

financial report no more than 90 days after the expiration of the award;

b. Quarterly financial reports; and

c. Program reports after each major phase of activity, e.g., after each international travel phase.

Grantees will be required to provide reports analyzing their evaluation findings to the Bureau in their regular program reports. Please refer to Application and Submission Instructions (IV.3.d.3) above for Program Monitoring and Evaluation information.

All data collected, including survey responses and contact information, must be maintained for a minimum of three years and provided to the Bureau upon request.

All reports must be sent to the ECA Grants Officer and ECA Program Officer listed in the final assistance award document.

#### VI.4. Program Data Requirements

Organizations awarded grants will be required to maintain specific data on program participants and activities in an electronically accessible database format that can be shared with the Bureau as requested. As a minimum, the data must include the following:

(a) Name, address, contact information and biographic sketch of all persons who travel internationally on funds provided by the grant.

(b) Itineraries of international and domestic travel, providing dates of travel and cities in which any exchange experiences take place. Final schedules for in-country and U.S. activities must be received by the ECA Program Officer at least three work days prior to the official opening of the activity.

#### VII. Agency Contacts

For questions about this announcement, contact: Katherine Van de Vate ((202) 619-5320, [vandevatek@state.gov](mailto:vandevatek@state.gov)) or Thomas Johnston ((202) 619-5325, [JohnstonTJ@state.gov](mailto:JohnstonTJ@state.gov)), room 216, Office of Citizen Exchanges, ECA/PE/C/NEAAF, U.S. Department of State, SA-44, 301 Fourth Street, SW., Washington, DC 20547. All correspondence with the Bureau concerning this RFGP should reference the above title and number ECA/PE/C/NEAAF-05-02.

Please read the complete **Federal Register** announcement before sending inquiries or submitting proposals. Once the RFGP deadline has passed, Bureau staff may not discuss this competition with applicants until the proposal review process has been completed.

#### VIII. Other Information

##### Notice

The terms and conditions published in this RFGP are binding and may not be modified by any Bureau representative. Explanatory information provided by the Bureau that contradicts published language will not be binding. Issuance of the RFGP does not constitute an award commitment on the part of the Government. The Bureau reserves the right to reduce, revise, or increase proposal budgets in accordance with the needs of the program and the availability of funds. Awards made will be subject to periodic reporting and evaluation requirements per section VI.3 above.

**Notification:** Final awards cannot be made until funds have been appropriated by Congress, allocated and committed through internal ECA Bureau procedures.

Dated: August 6, 2004.

**C. Miller Crouch,**

*Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.*

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#### OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

##### 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

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice and request for comments.

**SUMMARY:** The Trade Policy Staff Committee (TPSC) is requesting written public comments 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 noon, September 17, 2004.

**ADDRESSES:** Office of the U.S. Trade Representative, 600 17th Street, NW., Washington, DC 20508. Submissions by electronic mail: [FR0435@ustr.gov](mailto:FR0435@ustr.gov). Submissions by facsimile: Gloria Blue, Executive Secretary, Trade Policy Staff Committee, at (202) 395-6143.

**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 Sarah Bovim or Jean Janicke, Director, Market Access, USTR (202) 395-4994.

**SUPPLEMENTARY INFORMATION:** The Chairman of the TPSC invites written comments from the public on the expansion of the list of pharmaceutical products receiving duty-free treatment from certain members of the World Trade Organization (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 2004 in the WTO with a view to adding new pharmaceuticals to the zero duty list. Any amendments to the list of pharmaceuticals will be subject to approval by all participants in the negotiations. A copy of the initial list of proposed items is available on the USTR Web site at: <http://www.ustr.gov>.

#### 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 zero duty list of pharmaceuticals. As a result of multilateral negotiations in 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, and on an additional 630 such products on July 1, 1999.

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 as a result of the Uruguay Round zero for zero agreement on pharmaceuticals and the subsequent updates by WTO members. The HTSUS can be purchased from the United States Government Printing Office. An electronic version of the HTSUS can be found at <http://www.usitc.gov>. The Pharmaceutical Appendix of the HTSUS consists of

three tables. Table 1 lists active pharmaceutical ingredients and dosage-form products by their International Nonproprietary Names (INNs) from the World Health Organization (WHO).

