

**[Billing Code 3190-W0-P]**

**Office of the United States Trade Representative**

**Public Comments for Multilateral Negotiations in the World Trade Organization on  
Expansion of the Lists of Pharmaceutical Products Receiving Zero Duties**

**Agency:** Office of the United States Trade Representative

**Action:** Notice and request for comments

**Summary:** The Trade Policy Staff Committee (TPSC) is requesting written comments from the public with respect to the expansion of the list of pharmaceuticals subject to reciprocal duty elimination by certain members of the World Trade Organization (WTO). The specific information being sought is described in the background section below.

**Dates:** Public comments are due by midnight, April 9, 2010.

**For Further Information Contact:** For procedural questions concerning public comments, contact Gloria Blue, Executive Secretary, TPSC, Office of the USTR, 1724 F Street, NW., Washington, DC 20508, telephone (202) 395-3475. Questions concerning the expansion of the list of pharmaceutical products receiving zero duties should be addressed to Fred Fischer

or Mary Thornton, Office of Small Business, Market Access, and Industrial Competitiveness, USTR, telephone (202) 395-5656.

**Supplementary Information:** The Chairman of the TPSC invites comments in writing from the public on the expansion of the lists of pharmaceutical products receiving duty-free treatment from certain Members of the WTO, specifically additions to the lists of pharmaceutical active ingredients; prefixes and suffixes that could be associated with an active ingredient in order to designate its salt, ester or hydrate form; or chemical intermediates intended for the manufacture of pharmaceutical active ingredients. Negotiations will begin in the latter part of April 2010 in the WTO with a view to adding new pharmaceuticals to the list of products subject to a zero tariff rate. Any amendments to the lists of pharmaceuticals will be subject to approval by all participants in the negotiations. A copy of the initial lists of proposed items is available on the USTR Web site at: <http://www.ustr.gov> under the “Federal Register Notices” tab in the middle of the home page. The list is also available on the Regulations.gov Web site at: <http://www.regulations.gov> under the keyword “USTR-2010-0006.”

## **1. Background Information**

During the Uruguay Round of multilateral trade negotiations, the United States and 16 trading partners agreed to the reciprocal elimination of duties on approximately 7,000 pharmaceutical products and chemical intermediates on January 1, 1995. Participants also agreed to periodically update the lists of pharmaceuticals subject to a zero tariff rate. As a result of multilateral negotiations under the auspices of the WTO during 1996 and again in 1998, the United States and other participants in the negotiations eliminated duties on an additional 750 international nonproprietary names (INNs) and chemical intermediates on April 1, 1997. An

additional 630 such products were added on July 1, 1999. The most recent update incorporating 1,300 additional products were added on December 29, 2006 (72 FR 429, January 4, 2007).

The Pharmaceutical Appendix to the Harmonized Tariff Schedule of the United States (HTSUS) enumerates the products and chemical intermediates that are eligible to enter free of duty. An electronic version of the HTSUS can be found at: <http://www.usitc.gov> and on the Web site. The current Pharmaceutical Appendix to the HTSUS can be found at: <http://www.usitc.gov/publications/docs/tata/hts/bychapter/1000PHARMAPPX.pdf>.

The Pharmaceutical Appendix of the HTSUS consists of three tables. Table 1 lists active pharmaceutical ingredients and dosage-form products by their INNs from the World Health Organization (WHO). (Table 1 currently includes INNs from WHO lists 1–93.) Prefixes and suffixes that could be associated with the INNs in Table 1, potentially resulting in multiple permutations in derivatives, are enumerated in Table 2. Chemical intermediates intended for the manufacture of pharmaceuticals are listed in Table 3.

## **2. Public Comments**

Comments are requested on pharmaceutical items which would be in the interest of the United States to add to the WTO Pharmaceutical Agreement. Negotiators will be reviewing the INNs on the most recent WHO lists (i.e., lists 94–99) in this latest review cycle.

Comments pertaining to the pharmaceutical active ingredients covered by these lists need only provide the INN name and reference the appropriate WHO list. If that information is not available, the following information must be supplied for each pharmaceutical active ingredient or chemical intermediate to provide the technical basis for reviewing the submissions: (1) the precise chemical name; (2) the Chemical Abstracts Service (CAS) registry number; (3) a

diagram of the molecular structure; and (4) the six-digit Harmonized System classification number. Submissions of chemical intermediates also must provide the INN and chemical name of the active ingredient into which the intermediate is incorporated, the CAS number of this active ingredient, and a diagram of the molecular structure of this active ingredient. In addition, submissions of chemical intermediates must demonstrate that the product meets the following conditions: (1) the chemical is a sole-pharmaceutical use intermediate; (2) some portion of the intermediate is incorporated in the final active ingredient molecule, and (3) the intermediate is used in producing an active ingredient that has reached at least Phase III of clinical trials of the Food and Drug Administration (or other national equivalent).

Comments pertaining to the additions to the list of prefixes or suffixes for salt, ester or hydrate forms of an INN active ingredient should state a rationale for the nomination. Only comments containing all of the above information will be considered in developing U.S. positions for the negotiations.

### **3. Requirements for Submissions**

Persons submitting comments must do so in English and must identify (on the first page of the submission) the “Pharmaceutical Appendix Update.” In order to be assured of consideration, comments should be submitted by April 9, 2010.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the <http://www.regulations.gov> Web site. Comments should be submitted under the following docket: USTR-2010-0006. To find the docket, enter the docket number in the “Enter Keyword or ID” window at the <http://www.regulations.gov> home page and click “Search.” The site will provide a search-results

page listing all documents associated with this docket. Find a reference to this notice by selecting “Notices” under “Document Type” on the search-results page, and click on the link entitled “Submit a Comment.” (For further information on using the [www.regulations.gov](http://www.regulations.gov) Web site, please consult the resources provided on the Web site by clicking on the “Help” tab.)

The <http://www.regulations.gov> Web site provides the option of making submissions by filling in a comments field, or by attaching a document. USTR prefers submissions to be provided in an attached document. If a document is attached, it is sufficient to type “See attached” in the “Type comment & Upload File” field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the “Comments” field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters “BC.” Any page containing business confidential information must be clearly marked “BUSINESS CONFIDENTIAL” on the top of that page. Filers of submissions containing business confidential information must also submit a public version of their comments. The file name of the public version should begin with the character “P.” The “BC” and “P” should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the character “P,” followed by the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

#### **4. Public inspection of submissions**

Comments will be placed in the docket and open to public inspection pursuant to 15 CFR 2006.13, except confidential business information exempt from public inspection in accordance with 15 CFR 2006.15. Comments may be viewed on the <http://www.regulations.gov> Web site by entering docket number USTR-2010-0006 in the search field on the home page.

USTR strongly urges submitters to file comments through [regulations.gov](http://www.regulations.gov), if at all possible. Any alternative arrangements must be made with Ms. Blue in advance of transmitting a comment. Ms. Blue should be contacted at (202) 395-3475. General information concerning USTR is available at <http://www.ustr.gov>.

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Carmen Suro-Bredie

Chair, Trade Policy Staff Committee

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