the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: *February 11, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

FR Doc. 2011–3475 Filed 2–15–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0543]

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 March 18, 2011.

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 e-mailed 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: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezutto@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)—Revision

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 801 of the FD&C Act, as amended by the Tobacco Control Act, charges the Secretary of Health and Human Services (HHS), 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 was approved by OMB on August 10, 2009, and received an expiration date of August 31, 2012 (ICR Reference Number 200905–0910–006). However, because tobacco products had only recently been added to FDA's listing of regulated products when this collection of information was approved, the approved collection did not reflect information regarding tobacco products offered for import into and for prevention from them from entering the United States if they did not meet the same requirements of the FD&C Act as domestic products. The revision to this collection of information expands the universe of respondents being regulated under the FD&C Act, as amended, to include importers of tobacco products.

In the most recent OMB approval of this information collection package, FDA noted that in order to make an admissibility decision for each entry, the Agency needed four additional pieces of information that were not available from USCS's system. These data elements were the FDA Product Code, FDA country of production, manufacturer/shipper, and ultimate consignee. It was the "automated" collection of these four data elements for which OMB approval was being requested. When this package was sent to OMB for approval, FDA construed this request as an extension of the prior approval of collection of this data via a different media, i.e., paper. FDA noted that there were additional data elements which filers could provide to FDA along with other entry-related information. Doing so could 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 Custom'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 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 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 module, which 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 covering each entry line, i.e., "MAY PROCEED" or "FDA REVIEW."

Examples of FDA's need to further review an entry may result from some products originating from a specific country or manufacturer known to have a history of problems, FDA having no previous knowledge of the foreign manufacturer and/or product, or a product import alert may have 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 in their review.

Since the inception of the interface with ACS, FDA's electronic screening criteria program is applied nationwide. This eliminates problems such as "port shopping," e.g., 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. 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 in the event there is a need to

immediately halt a specific product from entering the United States.

In the **Federal Register** of November 4, 2010 (75 FR 67981), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA imported products	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Non-Tobacco (approved by OMB 09/01/2009)	3,406	1,089	3,709,134	.14	519,279
Tobacco (new estimated burden)	200	68	13,600	.14	1,904
Total					521,183

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

Dated: February 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–3466 Filed 2–15–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0076]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

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 information collection provisions relating to FDA's electronic records and electronic signatures.

DATES: Submit either electronic or written comments on the collection of information by April 18, 2011.

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.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

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.

Electronic Records; Electronic Signatures—21 CFR Part 11 (OMB Control Number 0910–0303)—Extension

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the Agency has stated its ability to accept the records electronically in an Agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require the following standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The Agency anticipates the use of electronic media will