Table 1 currently includes INNs from WHO lists 1–78. 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. The interagency TPSC committee, led by USTR and with input from appropriate industry association and private sector advisory groups, is in the process of preparing negotiating positions. Comments are requested for pharmaceutical items which would be in the interest of the United States to add to the existing WTO zero for zero agreement.

Negotiators will be reviewing the INNs on the most recent WHO lists (*i.e.*, lists 79–90) 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. Otherwise, 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 it is incorporated, the CAS number of this active ingredient, and a diagram of the molecular structure of this active

ingredient. A suggested format for presenting this information is presented below. 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.

**2. Requirements for Submissions**

In order to facilitate prompt processing of submissions, USTR strongly urges and prefers electronic (e-mail) submissions in response to this notice.

Persons making submissions by e-mail should use the following subject line: “Expansion of the List of Pharmaceutical Products Receiving Zero Duties” followed by “Written Comments.” Documents should be submitted as either WordPerfect, MSWord, or text (.txt) files. Supporting documentation submitted as spreadsheets are acceptable as Quattro Pro or Excel. More detailed information regarding the content of the submissions is listed below.

For any document containing business confidential information submitted electronically, the file name of the business confidential version should begin with the characters “BC-”,

and the file name of the public version should begin with the characters “P-”. The “P-” or “BC-” should be followed by the name of the submitter. Persons who make submissions by e-mail should not provide separate cover letters; information that might appear in a cover letter should be included in the submission itself. To the extent possible, any attachments to the submission should be included in the same file as the submission itself, and not as separate files.

Written comments submitted in response to this request will be placed in a file open to public inspection pursuant to 15 *CFR* 2003.5, except business confidential information exempt from public inspection in accordance with 15 *CFR* 2003.6. Business confidential information submitted in accordance with 15 *CFR* 2003.6 must be clearly marked “Business Confidential” at the top of each page, including any cover letter or cover page, and must be accompanied by a nonconfidential summary of the confidential information. All public documents and nonconfidential summaries shall be available for public inspection in the USTR Reading Room. The USTR Reading Room is open to the public, by appointment only, from 10 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday. An appointment to review the file must be scheduled at least 48 hours in advance and may be made by calling (202) 395–6186.

General information concerning the Office of the United States Trade Representative may be obtained by accessing its Internet Web site (<http://www.ustr.gov>).

**Carmen Suro-Bredie,**  
*Chair, Trade Policy Staff Committee.*

Suggested format for submissions:

HS code (6-digit)	CAS number	Chemical name ( <i>e.g.</i> , chemical abstracts index name)
Molecular structure:		

For all chemical intermediates, the following information is provided on the pharmaceutical active ingredient into which the intermediate is incorporated:

INN of active ingredient	CAS number of active ingredient	Chemical name of active ingredient
Molecular structure of active ingredient:		

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**OFFICE OF THE UNITED STATES  
TRADE REPRESENTATIVE**

[Docket No. WTO/DS-245]

**WTO Dispute Settlement Proceeding  
Regarding Japanese Measures  
Affecting the Importation of Apples**

**AGENCY:** Office of the United States Trade Representative.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Office of the United States Trade Representative ("USTR") is providing notice that on July 30, 2004, at the request of the United States, the Dispute Settlement Body (DSB) of the World Trade Organization (WTO) established a dispute settlement panel under the Marrakesh Agreement Establishing the WTO to examine whether Japan has implemented the recommendations and rulings of the DSB in a dispute involving Japanese phytosanitary measures restricting the importation of U.S. apples. Japan justifies the measures as relating to the plant disease fire blight and the fire blight-causing organism, *Erwinia amylovora*. On December 10, 2003, the DSB adopted the findings of the panel and Appellate Body in this proceeding, which found that Japan's apple import regime was maintained in breach of various provisions of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement"). Japan issued revised measures on June 30, 2004 in response to the DSB's recommendations and rulings. The United States subsequently requested the establishment of the dispute settlement panel because it believes that Japan's revised measures do not comply with the DSB's recommendations and rulings or the SPS Agreement. USTR invites written comments from the public concerning the issues raised in this dispute.

**DATES:** Although USTR will accept any comments received during the course of the dispute settlement proceedings, comments should be submitted on or before September 1, 2004 to be assured of timely consideration by USTR.

**ADDRESSES:** Comments should be submitted (i) electronically, to [FR0438@ustr.gov](mailto:FR0438@ustr.gov), Attn: "Japan Apples" in the subject line, or (ii) by fax, to Sandy McKinzy at (202) 395-3640, with a confirmation copy sent electronically to the email address above.

**FOR FURTHER INFORMATION CONTACT:** Jay T. Taylor, Assistant General Counsel, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20508, (202) 395-3150.

**SUPPLEMENTARY INFORMATION:** Section 127(b) of the Uruguay Round Agreements Act ("URAA") (19 U.S.C. § 3537(b)(1)) requires that notice and opportunity for comment be provided after the United States submits or receives a request for the establishment of a WTO dispute settlement panel. If a dispute settlement panel is established pursuant to the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), the panel, which would hold its meetings in Geneva, Switzerland, would be expected to issue a report on its findings and recommendations within approximately three months of the date it is established.

**Prior WTO Proceedings**

On December 10, 2003, the WTO DSB adopted the reports of a dispute settlement panel and the WTO Appellate Body in a dispute brought by the United States challenging Japanese phytosanitary restrictions on the import of U.S. apples in connection with fire blight or the fire blight-causing organism, *Erwinia amylovora*. The panel found, and the Appellate Body confirmed, that Japan's restrictions were not consistent with its obligations under the SPS Agreement. The DSB recommended that Japan revise its measure accordingly. The dispute settlement panel and Appellate Body reports are publicly available in the USTR reading room and on the WTO Web site <http://www.wto.org>.

**Article 21.5 Proceeding**

The United States and Japan agreed that Japan would have until June 30, 2004 as the reasonable period of time to implement the DSB's recommendations and rulings. The United States and Japan met several times during that period in an attempt to reach an agreement regarding Japan's restrictions on U.S. apples, but were unable to agree on a satisfactory result. Japan issued revised measures on June 30, which the United States believes fail to comply with the DSB's recommendations and rulings and the SPS Agreement. Accordingly, the United States requested the establishment of an Article 21.5 compliance panel to determine the WTO-consistency of Japan's revised measures. The DSB established the panel on July 30, 2004.

The European Communities, New Zealand, Chinese Taipei, and Australia have indicated their interest to

participate in the dispute as third parties.

Japan's new measures retain almost all of the phytosanitary restrictions of the original measure, which was found by the Appellate Body and Panel to be inconsistent with Japan's obligations under the SPS Agreement. The restrictions include: the prohibition of imported apples other than those produced in designated orchards in the U.S. States of Washington and Oregon; the prohibition of imported apples from orchards in which any fire blight is detected; the prohibition of imported apples from any orchard (whether or not it is free of fire blight) should fire blight be detected in a "buffer zone" surrounding the orchard; the requirement that export orchards be inspected for the presence of fire blight for purposes of applying the above-mentioned prohibitions; a post-harvest surface treatment of exported apples with chlorine; production requirements, such as chlorine treatment of the interior of the packing facility; post-harvest separation of apples for export to Japan from those apples for other destinations; a requirement that U.S. plant protection officials certify or declare that the apples are free of quarantine pests, not infested/infested with fire blight, and have been treated with chlorine; and a requirement that Japanese officials confirm that the certification, orchard designation and chlorine treatment have been properly administered and inspect the disinfestation and packing facilities. The United States believes that Japan's revised measures are inconsistent with Articles 2.2, 2.3, 5.1, 5.2, 5.3, 5.5, 5.6, 6.1 and 6.2 of the SPS Agreement, Article XI of the *General Agreement on Tariffs and Trade 1994* and Article 4.2 of the *Agreement on Agriculture*.

**Public Comment: Requirements for Submissions**

Interested persons are invited to submit written comments concerning the issues raised in this dispute. Persons submitting comments may either send one copy by fax to Sandy McKinzy at (202) 395-3640, or transmit a copy electronically to [FR0438@ustr.gov](mailto:FR0438@ustr.gov), with "Japan Apples (DS245)" in the subject line. For documents sent by fax, USTR requests that the submitter provide a confirmation copy to the electronic mail address listed above.

USTR encourages the submission of documents in Adobe PDF format, as attachments to an electronic mail. Interested persons who make submissions by electronic mail should not provide separate cover letters; information that might appear in a cover