-7
α-Hydroxy-ß,ß-dimethyl-γ-butyrolactone	599-04-2
DL-α-Hydroxy-ß,ß-dimethyl-γ-butyrolactone	79-50-5
17α-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
11α-Hydroxy-7α-(methoxycarbonyl)-3-oxopregn-4-ene-21,17α-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
17α-Hydroxy-16α-methyl-3,20-dioxopregna-1,4-dien-21-yl acetate	24510-54-1
17α-Hydroxy-16ß-methyl-3,20-dioxopregna-1,4-dien-21-yl acetate	24510-55-2
17α-Hydroxy-16ß-methyl-3,20-dioxopregna-1,4,9(11)-trien-21-yl acetate	910-99-6
17-Hydroxy-16α-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-nitrobenzyloxycarbonyl)-L-proline	96034-57-0
11α-Hydroxy-3-oxopregna-4,6-diene-21,17α-carbolactone	73726-56-4
(3R,4S)-3-Hydroxy-4-phenylazetidin-2-one	132127-34-5
D-2-(4-Hydroxyphenyl)glycine	22818-40-2
11α-Hydroxypregn-4-ene-3,20-dione	80-75-1
3ß-Hydroxy-5α-spirostan-12-one	467-55-0
5-Hydroxy-1,2,3,4-tetrahyudro-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 α-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 m2. 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 dies 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. Waiser, 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 feel 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. Waiser 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 is 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

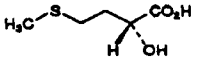
International Nonproprietary Names for Pharmaceutical Substances (INN)

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.

Proposed International Nonproprietary Name (Latin, English)	*Chemical Name or Description; Molecular and Graphic formulae Chemical Abstracts Service (CAS) registry number Action and Use**
desmeninolum desmeninol	(±)-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:

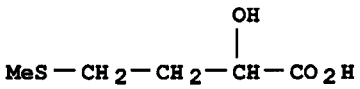
~418 References

Commercial Sources

Regulated Chemicals Listing

Reaction Information

Registry Number: 583-91-5



Formula: C5 H10 O3 S

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

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 --

Property	Calculated Value	Condition	Note
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)

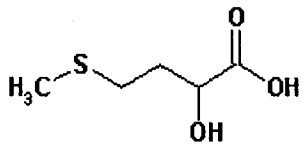
Deleted Registry Number(s): 120-91-2, 96661-25-5, 110518-19-9

Database: REGISTRY (Copyright 2004 ACS)

ChemIDplus Record

▷ Tox. & Env. Health ▷ TOXNET ▷ Return to Results Page

Desmeninol [INN]
RN: 583-91-5



CAS Registry Number
583-91-5

Other Registry Number
110518-19-9
120-91-2
96661-25-5

Related Registry Number
14676-91-6 (calcium salt)
14676-91-6 (unspecified calcium salt)
23597-90-2 (mono-hydrochloride salt)
4857-44-7 (calcium[2:1] salt)

System Generated Number
000583915

ATTACHMENT 6

Trade Facts

From the Office of the United States Trade Representative
Washington, DC 20508 www.ustr.gov

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

Phase One, 2005-2010 – Cut and Harmonize

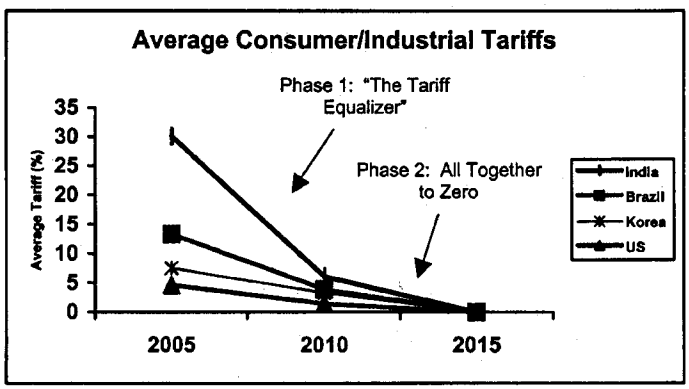
1. **Eliminate low tariffs of 5% or less by 2010.**

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
Bicycle parts
Chemicals and allied products including photo film & soda ash
Civil aircraft
Construction Equipment
Environmental technologies
Fish and Fish Products
Furniture
Information Technology and Electronics Products
Medical Equipment
Non-Ferrous Metals
Paper
Pharmaceuticals
Scientific Equipment
Steel
Toys
Wood 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_1 = new tariff; T_0 = 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
	In 1,000							
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	2005 YTD	2006 YTD	Percent Change YTD2005 - YTD2006
	In 1,000 Dollars							
$	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
	In 1,000							
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

TOTAL	2001	2002	2003	2004	2005	2005 YTD	2006 YTD	Percent Change YTD2005 - YTD2006
	In 1,000 Dollars							
$	182,674	194,162	199,975	185,521	135,431	51,146	42,128	-17.60%