

voluntary report to be 0.6 hours for a total burden of 98 hours (163 reports x 0.6 hours = 97.8 hours).

FDA received 35,765 mandatory reports to CVM during 2007. Based on this experience, FDA estimates that CVM will receive 35,765 mandatory reports annually from 808 users of the electronic reporting system. FDA estimates the maximum reporting burden for a mandatory report to be 1 hour, for a total burden of 35,765 hours (35,765 reports x 1 hour = 35,765 hours) or a minimum burden of 24,320 hours with ((35,765 reports x 80% x 0.60 hour) + (35,765 reports x 20% x 1 hour) = 24,320.20 hours).

FDA received 5,000 voluntary reports to ORA during 2007. Based on this experience, FDA estimates that ORA will receive 5,000 voluntary reports annually from 5,000 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary report to be 0.6 hours, for a total burden of 3,000 hours (5,000 reports x 0.6 hours = 3,000 hours). ORA does not receive mandatory reports.

FDAAA, Section 1005, the Reportable Food Registry, established new electronic mandatory and voluntary reporting requirements for instances of "reportable" food, meaning an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA received 625 voluntary food complaints leading to adverse events from January 1, 2008, to June 30, 2008, and there were 206 and 182 Class 1 Recalls for human food in Fiscal Years 2006 and 2007, respectively. Based on these experiences, FDA estimates that FDA could receive 200 to 1,200 "reportable" food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. FDA will utilize the upper-bound estimate of 1,200 for these calculations. FDA estimates the reporting burden for a mandatory "reportable" food report to be 0.6 hours, for a total burden of 720 hours (1,200 reports x 0.6 hours = 720 hours). FDA estimates the reporting burden for a voluntary "reportable" food report to be 0.6 hours, for a total burden of 720 hours (1,200 reports x 0.6 hours = 720 hours).

FDAAA, Section 1002, Early Warning Recall, mandated the FDA establish a system to receive voluntary pet food complaint reports and provide an Early Warning Recall system for the public. FDA received 270 voluntary pet food reports from January 1, 2008 to June 30, 2008. FDA received 10,740 and 99 pet food complaints in FY 2007 and 2006,

respectively. Based on these experiences, FDA estimates that FDA could receive 540 voluntary pet food reports annually from 540 users of the electronic reporting system. FDA estimates the reporting burden for a voluntary "Early Warning Recall" report to be 0.6 hours, for a total burden of 324 hours (540 reports x 0.6 hours = 324 hours).

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: October 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-25211 Filed 10-22-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0544]

Agency Information Collection Activities; Proposed Collection; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

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 record retention requirement of the soy protein/coronary heart disease health claim.

DATES: Submit written or electronic comments on the collection of information by December 22, 2008.

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 (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82(c)(2)(ii)(B) (OMB Control Number 0910-0428)—Extension

Section 403(r)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)(i)) provides for the use of food label statements characterizing a

relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health related condition only where that statement meets the requirements of the regulations promulgated by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of FDA's regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease. To bear the soy protein/coronary heart disease health claim, foods must contain at least 6.25 grams of soy protein per reference amount customarily

consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. However, at the present time there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the requirement that the food contain the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate

the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient databases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Part	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
101.82(c)(2)(ii)(B)	25	1	25	1	25

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

Based upon the agency's experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/coronary heart disease health claim and that only, perhaps, one of each firm's products might contain nonsoy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is that involved in assembling and providing the records to appropriate regulatory officials for review or copying.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: October 15, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-25336 Filed 10-22-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-N-0464]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing

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 November 24, 2008.

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, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0045. 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 (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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.

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing; Availability; Registration of Producers at Drugs and Listing of Drugs in Commercial Distribution—(OMB Control Number 0910-0045—Amendment)

Description of Respondents: Respondents to this collection of information are foreign and domestic owners and operators of establishments that engage in the manufacture, preparation, propagation, compounding, or processing (which includes, among other things, repackaging and relabeling) of a drug or drugs¹ and that are not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or subpart B of 21 CFR part 207 (part 207) (registrants).

A. Reporting Burden

The draft guidance describes how to electronically create and submit Structured Product Labeling (SPL) files using defined terminology for establishment registration and drug

¹ Means both human, including biological products, and animal drugs.