NFP for a lasagna product and has revised the NFPs for the lasagna pairs. In addition, FDA changed a product category from cookies to donuts edited and the NFPs for the new donut product pair to add a disclosure of cholesterol.

(Comment 5) One comment critiqued the draft Full Information treatment language. The comment criticized the one-page summary because: (1) It did not identify calories in the discussion of fat as a major source of energy and (2) it did not relate the calorie contribution of fat to that of carbohydrates and protein. The comment also criticized the information about sources of trans fat because it omitted mention of natural sources of trans fat in the diet, which the comment suggested would help ensure factually correct and balanced information about sources of trans in the diet. The comment questioned the value of stating that trans fat extends shelflife and has desirable taste characteristics since many saturated fat sources are relatively shelf stable and have desirable taste characteristics.

(Response) FDA agrees and has revised the Full Information treatment in response to these concerns. Calories and other sources of energy are now mentioned in the introductory passage. Natural sources of trans fat are now mentioned and the similarity between trans fat and saturated fat in terms of shelflife and taste are now addressed. The revised draft will be included in the study pretest and further revisions will be made if FDA determines they are needed based upon pretest results.

(Comment 6) One comment suggested consumer confusion may be caused when a NFP for a product discloses 0g of trans fat but the ingredient list discloses an ingredient that contains trans fat, as is permitted by the trans fat labeling regulations. The comment concluded that FDA should add experimental conditions in which this occurs. The comment suggested that for this situation the study should test language for a footnote to the ingredient list to explain that there may be a trans fat ingredient in the product when the NFP shows trans fat as zero.

(Response) FDA disagrees with the proposed addition to the study's experimental conditions. Under existing trans fat labeling regulations, food manufacturers are allowed to list amounts of trans fat less than 0.5 g per serving as zero on the NFP. While such situations occur in the marketplace and are permitted by the trans fat labeling regulations, whether this causes consumer confusion is an issue outside the scope of the proposed research, which focuses on the effects of NFP footnotes and alternative presentations of trans fat information in the NFP on consumers' ability to correctly identify more healthful food products. The Office of Nutritional Products, Labeling, and Dietary Supplements has received and responded to a separate letter on this topic from the commenter.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	40	1	40	.25	10
Study	3,240	1	3,240	.25	810
Total					820

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

Dated: February 28, 2007.

Jeffrey Shuren,

Associate Commissioner for Policy.

[FR Doc. E7–3904 Filed 3–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0357]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

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 April 6, 2007.

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.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products—21 CFR Part 123 (OMB Control Number 0910–0354)—Extension

FDA regulations in part 123 (21 CFR part 123) mandate the application of hazard analysis and critical control point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (a)(4)), and became effective on December 18, 1997.

Certain provisions in part 123 require that processors and importers of seafood collect and record information. The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor's HACCP plan (e.g., the

values for processing times, temperatures, acidity, etc., as observed at critical control points). The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided. HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 123.12 requires that importers of seafood products take affirmative steps and maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. These records are also to be made available for review by FDA as provided in § 123.12(c).

The time and costs of these recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and on the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry. Costs were estimated for the collection of HACCP data for each type of recordkeeping activity using a labor cost of $15.00 per hour.

The burden estimate in table 1 of this document includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. The estimate also does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors. Consequently, the estimates in table 1 of this document account only for information collection and recording requirements attributable to part 123.

Upon reevaluation of the burden estimates for part 123, we have determined that PRA requirements do not apply to § 123.10.

In the **Federal Register** of September 26, 2006 (71 FR 56154), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section[2]	No. of Recordkeepers	Annual Frequency per Recordkeeping[3]	Total Annual Records	Hours per Record[4]	Total Hours
123.6(a), (b), and (c)	275	1	275	16.00	4,400
123.6(c)(5)	5,500	4	22,000	0.30	6,600
123.8(a)(1) and (c)	5,500	1	5,500	4.00	22,000
123.12(a)(2)(ii)	1,100	80	88,000	0.20	17,600
123.6(c)(7)	5,500	280	1,540,000	0.30	462,000
123.7(d)	2,200	4	8,800	0.10	880
123.8(d)	5,500	47	258,500	0.10	25,850
123.11(c)	5,500	280	1,540,000	0.10	154,000
123.12(c)	1,100	80	88,000	0.10	8,800
123.12(a)(2)	55	1	55	4.00	220
TOTAL					702,350

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]These estimates include the information collection requirements in the following sections:
§ 123.16—Smoked Fish—process controls (see § 123.6(b))
§ 123.28(a)—Source Controls—molluscan shellfish (see § 123.6(b))
§ 123.28(c) and (d)—Records–molluscan shellfish (see § 123.6(c)(7))
[3]Based on an estimated 280 working days per year.
[4]Estimated average time per 8-hour workday unless one-time response.

