

supplement containing a new dietary ingredient is in full compliance with the act.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	71	1	71	20	1,420

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act will require a burden of approximately 20 hours of work per submission.

This estimate is based on the annual average number of premarket notifications FDA received during the last 3 years (i.e., 2002 to 2004), which was 47. Forty-seven represents 24 more notifications than the agency received as an annual average during the previous 3-year period (i.e., 1999 to 2001). Therefore, FDA anticipates a similar upward trend will be seen in the annual average number of notifications the agency receives during 2005 to 2007, which is estimated to be 71.

Dated: January 28, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0093]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing

that a collection of information entitled "Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of July 19, 2004 (69 FR 42999), 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 0910-0045. The approval expires on December 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: January 28, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0032]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

**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 reporting and recordkeeping requirements for firms that process acidified foods and thermally processed low-acid foods in hermetically sealed containers.

**DATES:** Submit written or electronic comments on the collection of information by April 8, 2005.

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

**FOR FURTHER INFORMATION CONTACT:** Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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 functions, including whether the information will have practical utility; (2) the accuracy of FDA 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.

**Food Canning Establishment Registration, Process Filing, and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers (OMB Control Number 0910-0037)—Extension**

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is authorized to prevent the interstate distribution of food products that may be injurious to health or that are otherwise adulterated, as defined in section 402 of the act (21 U.S.C. 342). Under the authority granted to FDA by section 404 of the act (21 U.S.C. 344), FDA regulations require registration of

food processing establishments, filing of process or other data, and maintenance of processing and production records for acidified foods and thermally processed low-acid foods in hermetically sealed containers. These requirements are intended to ensure safe manufacturing, processing, and packing procedures and to permit FDA to verify that these procedures are being followed. Improperly processed low-acid foods present life-threatening hazards if contaminated with foodborne microorganisms, especially *Clostridium botulinum*. The spores of *C. botulinum* must be destroyed or inhibited to avoid production of the deadly toxin that causes botulism. This is accomplished with good manufacturing procedures, which must include the use of adequate heat processes or other means of preservation.

To protect the public health, FDA regulations require that each firm that manufactures, processes, or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce register the establishment with FDA using Form FDA 2541 (§§ 108.25(c)(1) and 108.35(c)(2) (21 CFR 108.25(c)(1) and 108.35(c)(2))). In addition to registering the plant, each firm is required to provide data on the processes used to produce these foods, using Form FDA 2541a for all methods except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid foods in hermetically sealed containers (§§ 108.25(c)(2) and 108.35(c)(2)). Plant

registration and process filing may be accomplished simultaneously. Process data must be filed prior to packing any new product, and operating processes and procedures must be posted near the processing equipment or made available to the operator (§ 113.87(a) (21 CFR 113.87(a))).

Regulations in parts 108, 113, and 114 (21 CFR part 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms are also required to document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods) and 114.80(b) (acidified foods)).

FDA estimates the burden of complying with the information collection provisions of the agency's regulations for acidified foods and thermally processed low-acid foods in hermetically sealed containers as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 2541 (Registration)	108.25 and 108.35	585	1	585	.17	99
FDA 2541a (Process Filing)	108.25 and 108.35	1,778	9	16,002	.333	5,329
FDA 2541c (Process Filing)	108.35	124	10	1,240	.75	930
Total						6,358

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Part	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
113 and 114	7,915	1	7,915	250	1,978,750

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is insignificant because notification of spoilage, process deviation or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double-counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross reference recordkeeping requirements contained in parts 113 and 114.

Dated: January 28, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N–0045]

#### 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 written or electronic comments on the collection of information by April 8, 2005.

**ADDRESSES:** Submit electronic comments on the collection of

information to: <http://www.fda.gov/dockets/ecomments>. 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:** Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**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 our 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 standard operating procedures (SOPs) to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) Section 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) section 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) section 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) section 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 SOPs, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, state or local governments, Federal agencies, and nonprofit institutions.

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