DATES AND DRAFT AGENDA OF THE FIFTY-FIRST SESSION OF THE HARMONIZED SYSTEM COMMITTEE OF THE WORLD CUSTOMS ORGANIZATION


ACTION: Publication of the dates and draft agenda for the fifty-first session of the Harmonized System Committee of the World Customs Organization.

SUMMARY: This notice sets forth the dates and draft agenda for the next session of the Harmonized System Committee of the World Customs Organization.

DATES: JAN 16, 2013


SUPPLEMENTARY INFORMATION:

BACKGROUND

The United States is a contracting party to the International Convention on the Harmonized Commodity Description and Coding System (“Harmonized System Convention”). The Harmonized Commodity Description and Coding System (“Harmonized System”), an international nomenclature system, forms the core of the U.S. tariff, the Harmonized Tariff Schedule of the United States. The Harmonized System Convention is under the jurisdiction of the World Customs Organization (established as the Customs Cooperation Council).

Article 6 of the Harmonized System Convention establishes a Harmonized System Committee (“HSC”). The HSC is composed of representatives from each of the contracting parties to the Harmonized System Convention. The HSC’s responsibilities include issuing classification decisions on the interpretation of the Harmonized System. Those decisions may take the form of published tariff classification...
opinions concerning the classification of an article under the Harmonized System or amendments to the Explanatory Notes to the Harmonized System. The HSC also considers amendments to the legal text of the Harmonized System. The HSC meets twice a year in Brussels, Belgium. The next session of the HSC will be the fifty-first and it will be held from March 6, 2013 to March 15, 2013.

In accordance with section 1210 of the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418), the Department of Homeland Security, represented by U.S. Customs and Border Protection, the Department of Commerce, represented by the Census Bureau, and the U.S. International Trade Commission (“ITC”), jointly represent the U.S. government at the sessions of the HSC. The Customs and Border Protection representative serves as the head of the delegation at the sessions of the HSC.

Set forth below is the draft agenda for the next session of the HSC. Copies of available agenda-item documents may be obtained from either Customs and Border Protection or the ITC. Comments on agenda items may be directed to the above-listed individuals.

IEVA K. O’ROURKE,  
Chief  
Tariff Classification and Marking Branch

Attachment
DRAFT AGENDA FOR THE 51ST SESSION OF THE HARMONIZED SYSTEM COMMITTEE

From: Wednesday, 6 March 2013 (11.00 a.m.)
To: Friday, 15 March 2013

N.B.: Monday, 4 March 2013 (9.30 a.m.) to Tuesday 5 March 2013: Presessional Working Party (to examine the questions under Agenda Item VI)

I. ADOPTION OF THE AGENDA

1. Draft Agenda

II. REPORT BY THE SECRETARIAT

1. Position regarding Contracting Parties to the HS Convention and related matters and progress report on the implementation of HS 2012

2. Report on the last meetings of the Policy Commission (68th Session)

3. Approval of decisions taken by the Harmonized System Committee at its 50th Session

4. Capacity building activities of the Nomenclature and Classification Sub-Directorate

5. Co-operation with other international organizations

6. New information provided on the WCO Web site

7. Other
III. GENERAL QUESTIONS
1. Future of the Harmonized System NC1828E1a
2. Classification Advice provided by the Secretariat (Request by Switzerland) NC1829E1a
3. Possible amendment of Article 8 of the HS Convention with a view to removing the Council from its purely administrative role with regard to HS reservations, and to making the fast-track procedure the default reservation procedure NC1830E1a
4. New version of the HS Commodity Database: Electronic version of the HS Alphabetical Index and the Classification Decisions taken by the Harmonized System Committee. NC1850E1a
5. Procedure for the adoption of the Reports of the Committee NC1851E1a

IV. REPORT OF THE SCIENTIFIC SUB-COMMITTEE
1. Report of the 28th Session of the Scientific Sub-Committee NSOE
2. Matters for decision NC1831E1a
3. Possible amendments to the Explanatory Note to heading 15.09 (Request by Canada) NC1832E1a

