burden for these additional chains is 162 hours (= 81 chains × 1 responses/chain/year × 2 hours/response).

If all of these restaurant and similar retail food establishment chains choose to register with FDA, then FDA estimates the number of firms registering in the first year would be approximately 362 firms. At two hours per registration, the total initial hourly burden will then be 724 hours (= 362 firms × 2 hours/firm).

FDA estimates that the rate of growth for chains entering the 10 to 19 outlet segment will match the rate of growth out of this segment, so that the number of registrants will remain constant. County Business Patterns data shows an average growth rate in the number of establishments to be 2 percent per year over the 8 years from 1999 to 2007 for restaurants (Ref. 3). If the restaurant growth rate for outlets of approximately 2 percent per year applies to these chains, then new registrants will amount to approximately 7 per year, with the remaining 355 registrants only renewing their registration. The yearly burden for registration is estimated to be 1 hour per new registrant. Thus, the total hour burden will be 7 hours (7 firms × 1 hour/firm). The yearly burden for renewing registration is estimated to be 0.25 hour per continuing registrant. Thus, the total hour burden will be 89 hours (355 firms × 0.25 hour/firm = 88.75, rounded to 89). This yields a recurring hourly burden of 96 hours per year (7 hours + 89 hours).

II. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

1. Food and Drug Administration, "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 68 FR 5378, February 3, 2003.

2. The NPD Group, "Chains System Size Trend Report for U.S. FDA," *ReCount,* Spring 2010.

3. U.S. Census Bureau, 2007, County Business Patterns, *http://www.census.gov/econ/cbp/index.html,* 2007, version date September 22, 2009.

4. Moran, M., J. McTaggart, and D. Chanil, "Looking Up, Cautiously," *Progressive Grocer* 89(3): 20–52, 2010.

5. Food Marketing Institute, Top U.S. Supermarket & Grocery Chains (by 2007 grocery sales), *http://www.fmi.org,* 2008.

6. Stagnito Media, "Directory of Convenience Stores: FAQ," *http://www.conveniencestores.com/faq.html,* accessed June 1, 2010.

7. Longo, D. "Convenience Store News: Hot Top 100," *Convenience Store News,* 45(10), pp. 27–32, August 10, 2009.

Dated: October 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–27854 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0543]

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 revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the revision of an approved Office of Management and Budget (OMB) collection of information for FDA's Importer's Entry Notice. This revision reflects additional burden recognized as a result of including tobacco products to the list of FDA-regulated products under the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act).

DATES: Submit either electronic or written comments on the collection of information by January 3, 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: 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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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 revision 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.

Information Request Regarding Importer's Entry Notice—(OMB Control Number 0910–0046)—Revision

On June 22, 2009, the President signed 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 the 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 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.

FDA estimates the revised reporting burden for this collection of information is 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	3,606		3,722,734	.28	521,183

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

Dated: October 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–27850 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0190]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Infant Formula Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Infant Formula Requirements" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Johnny Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, e-mail: *Juanmanuel.Vilela@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 10, 2010 (75 FR 48350), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0256. The approval expires on October 31, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: October 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–27849 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0098]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Evaluation of Potential Data Sources for the Sentinel Initiative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Evaluation of Potential Data Sources for the Sentinel Initiative" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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.capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 4, 2009 (74 FR 45858), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0657. The approval expires on February 28, 2013. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–27848 Filed 11–3–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0536]

Agency Information Collection Activities: Proposed Collection; Comment Request, Guidance for Industry on Pharmacogenomic Data Submissions; Extension

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 the information collection resulting from recommendations to sponsors submitting or holding investigational new drug applications (INDs), new drug applications (NDAs), or biologic licensing applications (BLAs) on what pharmacogenomic data should be submitted to the agency during the drug development process.

DATES: Submit either electronic or written comments on the collection of information by January 3, 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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@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