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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier J.O.

Food and Drug Administration

[Docket No. FDA–2009–N–0050]

Agency Information Collection Activities; Proposed Collection; Comment Request; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's need to collect additional information in the Importer's Entry Notice.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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FOR FURTHER INFORMATION CONTACT: Elizabeth G. Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

In order to make an admissibility decision for each entry, FDA needs four additional pieces of information that are not available in the U.S. Customs and Border Protection's (CBP's) data set. These data elements are the FDA Product Code, FDA country of production, FDA manufacturer/shipper, and ultimate consignee. It is the "automated" collection of these four data elements for which OMB approval is requested. FDA construes this request as an extension of the prior approval of collection of this data via a different media, i.e., paper. There are additional data elements that filers can provide to FDA along with other entry-related information that, by doing so, may result in their receiving an FDA admissibility decision more expeditiously, e.g., the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

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 CBP's Automated Commercial System (ACS) by the importer (or his agent) of the arrival of each entry. Following such notification FDA reviews relevant data to ensure the imported product meets the standards as are required for domestic products, makes an admissibility decision, and informs the importer and CBP of its decision. A single entry frequently contains multiple lines of different products. FDA may authorize specific lines to enter the U.S. unimpeded, while others in the same entry are to be held pending further FDA review/action.

An important feature developed and programmed into FDA's automated system is that all entry data passes through a screening criteria program. FDA's electronic screening criteria module makes the initial screening decision on every entry of foreign-origin FDA-regulated product. Virtually instantaneously

after the entry is filed, the filer receives FDA's admissibility decision covering each entry, i.e., "MAY PROCEED" or "FDA REVIEW."

Examples of FDA's need to further review an entry include: Products originating from a specific country or manufacturer known to have a history of problems, FDA has no previous knowledge of the foreign manufacturer and/or product, and an import alert covering the product has been issued, etc. The system assists FDA entry reviewers by notifying them of information such as the issuance of import alerts, thus averting the chance that such information will be missed.

With the inception of the interface with CBP's ACS, FDA's electronic screening criteria program is applied nationwide. This virtually eliminates problems such as "port shopping," e.g., attempts to intentionally slip products through one FDA port when refused by another, or to file 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 described previously in this document. The screening criteria can be set to be as specific or as broad as applicable; changes are virtually immediately effective. This capability is of tremendous value in protecting the public in the event there is a need to immediately halt a specific product from entering the United States.

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

Table 1.—Estimated Annual Reporting Burden[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,727	1,070	3,988,371	.263	1,048,447

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: FEB 17 2009

February 17, 2009.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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