

Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed 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 estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2012-21695 Filed 8-31-12; 8:45 am]

**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-P-0458]

#### **Determination That ALOXI (Palonosetron Hydrochloride) Capsules, 0.5 Milligram (Base), Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that ALOXI (palonosetron hydrochloride (HCl)) Capsules, 0.5 milligram (mg) (base), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for palonosetron

HCl capsules, 0.5 mg (base), if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:**

Molly Flannery, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993-0002, 301-796-3543.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), is the subject of NDA 22-233, held by Helsinn Healthcare, and initially approved on August 22, 2008. ALOXI is indicated for the prevention of acute nausea and vomiting associated with initial and repeat courses of

moderately emetogenic cancer chemotherapy.

Helsinn Healthcare has never marketed ALOXI (palonosetron HCl) Capsules, 0.5 mg (base). In previous instances (see, e.g., 72 FR 9763, March 5, 2007; 61 FR 25497, May 21, 1996), the Agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

Lachman Consultant Services, Inc. submitted a citizen petition dated May 7, 2012 (Docket No. FDA-2012-P-0458), under 21 CFR 10.30, requesting that the Agency determine whether ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to ALOXI (palonosetron HCl) Capsules, 0.5 mg (base), may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 27, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-21652 Filed 8-31-12; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Refugee Resettlement

[C.F.D.A. Number 93.584]

#### Notice of FY 2012 Refugee Targeted Assistance Formula Awards to States and Wilson/Fish Alternative Project Grantees

**AGENCY:** Office of Refugee Resettlement, ACF, HHS.

**ACTION:** Notice of awards.

**SUMMARY:** The Office of Refugee Resettlement, Administration for Children and Families (ACF), announces the allocation of Refugee Targeted Assistance formula awards to States and Wilson/Fish Alternative Project grantees. The purpose of the Targeted Assistance program is to provide employment and other resettlement services to refugees, Amerasians, asylees, Cuban and Haitian entrants, victims of trafficking, and Iraqis and Afghans with Special Immigrant Visas. The grant allocations are awarded to States on behalf of counties that have had high levels of arrivals of the eligible populations. The awards supplement available refugee resettlement resources to ensure that refugees and other eligible populations become employed and self-sufficient as soon as possible. Awards are determined by the number of the eligible populations residing in each county during the two-year period from October 1, 2009, to September 30, 2011.

Targeted Assistance allocations are available on the ORR Web page. The table of FY 2012 Allocations to Counties and Targeted Assistance Areas and the Table of FY 2012 Allocations to States may be found at: [http://www.acf.hhs.gov/programs/orr/policy/fy2012\\_formula\\_allocations\\_targeted\\_assistance.htm](http://www.acf.hhs.gov/programs/orr/policy/fy2012_formula_allocations_targeted_assistance.htm).

**DATES:** The awards are effective immediately. Funds must be obligated by September 30, 2013, and funds must be expended by September 30, 2014.

**FOR FURTHER INFORMATION CONTACT:** Henley Portner, Office of the Director, Office of Refugee Resettlement, (202) 401-5363, [Henley.Portner@acf.hhs.gov](mailto:Henley.Portner@acf.hhs.gov).

**Statutory Authority:** Section 412(c)(2)(A) of the Immigration and Nationality Act (INA) (8 U.S.C. 1522).

**Eskinder Negash,**

*Director, Office of Refugee Resettlement.*

[FR Doc. 2012-21584 Filed 8-31-12; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[Docket No. DHS-2012-0017]

#### Privacy Act of 1974; Department of Homeland Security U.S. Immigration and Customs Enforcement—005 Trade Transparency Analysis and Research (TTAR) System of Records

**AGENCY:** Privacy Office, DHS.

**ACTION:** Notice of amendment of Privacy Act system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to amend a current Department of Homeland Security system of records titled, “Department of Homeland Security/ Immigration and Customs Enforcement-005 Trade Transparency Analysis and Research (TTAR) System of Records.” This system of records is being modified to include new categories of individuals, categories of records, and purposes. The system is also being updated to update, consolidate, and clarify the existing routine uses, to reflect a proposed change to the retention period of the system’s data, and to update and simplify the description of the record sources. The data in the TTAR system of records is generally maintained in the ICE Data Analysis and Research Trade Transparency System (DARTTS), which is a software application and data repository that conducts analysis of trade and financial data to identify statistically anomalous transactions that may warrant investigation for money laundering or other import-export crimes. Additionally, an update to the Privacy Impact Assessment for DARTTS has been posted on the Department’s privacy web site (see [www.dhs.gov/privacy](http://www.dhs.gov/privacy)). The exemptions for the existing system of records notice will continue to be applicable for this system of records notice. This updated system will be included in the Department of Homeland Security’s inventory of record systems.

**DATES:** Submit comments on or before October 4, 2012. This updated system will be effective October 4, 2012.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2012-0017 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202-343-4010.

- *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Lynn Rahilly, Privacy Officer, (202-732-3300), U.S. Immigration and Customs Enforcement, 500 12th Street SW., Mail Stop 5004, Washington, DC 20536, email: [ICEPrivacy@dhs.gov](mailto:ICEPrivacy@dhs.gov), or Jonathan R. Cantor, Acting Chief Privacy Officer, (202-343-1717), Privacy Office, Department of Homeland Security, Washington, DC 20528.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Immigration and Customs Enforcement (ICE) proposes to amend a current DHS system of records titled “DHS/ICE-005 Trade Transparency Analysis and Research (TTAR) System of Records.” This system of records is being modified to include new categories of individuals, categories of records, and purposes. The system is also being updated to update, consolidate, and clarify the existing routine uses, to reflect a proposed change to the retention period of the data, and to update and simplify the description of the record sources.

With the previously-published DARTTS PIA update, ICE is also notifying the public of three other changes to the TTAR SORN’s associated IT system, DARTTS. First, ICE is expanding the use of DARTTS within DHS to permit select U.S. Customs and Border Protection (CBP) customs officers and import specialists to access and use the system to conduct trade transparency analysis. These CBP employees use DARTTS in support of the CBP mission to enforce U.S. trade laws and ensure the collection of all