TABLE 4.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Recordkeeping	Total Annual Responses	Hours per Response	Total Hours[2]
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40	88,320
203.31(d)(4)	442	1	442	24	10,608
203.31(e)	2,208	1	2,208	1	2,208
203.34	90	1	90	40	3,600
203.37(a)	50	4	200	6	1,200
203.37(b)	50	40	2,000	6	12,000
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8	25,768
203.39(g)	3,221	1	3,221	8	25,768
203.50(a)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2.0	1,382
Total Recordkeeping Burden Hours					332,769

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Estimates are not exact due to rounding.

Dated: August 25, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21026 Filed 8–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0406]

Agency Emergency Processing Under Office of Management and Budget Review; Tobacco Product Establishment Registration and Submission of Certain Health Information

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the submission of tobacco product establishment registration and submission of certain health information, including ingredient listing and health related documents, as required by The Family Smoking Prevention and Tobacco Control Act (FSPTCA).

DATES: Fax written comments on the collection of information by September 16, 2009. FDA is requesting approval of this emergency processing by September 16, 2009.

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: 202–395–6974. All comments should be identified with the title, ''Tobacco Product Establishment Registration and Submission of Certain Health Information.'' Also include the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794, e-mail: *Jonnalynn.Capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. On June 22, 2009, the President signed FSPTCA into law (Public Law 111–31). Section 101 of FSPTCA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding, among other things, new sections 904 (21 U.S.C. 394) and 905 (21 U.S.C. 395). Section 905 requires the annual registration of any ''establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.'' Section 905 also requires this registration be completed by December 31 of each year. To allow adequate time for establishment owners and operators to complete the registration process, and to match similar provisions applicable to other FDA regulated products, FDA plans to begin accepting establishment registrations on October 1, 2009.

Section 904(a)(1) of the act requires each tobacco product manufacturer or importer, or agent thereof to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand. Section 904(a)(4) requires each tobacco

product manufacturer or importer, or agent thereof to submit all documents developed after enactment of the FSPTCA that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives. This information must be submitted by December 22, 2009 (6 months after the date of enactment of FSPTCA).

FDA plans to collect the information submission requirements of sections 905, 904(a)(1), and 904(a)(4) of the act through a single electronic portal. In order to provide respondents with adequate time to prepare information for submission, FDA plans to launch the electronic portal for the collection of this information on October 1, 2009. If FDA were to use the normal PRA clearance procedures, the availability of the electronic portal and the submission of information by respondents could not begin with adequate time to meet the respective statutory deadlines.

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.

Title: Tobacco Product Establishment Registration and Submission of Certain Health Information

Description of Respondents: Respondents to this collection of information are: (1) All persons who own or operate any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products; and (2) each tobacco product manufacturer or importer, or agents thereof.

FSPTCA amends the act by creating a new category of regulated products, tobacco products. FSPTCA creates many new requirements for the tobacco industry. Section 101 of FSPTCA amends the act by adding, among other things, new sections 904 and 905. Section 905 requires the annual registration of any ''establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.'' The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of Food and Drugs (the Commissioner) the responsibility for administering the act, including section 905.

Section 905 requires owners or operators of each establishment to register:

1. Their name,
2. Places of business,
3. A list of all tobacco products which are manufactured by that person,
4. A copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco product standard under section 907 of the act (21 U.S.C. 397) or to premarket review under section 910 of the act (21 U.S.C. 399a),
5. A copy of all consumer information and other labeling,
6. A representative sampling of advertisements,
7. Upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product, and
8. Upon request made by the Secretary, if the registrant has determined that a tobacco product contained in the product list is not subject to a tobacco product standard established under section 907, a brief statement of the basis upon which the registrant made such determination.

Section 904(a)(1) of the act requires each tobacco product manufacturer or importer, or agent thereof to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand. Section 904(a)(4) requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after enactment of the FSPTCA that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

The Secretary has delegated to the Commissioner the responsibility for administering the act, including section 904.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Tobacco Product Establishment Registration	100,000	1	100,000	0.75	75,000
Tobacco Product Ingredient Listing	100,000	1	100,000	0.75	75,000
Documents Related to Health Information	10	1	10	1	10
Total					150,010

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

Dated: August 27, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21099 Filed 8–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0050]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Importer's Entry Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Importer's Entry Notice'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792, e-mail: *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 28, 2009 (74 FR 25554), 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 0910–0046. The approval expires on August 31, 2012. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: August 26, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–21097 Filed 8–31–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0209] (formerly Docket No. 2007D–0491)

Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The document provides guidance to the dietary supplement industry for complying with the labeling requirements prescribed for dietary supplement manufacturers, packers, and distributors by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA). Separate guidance on labeling requirements for nonprescription (over-the-counter) human drugs marketed without an approved application, issued by FDA's Center for Drug Evaluation and Research, is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written requests for single copies of the guidance to the Office of Nutrition, Labeling, and Dietary Supplements (HFS–800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20750. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Vasilios Frankos, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION:

I. Background

On December 22, 2006, the President signed into law DSNDCPA (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The law also amended the act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer, or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the **Federal Register** of January 2, 2008 (73 FR 197), FDA announced the availability of a draft guidance entitled ''Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' In addition to providing guidance for industry on how to comply with the labeling requirements in section 403(y) of the act, the draft guidance stated that FDA intended to begin enforcing the requirements of section 403(y) for dietary supplements labeled on or after January 1, 2009. Although interested parties can comment on any guidance at any time, to ensure that the agency would have the opportunity to consider comments on the draft guidance before it began work on the final version, FDA requested that interested parties submit comments by March 3, 2008. On December 11, 2008 (73 FR 75438), FDA announced the availability of a revised version of the draft guidance document to notify the dietary supplement industry and other members of the public that it intended to exercise enforcement discretion with regard to the labeling requirements of section 403(y) of the act for an additional 1-year period (i.e., for dietary supplements labeled before January 1, 2010) because the agency was still in the process of reviewing the comments and finalizing the guidance. The agency has now completed its review and evaluation of the comments received and has modified the guidance where appropriate.

The guidance contains questions and answers relating to the labeling requirements in section 403(y) of the act and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the