DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1423]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 14, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0046. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Importer's Entry Notice—(OMB Control Number 0910–0046)—Extension

Section 801 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381) charges the Secretary of Health and Human Services, through FDA, with the responsibility of assuring foreign-origin, FDA-regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products offered for import into the United States meet the same requirements of the FD&C Act as do domestic products, and for preventing products from entering the country if they are not in compliance. The discharge of this responsibility involves close coordination and cooperation between FDA headquarters and field inspectional personnel and the U.S. Customs Service (USCS), as the USCS is responsible for enforcing the revenue laws covering the very same products.

This collection of information gathers data for FDA-regulated products being imported into the United States and is being used by FDA to review and prevent imported products from entering the United States if the products do not meet the same requirements of the FD&C Act as domestic products.

Until October 1995, importers were required to file manual entries on OMB-approved forms that were accompanied by related documents. FDA did away with use of the paper forms effective October 1, 1995, to eliminate duplicity of information and to reduce the paperwork burden both on the import community and FDA. FDA then implemented an automated nationwide entry processing system, which enabled FDA to more efficiently obtain and process the information it requires to fulfill its regulatory responsibility.

Most of the information FDA requires to carry out its regulatory responsibilities under section 801 is already provided electronically by filers to USCS. Because USCS relays this data to FDA using an electronic interface, the majority of data submitted by the entry filer need be completed only once.

At each U.S. port of entry (seaport, landport, and airport) where foreign-origin, FDA-regulated products are offered for import, FDA is notified through USCS's Automated Commercial System (ACS) by the importer (or his/her agent) of the arrival of each entry. Following such notification, FDA reviews relevant data to ensure the imported product meets the standards as required for domestic products, decides on the admissibility of the imported product, and informs the importer and USCS of its decision. A single entry frequently contains multiple lines of different products. FDA may authorize products listed on specific lines to enter the United States unimpeded, while other products listed in the same entry may be held pending further FDA review/action.

All entry data pass through a screening criteria program resident on a USCS computer. This screening program was developed and is maintained by FDA. This electronic screening criteria module makes the initial screening decision on every entry of foreign-origin, FDA-regulated product. Almost instantaneously after the entry is filed, the filer receives FDA's admissibility decision for each entry, i.e., ''MAY PROCEED'' or ''FDA REVIEW.''

In addition to the information collected by USCS, FDA requires four additional pieces of information that were not available from USCS's system in order to make an admissibility decision for each entry. These data elements include the FDA Product Code, FDA country of production, manufacturer/shipper, and ultimate consignee. OMB has previously approved the automated collection of these four data elements for tobacco products that filers could provide to FDA along with other entry-related information. Providing this information to FDA results in importers receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

Since the inception of the interface with ACS, FDA's electronic screening criteria program has been applied nationwide. This eliminates issues such as ''port shopping'' (attempts to intentionally slip products through one FDA port when refused by another, or filing entries at a port known to receive a high volume of entries). Every electronically submitted entry line of foreign-origin, FDA-regulated product undergoes automated screening and the screening criteria can be set to be as specific or as broad as applicable; changes are immediately effective. This capability is of tremendous value in protecting the public if there is a need to immediately halt specific product from entering the United States.

If the data in this collection of information is not collected, FDA could not adequately meet its statutory responsibilities to regulate imported products, nor control potentially dangerous products from entering the U.S. marketplace.

In the **Federal Register** of November 27, 2013 (78 FR 70951), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA imported products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Non-Tobacco	3,406	1,089	3,709,134	[2] 0.14	519,279
Tobacco	330	68	22,440	[2] 0.14	3,142
Total					522,421

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] (8 minutes).

The hourly burden for this information collection is based on FDA's averaging of data obtained during a survey of nine representative filers nationwide and FDA's experience. For purposes of comparison of hourly burden, the filers also were requested to provide the same information with regard to filing entries manually. FDA felt that the average time for completing either electronic or manual entries was very similar.

Based on data collected by FDA's survey of nine filers and its experience, the total annual burden to the import community to submit information electronically for 3,731,574 average annual responses was 522,421 hours. The previously OMB-approved hours per response (0.14 hours) are expected to remain the same.

This burden includes the time FDA estimates it will take respondents to compile and provide documents to FDA for those entries where FDA cannot make an admissibility decision based on the electronic data alone. Based on the survey of nine filers and FDA's past experience, FDA estimates that there will be no additional costs to provide import data electronically to FDA, as filers already have equipment and software in place to enable them to provide data to USCS via the automated system. Therefore, no additional software or hardware need be developed or purchased to enable filers to file the FDA data elements at the same time they file entries electronically with USCS.

Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NINDS, NIMH, OAR)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Julie Schneider, Program Director, Center for Global Health, National Cancer Institute, 9609 Medical Center Dr., RM 3W564, Rockville, MD 20850 or call non-toll-free number 240–276–5795 or Email your request, including your address to: *schneidj@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Evaluation of National Institutes of Health International Bilateral Programs (FIC, NCI, NIAAA, NIAID, NICHD, NIDA, NIMH, NINDS, OAR), 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This submission is a request for OMB to approve the Evaluation of National Institutes of Health (NIH) International Bilateral Programs for three years. The bilateral awards are made through the Funding Opportunity Announcement mechanism and administrative supplements, meaning they are funded by set-aside funds that are separate from the general pool of research program grant funds used to support investigator initiated research at NIH. The bilateral programs to be evaluated are the U.S.-China Program for Biomedical Research Cooperation, U.S.—India Bilateral Collaborative Research Partnerships on the Prevention of HIV/AIDS and Co-morbidities, U.S.-Russia Bilateral Collaborative Research Partnerships on the Prevention and Treatment of HIV/AIDS and Co-morbidities, and U.S.-South Africa Program for Collaborative Biomedical Research. These programs are funded and administered by various combinations of the following institutes: Fogarty International Center (FIC), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Cancer Institute (NCI), National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institute for Allergy and Infectious Diseases (NIAID), National Institute on Drug Abuse (NIDA), National Institute of Mental Health (NIMH), National Institute of Neurological Disorders and Stroke