V. REPORT OF THE REVIEW SUB-COMMITTEE
1. Report of the 44th Session of the Review Sub-Committee NR0916E1b
2. Matters for decision NC1833E1a

VI. REPORT OF THE PRESESSIONAL WORKING PARTY
1. Amendments to the Explanatory Notes to clarify the classification of the “HALVA Sesame Snack with Honey” NC1834E1a, Annex A
2. Amendments to the Compendium of Classification Opinions to reflect the decision to classify a dog collar named “Klitix®” in heading 38.08 (subheading 3808.91) NC1834E1a, Annex B NC1821E1a
3. Amendments to the Compendium of Classification Opinions to reflect the decision to classify three products referred to as “water bottles for bicycles” (Products 1, 2 and 3) in heading 39.24 (subheading 3924.90) NC1834E1a, Annex C
4. Amendments to the Compendium of Classification Opinions to reflect the decision to classify terracotta cladding elements in heading 69.07 (subheading 6907.90) NC1834E1a, Annex D
5. Amendments to the Compendium of Classification Opinions to reflect the decision to classify a “Heat and Sound Insulation Material” in heading 70.19 (subheading 7019.39) NC1834E1a, Annex E
6. Amendments to the Compendium of Classification Opinions to reflect the decision to classify a charcoal starter in heading 73.21 (subheading 7321.89) NC1834E1a, Annex F
7. Amendments to the Compendium of Classification Opinions to reflect the decision to classify a “connecting link” in heading 73.26 (subheading 7326.90) NC1834E1a, Annex G

Amendments to the Compendium of Classification Opinions to reflect the decision to classify certain types of “peelers and graters for vegetables or fruit” (two products) in heading 82.05 (subheading 8205.51) NC1834E1a, Annex H

9. Amendments to the Compendium of Classification Opinions to reflect the decision to classify self-propelled machinery in heading 84.26 (subheading 8426.41) NC1834E1a, Annex IJ

10. Amendments to the Compendium of Classification Opinions to reflect the decision to classify the “Samsung Galaxy Tab” commercially referred to as a tablet computer in heading 84.71 (subheading 8471.30) NC1834E1a, Annex K

11. Amendments to the Compendium of Classification Opinions to reflect the decision to classify certain types of monitors referred to as 23.1-inch Maritime Multi Display (MMD) Model JH 23T14 MMD in heading 85.28 (subheading 8528.51) NC1834E1a, Annex L

12. Amendments to the Compendium of Classification Opinions to reflect the decision to classify two types of monitors in heading 85.28 (subheading 8528.51) NC1834E1a, Annex M

13. Amendments to the Compendium of Classification Opinions to reflect the decision to classify packaged “Insulated Gate Bipolar Transistors (IGBTs)” in heading 85.41 (subheading 8541.29) NC1834E1a, Annex N

14. Amendments to the Compendium of Classification Opinions to reflect the decision to classify a “Motor-home” in heading 87.03 NC1834E1a, Annex O

15. Amendments to the Compendium of Classification Opinions to reflect the decision to classify a self-propelled rail welding machine (Vaia Car “Spark-rail” Model) in heading 87.05 (subheading 8705.90) NC1834E1a, Annex P

16. Amendments to the Compendium of Classification Opinions to reflect the decision to classify “roofer-mounted cargo boxes for motor vehicles” (Products 1 and 2) in heading 87.08 (subheading 8708.99) NC1834E1a, Annex Q

17. Amendments to the Compendium of Classification Opinions to reflect the decision to classify a “Separately Presented Photofluorographic Chamber Model KF-400” in heading 90.06 (subheading 9006.30) NC1834E1a, Annex R

18. Amendments to the Compendium of Classification Opinions to reflect the decision to classify certain types of tripods (Product 1) in heading 90.06 (subheading 9006.91) NC1834E1a, Annex S

VII. FURTHER STUDIES

1. Possible amendments to the Explanatory Note to heading 30.02 NC1835E1a
2. Classification of “cobalt manganese nickel hydroxide (CoMnNi(OH)₂)” used for lithium-ion batteries (Request by Japan) NC1836E1a

3. Possible amendments to the Explanatory Notes in respect of the term “roes” NC1837E1a

4. Classification of “Xanthan Gum” (Request by India) NC1838E1a

5. Classification of portable floor air conditioning units NC1839E1a

6. Classification of the product named “Xenical” (Request by Switzerland) NC1840E1a

7. Classification of garments known as “Shalwar-Kameez” (Request by Sri Lanka) NC1841E1a NC1821E1a

8. Classification of certain products named “Panaxea” (Request by South Africa) NC1842E1a

9. Classification of a jar of coffee, a cup and a saucer put up for retail sale in a paperboard box (Request by Moldova) NC1843E1a

10. Classification of the product called “Dabur Hajmola” candy/tablets (Request by Pakistan) NC1844E1a

11. Possible amendments to the Explanatory Notes in respect of terracotta cladding elements (Request by the Secretariat) NC1845E1a

12. Possible amendment to the Explanatory Notes in respect of certain amplifiers combined in a single housing with loudspeakers (Proposal by Canada) NC1846E1a

13. Classification of light emitting diode (LED) backlights for liquid crystal displays (Request by Korea) NC1847E1a

14. Classification of certain light emitting diode (LED) assemblies (Request by Korea) NC1848E1a

15. Corrigendum to the provisionally adopted New Subheading Note 1 to Chapter 84 (Request by the EU) NC1849E1a

VIII. NEW QUESTIONS

1. Classification of the product called “Vita hjertego’ Gul” (Request by Norway) NC1852E1a

2. Classification of peach pulp concentrate (Request by South Africa) NC1853E1a

3. Possible amendment of the HS in respect of certain categories of waste (Proposal by the Secretariat of Basel Convention) NC1854E1a

4. Classification of certain cabinets in unassembled form with or without apparatus to be housed therein (Request by the Secretariat) NC1855E1a

5. Possible amendment of Exclusion (a) to the Explanatory Note to heading 71.13 (Request by the Secretariat) NC1856E1a

6. Possible amendments to the Nomenclature in respect of the “Radiators and parts thereof” of heading 87.08 (Proposal by Thailand) NC1857E1a
7. Classification of two types of touch-sensitive screens (Request by Korea) NC1858E1a
8. Classification of an AMOLED touch assembly for a mobile phone (Request by Korea) NC1859E1a
9. Clarification of the scope of the concept “natural” in Chapters 25 and 28 of the HS (Request by the Russian Federation) NC1860E1a

IX. ADDITIONAL LIST
X. 25th ANNIVERSARY OF THE HARMONIZED SYSTEM COMMITTEE
XI. OTHER BUSINESS
   1. List of questions which might be examined at a future session NC1861E1a
XII. ELECTIONS
XIII. DATES OF NEXT SESSIONS
NOTICE OF ISSUANCE OF FINAL DETERMINATION CONCERNING RYBIX® (TRAMADOL HYDROCHLORIDE) TABLETS


ACTION: Notice of final determination.

SUMMARY:

This document provides notice that U.S. Customs and Border Protection ("CBP") has issued a final determination concerning the country of origin of Rybix® (tramadol hydrochloride) tablets. Based upon the facts presented, CBP has concluded in the final determination that India is the country of origin of the Rybix (tramadol hydrochloride) tablets for purposes of U.S. Government procurement.

DATES: The final determination was issued on December 26, 2012. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR § 177.22(d), may seek judicial review of this final determination on or before February 11, 2013.

FOR FURTHER INFORMATION CONTACT: Karen S. Greene, Valuation and Special Programs Branch: (202) 325–0041.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on December 26, 2012, pursuant to subpart B of Part 177, Customs and Border Protection Regulations (19 CFR part 177, subpart B), CBP issued a final determination concerning the country of origin of Rybix (tramadol hydrochloride) tablets, which may be offered to the U.S. Government under an undesignated government procurement contract. This final determination, in HQ H215656, was issued at the request of Shionogi Inc., under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination CBP concluded that, based upon the facts presented, tramadol hydrochloride from India, blended with excipients and packaged into dosage form in France, was not substantially transformed in France, such that India is the country of origin of the finished Rybix (tramadol hydrochloride) tablets for purposes of U.S. Government procurement.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the Federal Register within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any
party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.


**Jeremy Baskin,**

*Acting Executive Director, Regulations and Rulings, Office of International Trade.*

Attachment
RE: U.S. Government procurement; Trade Agreement Act; Country of Origin of Rybix ODT; substantial transformation

DEAR MR. KIRSCHENBAUM:

This is in response to your ruling request, submitted April 6, 2012, requesting a final determination on behalf of Shionogi Inc., pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (“CBP”) Regulations (19 CFR Part 177) which was forwarded to this office for a response. Under these regulations, which implement Title III of the Trade Agreements Act of 1979 (“TAA”), as amended (19 U.S.C. 2511 et seq.), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers of certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. Government.

This final determination concerns the country of origin of Rybix ODT (tramadol hydrochloride orally disintegrating tablets). As a U.S. importer, Shionogi Inc. is a party-at-interest within the meaning of 19 CFR 177.22(d)(1), and is entitled to request this final determination.

FACTS:

Rybix ODT is a pharmaceutical product used for the management of moderate to moderately severe pain in adults. The active pharmaceutical ingredient (“API”), tramadol hydrochloride, is manufactured in India. The API is shipped to France where it undergoes four stages of manufacturing. Inactive ingredients (excipients) used in production in France are: aspartame, copovidone, crospovidone, ethylcellulose, magnesium stearate, mannitol 60, mannitol M300, mint rootbeer flavor, and silicon dioxide.

The first stage of French manufacturing is preparation of tramadol hydrochloride granules (the API). The API and silicon dioxide are de-lumped and granulated with a suspension of ethylcellulose, copovidone, silicon dioxide, and ethanol. The uncoated granules are sieved and sized. These granules are then coated and sieved to remove any granules larger than 710 microns.

The second stage of French manufacturing is preparation of the tablet blend. A number of excipients such as mint rootbeer flavor, aspartame, crospovidone, mannitol 60, and mannitol M300, are de-lumped by passing them through a sieve. An excipient is defined on www.thefreedictionary.com as “an inactive substance that serves as the vehicle or medium for a drug” or “a substance, such as sugar or gum, used to prepare a drug or drugs in a form suitable for administration.” The excipients are combined to make a flavor preblend. The tramadol hydrochloride coated granules are also de-lumped by
passing them through a screen and then the flavor preblend is added and blended. The blended product is discharged into polyethylene-lined drums.

The third stage of French manufacturing is tablet compression. Magnesium stearate is sprayed onto upper and lower punch faces on a tablet press (to prevent sticking) and tablets are formed. The bulk tablets are collected in polyethylene-lined foil bags, which are heat-sealed and packaged in fiber-board drums.

The fourth stage of French manufacturing is packaging in child-resistant blister packs. The tablets are fed through a tablet feeder and packaged into cold form blisters sealed with child-resistant blister lidstock. The blister pack cards are then packed into cartons of 30 tablets each with FDA-compliant labeling, packaged in cartons and shipped to the importer’s warehouses in the U.S.

**ISSUE:**

What is the country of origin of imported Rybix ODT (tramadol hydrochloride), processed as described above?

**LAW AND ANALYSIS:**

Pursuant to Subpart B of Part 177, 19 CFR 177.21 et seq., which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511 et seq.), CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purposes of granting waivers if certain “Buy American” restrictions in U.S. law or practice for products offered for sale to the U.S. government. Under the rule of origin set forth under 19 U.S.C. 2518(4)(B), an article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed. See also 19 CFR 177.22(a).

In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing, and whether the final article retains the essential identity and character of the raw material. To that end, CBP has generally held that the processing of pharmaceutical products from bulk form into measured doses, filtering and packaging does not result in a substantial transformation. See Headquarters Ruling Letter (“HRL”) H197582, dated August 9, 2012, HRL 561975, dated April 3, 2002, HRL 561544, dated May 1, 2000.