Dated: February 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3915 Filed 3–6–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0062]

Guidance on Drug Safety Information—Food and Drug Administration's Communication to the Public; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance titled ''Drug Safety Information—FDA's Communication to the Public.'' This guidance describes FDA's current approach to communicating important drug safety information, including emerging drug safety information, to the public and the factors that influence when such information is communicated. This guidance was developed in connection with FDA's Drug Safety Initiative. This guidance is the final version and supersedes the previously issued draft guidance titled ''FDA's Drug Watch for Emerging Drug Safety Information'' (70 FR 24606, May 10, 2005).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. 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 to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Paul J. Seligman, Associate Director for Safety Policy and Communication, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5570.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Drug Safety Information—FDA's Communication to the Public.'' This guidance describes FDA's current approach to communicating important drug safety information, including emerging drug safety information, to the public and the factors that influence when such information is communicated.

For many years, FDA has provided information on drug risks and benefits to healthcare professionals and patients when that information has generated a specific concern or prompted a regulatory action, such as a revision to the drug product's labeling. FDA has been reexamining its risk communication program, including how and when we communicate emerging drug safety information to the public. More recently, FDA has begun taking a more comprehensive approach to making information on potential drug risks available to the public earlier, in some cases while the agency still is evaluating whether any regulatory action is warranted. FDA believes that timely communication of important drug safety information will give healthcare professionals, patients, consumers, and other interested persons access to the most current information concerning the potential risks and benefits of a marketed drug, helping them to make more informed individual treatment choices.

FDA's risk communication efforts are part of a larger drug safety initiative that began in November 2004, when FDA announced an initiative to strengthen the safety program for marketed drugs. This initiative included the following: (1) Sponsoring an independent study by the Institute of Medicine of the National Academies of the effectiveness of the drug safety system, with emphasis on postmarketing risk assessment and surveillance; (2) conducting workshops and Advisory Committee meetings regarding complex drug safety and risk management issues, including emerging concerns; and (3) publishing three risk management guidances. FDA augmented its drug safety initiative in February 2005 by creating an independent Drug Safety Oversight Board to enhance oversight of drug safety decision making within the Center for Drug Evaluation and Research (CDER).

In May 2005, FDA issued a draft guidance titled ''FDA's Drug Watch for Emerging Drug Safety Information'' (70 FR 24606, May 10, 2005). The draft guidance described a proposal to establish a new communication channel, called the ''Drug Watch'' Web page, to provide information to the public on emerging drug safety issues. In December 2005, FDA held a public hearing regarding ''FDA's Communication of Drug Safety Information'' that examined the various risk communication tools employed by FDA. FDA has carefully reviewed the comments it received on the draft guidance (30 comments were submitted to the public docket) and during the public hearing. This final version of the guidance reflects our consideration of these comments, as well as our experience with posting emerging drug safety information.

Due to potential confusion between the proposed ''Drug Watch'' and FDA's existing ''MedWatch'' program, FDA no longer plans to use the name ''Drug Watch'' to describe the Web page that contains drug safety information. We have identified drugs that have been the subject of a Public Health Advisory or an Alert on a single Web page, the Index to Drug-Specific Information, linked from FDA's Web site. This is part of our ongoing effort to use and enhance existing FDA communications mechanisms to better convey important drug safety information to the public. In addition, we have revised this guidance to describe the various methods FDA currently uses to communicate established and emerging drug safety information to the public. It should be noted that we will continue to evaluate and enhance the effectiveness of the various methods we use to communicate about important drug safety issues, including the mechanisms described in this guidance and the presentation of drug safety information on the Agency Web sites (*http://www.fda.gov* and *http://www.fda.gov/cder*). We intend to update this guidance, as appropriate, to reflect any substantial modifications to our communication of drug safety information to the public.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic