

estimated for an average respondent to respond: 2,384 responses at 2 hours per response.

(6) An estimate of the total public burden (in hours) associated with the collection: 4,768 annual burden hours.

If you need a copy of the information collection instrument with supplementary documents, or need additional information, please visit <http://www.regulations.gov>. We may also be contacted at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529-2140; Telephone 202-272-8377.

Dated: January 8, 2013.

**Laura Dawkins,**

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2013-00471 Filed 1-10-13; 8:45 am]

BILLING CODE 9111-97-P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Agency Information Collection Activities: Application To Establish a Centralized Examination Station

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**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.

**ADDRESSES:** Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Office of Regulations and Rulings, 799 9th Street NW., 5th Floor, Washington, DC 20229-1177.

**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.

[FR Doc. 2013-00415 Filed 1-10-13; 8:45 am]

BILLING CODE 9111-14-P

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Issuance of Final Determination Concerning Rybix® (Tramadol Hydrochloride) Tablets

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**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**.

Dated: December 26, 2012.

**Jeremy Baskin,**

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

#### Attachment

HQ H215656

December 26, 2012

MAR-02 OT:RR:CTF:VS KSG

CATEGORY: Origin

Alan M. Kirschenbaum

Hyman, Phelps & McNamara P.C.

700 13th Street, NW.

Suite 1200

Washington, DC 20815

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 eruling 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](http://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 fiberboard 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 antibiotic 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

[FR Doc. 2013-00414 Filed 1-10-13; 8:45 am]

**BILLING CODE P**

---

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5681-N-02]

### Federal Property Suitable as Facilities To Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

**FOR FURTHER INFORMATION CONTACT:** Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7262, Washington, DC 20410; telephone (202) 402-3970; TTY number for the hearing- and speech-impaired (202) 708-2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800-927-7588.

**SUPPLEMENTARY INFORMATION:** In accordance with the December 12, 1988 court order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 3, 2013.

**Mark Johnston,**

*Deputy Assistant Secretary for Special Needs.*

[FR Doc. 2013-00152 Filed 1-10-13; 8:45 am]

**BILLING CODE 4210-67-P**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5613-N-12]

### Privacy Act; Notification of New Privacy Act System of Records, Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation Random Assignment and Service Tracking (RAST) System

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Establishment of a new Privacy Act System of Records.

**SUMMARY:** The Department of Housing and Urban Development (HUD) proposes to establish a new record system to add to its inventory of systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended. The proposed new system of record is the Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation Random Assignment and Service Tracking (RAST) System. This system will be used by HUD's Office of Policy Development and Research (PD&R) and its contractors to conduct a random assignment and impact evaluation study of the impact that different types of pre-purchase counseling have on mortgage preparedness, homeowner outcomes, and loan performance for prospective low-to-moderate income, first-time homebuyers. Refer to the "Purpose" section to obtain detailed information about the purpose of this study.

**DATES:** *Effective Date:* This action shall be effective without further notice on *February 11, 2013* unless comments are received that would result in a contrary determination.

*Comments Due Date:* February 11, 2013.

**ADDRESSES:** Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying between 8:00 a.m. and 5:00 p.m. weekdays at the above address.

**FOR FURTHER INFORMATION CONTACT:** Donna Robinson-Staton, Chief Privacy Officer, Department of Housing and Urban Development, 451 Seventh Street SW., (Attention: Capitol View Building, 4th Floor), Washington, DC 20410, Telephone Number (202) 402-8073. (This is not a toll-free number.) A

telecommunication device for hearing- and speech-impaired individuals (TTY) is available at 1-800-877-8339 (Federal Information Relay Service).

**SUPPLEMENTARY INFORMATION:** Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), as amended notice is given that HUD proposes to establish a new system of records as identified as Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation Random Assignment and Service Tracking (RAST) System. Title 5 U.S.C. 552a (e)(4) and (11) provide that the public be afforded a 30-day period in which to comment on the new system of records, and require published notice of the existence and character of the system of records. The new system report was submitted to the Office of Management and Budget (OMB), the Senate Committee on Governmental Affairs, and the House Committee on Government Reform pursuant to paragraph 4c of Appendix 1 to OMB Circular No. A-130, "Federal Agency Responsibilities for Maintaining Records About Individuals," July 25, 1994; 59 FR 37914.

**Authority:** 5 U.S.C. 552a 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: December 11, 2012.

**Jerry E. Williams,**  
*Chief Information Officer.*

**PDR/RRE.01**

**SYSTEM NAME:**

Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation Random Assignment and Service Tracking (RAST) System.

**SYSTEM LOCATION:**

Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation data files are to be located at Abt Associates Inc., 55 Wheeler Street, Cambridge, MA 02138; Abt Associates Inc., 4550 Montgomery Avenue, Bethesda, MD 20814; Abt Associates Inc., 275 Seventh Avenue, Suite 2700, New York, NY 10001; Sage Computing Inc., 11491 Sunset Hills Road, Suite 350, Reston, VA 20190; HUD Office of Policy Development and Research, 451 7th Street SW., Rm. 8120, Washington, DC 20410; HUD Records Management Facility, 451 7th Street SW., Rm. B229, Washington, DC 20410.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Households enrolled in the Pre-Purchase Homeownership Counseling Demonstration and Impact Evaluation.