In HRL 561975, dated April 3, 2002, an anesthetic drug known as sevofurane was imported in bulk form from Japan and in the U.S., processed into dosage form, filtered and subjected to FDA testing. CBP held that the imported good did not undergo a substantial transformation in the U.S.—the chemical and physical properties of the drug remained the same, and the medicinal use did not change.

Likewise, in HRL 561544, dated May 1, 2000, the testing, filtering and sterile packaging of Geneticin Sulfate bulk powder to create Geneticin Selective antibiotic, was not found to have substantially transformed the anti-
biotic substance because the processing only involved the removal of impurities from the bulk chemical and the placement of the chemical into smaller packaging.

In HRL H040735, dated January 21, 2009, CBP considered whether imported Sumatriptan was substantially transformed in the UK, where it was compounded with sodium chloride and water using helium USP for a processing aid to reduce dissolved air. The pharmaceutical then went through a series of sterilizing filters, and was filled into an empty capsule subassembly. The drug capsule subassembly, which contained the dose of sumatriptan succinate, and the actuator subassembly, which consisted of a nitrogen gas powered ram and piston, were then combined. CBP held that the active ingredient which was produced in India, did not undergo a substantial transformation even though the injection system was sophisticated and valuable. The active ingredient did not undergo a change in character.

In this case, the processing in France does not result in a change in the medicinal use of the finished product and the active ingredient retains its chemical and physical properties and is merely put into a dosage form and packaged. The active ingredient does not undergo a change in name, character or use. Accordingly, we find that there no substantial transformation occurs in France, and the imported product would be considered a product of India for purposes of government procurement.

HOLDING:

Based upon the facts in this case, we find that the imported Rybix ODT (tramadol hydrochloride) is not substantially transformed in France. The country of origin for government procurement purposes is India.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the Federal Register notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

JEREMY BASKIN
Acting Executive Director
Office of Regulations and Rulings,
Office of International Trade

[Published in the Federal Register, January 11, 2013 (78 FR 2416)]
AGENCY INFORMATION COLLECTION ACTIVITIES:
Application To Establish a Centralized Examination Station


ACTION: 60-Day notice and request for comments; Extension of an existing collection of information.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, CBP invites the general public and other Federal agencies to comment on an information collection requirement concerning the: Application to Establish a Centralized Examination Station. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

DATES: Written comments should be received on or before March 12, 2013, to be assured of consideration.


FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street NW., 5th Floor, Washington, DC. 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs burden to respondents or record keepers from the collection of information (a total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for Office of
Management and Budget (OMB) approval. All comments will become a matter of public record. In this document CBP is soliciting comments concerning the following information collection:

**Title:** Application to Establish a Centralized Examination Station.

**OMB Number:** 1651–0061.

**Form Number:** None.

**Abstract:** A Customs and Border Protection (CBP) port director decides when his or her port needs one or more Centralized Examination Stations (CES). If it is decided that a CES is needed, the port director solicits applications to operate a CES. The information contained in the application will be used to determine the suitability of the applicant’s facility; the fairness of fee structure; and knowledge of cargo handling operations and of CBP procedures. The names of all corporate officers and all employees who will come in contact with uncleared cargo will also be provided so that CBP may perform background investigations. The CES application is provided for by 19 CFR 118.11 and is authorized by 19 USC 1499, Tariff Act of 1930.

**Current Actions:** This submission is being made to extend the expiration date with no changes to the burden hours or to the information collected.

**Type of Review:** Extension (without change).

**Affected Public:** Businesses.

**Estimated Number of Respondents:** 50.

**Estimated Time per Respondent:** 2 hours.

**Estimated Total Annual Burden Hours:** 100.

Dated: January 8, 2013.

**Tracey Denning,**

*Agency Clearance Officer,*

*U.S. Customs and Border Protection.*

[Published in the Federal Register, January 11, 2013 (78 FR 2416)]