seafood HACCP regulations that are not already required under other statutes and regulations. For example, the current food manufacturing practices provisions in 21 CFR part 110 already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures. Furthermore, the estimate 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 account only for new information collection and recording requirements attributable to part 123.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping[2]	Total Annual Records	Hours per Recordkeeper[3]	Total Hours	Total Operating and Maintenance Costs (in dollars)
123.6(a), (b), and (c)	243	1	243	16.00	3,888	58,320
123.6(c)(5)	4,850	4	19,400	0.30	5,820	87,300
123.8(a)(1) and (c)	4,850	1	4,850	4.00	19,400	291,000
123.12(a)(2)(ii)	1,000	80	80,000	0.20	16,000	240,000
123.6(c)(7)	4,850	280	1,358,000	0.30	407,400	6,111,000
123.7(d)	1,940	4	7,760	0.10	1,940	29,100
123.8(d)	4,850	47	227,950	0.10	22,795	341,925
123.11(c)	4,850	280	1,358,000	0.10	135,800	2,037,000
123.12(c)	1,000	80	80,000	0.10	8,000	120,000
123.12(a)(2)	50	1	50	4.00	200	3,000
123.10	243	1	24	24.00	5,832	87,480
Annual burden hours 627,075						9,406,125

[1] 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))
[2] Based on an estimated 280 working days per year.
[3] Estimated average time per 8 hour work day unless one time response.

Dated: July 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19032 Filed 7–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0106]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; and Electronic Submission Using FDA Forms 3503 and 3504

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: Submit written comments on the collection of information by August 27, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974. 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation; Electronic Submission Using FDA Forms 3503 and 3504 (OMB Control Number 0910–0016)—Extension

This notice solicits comments on a proposed collection of the following four existing submissions of petitions: (1) Food additive and food additive petitions (FAPs) (OMB control number 0910–0016), (2) affirmation of generally

recognized as safe (GRAS) status (OMB control number 0910–0132), (3) labeling requirements for color additives (other than hair dyes) and petitions (CAPs) (OMB control number 0910–0185), and (4) electronic submission of food and color additive petitions (OMB control number 0910–0480).

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the act that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the act is effective. FAPs are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 175 through 178, and 180 (21 CFR parts 172, 173, 175 through 178, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. CAPs are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 (21 CFR part 71.1) specifies the information that a petitioner must submit in order to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR part 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

Under authority of sections 201, 402, 409, and 701 of the act (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS that are submitted on a voluntary basis by the food industry and other interested parties. Specifically under section 201(s) of the act, a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The act has historically been interpreted to permit food manufacturers to make their own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under 21 CFR 170.35(c)(1).

In the **Federal Register** of July 31, 2001 (66 FR 39517), FDA announced the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions to Office of Food Additive Safety in Electronic Format for Food Additive and Color Additive Petitions.'' This guidance describes the procedures for electronic submission of FAPs and CAPs using FDA Form No. 3503, entitled ''Food Additive Petition Submission Application,'' and FDA Form No. 3504, entitled ''Color Additive Petition Submission Application.''

FDA scientific personnel review food and color additive and GRAS affirmation petitions to ensure the safety of the intended use of the substance in or on food, or of a food additive that may be present in food as a result of its use in articles that contact food (or for color additives, its use in food, drugs, cosmetics, or medical devices). Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

In the **Federal Register** of April 4, 2003 (68 FR 16517) FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating and Maintenance Costs	Total Hours
CAPS						
70.25	0	1	0	0	0	0
71.1	2	1	2	1,652	$5,600	3,304
FDA Form 3504	1	1	1	1	0	1
GRAS Affirmation Petitions						
170.35	1	1	1	2,598		2,598
FAPs						
171.1	7	1	7	3,640		25,480
FDA Form 3503	2	1	2	1		2
Total					$5,600	31,385

[1] There are no capital costs associated with this collection of information.

The estimate of burden for FAPs and CAPs is based on the average number of new FAPs and CAPs received in calendar years 2000 through 2002 and the total hours expended in preparing the petitions. Although the burden varies with the type of petition submitted, an average FAP or CAP, or GRAS affirmation petition, involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Electronic submissions of petitions contain the same petition information required for paper submission. The agency estimates that up to 30 percent of the petitioners for both food and color additives will take advantage of the electronic submission process. By using the guidelines and forms that FDA is providing, the petitioner will be able to organize the petition to focus on the information needed for FDA's safety review. Therefore, we estimate that petitioners will only need to spend approximately 1 hour completing the electronic submission application form (Form 3503 or 3504, as appropriate) because they will have already used the guidelines to organize the petition information needed for the submission.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for §§ 70.25 and 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 175 through 178, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: July 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19075 Filed 7–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0034]

Agency Information Collection Activities; Announcement of OMB Approval; FDA Safety Alert/Public Health Advisory Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''FDA Safety Alert/Public Health Advisory Readership Survey'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of May 13, 2003 (68 FR 25616), 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 0910–0341. The approval expires on July 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: July 21, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19076 Filed 7–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0312]

Discussion of Animal Feed Safety System: A Comprehensive Risk-Based Safety Program for the Manufacture and Distribution of Animal Feeds; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting to discuss the potential development of a comprehensive, risk-based animal feed safety system (AFSS) describing how animal feeds (individual ingredients and mixed feeds) should be manufactured and distributed to minimize risks to animals consuming the feed and people consuming food products from animals. We are informing you (consumers, animal feed processors, animal producers, State and local officials, and other interested persons) of this meeting in an effort to solicit comments and seek your assistance in our consideration of a safety program to effectively minimize the hazards to public health, both human and animal health, posed by animal feed products.

Date and Time: The public meeting will be held on Tuesday, September 23, 2003, from 1 p.m. to 5 p.m., and Wednesday, September 24, 2003, from 8 a.m. to 3 p.m. You may submit written or electronic comments at any time, but they would be most helpful if received either before or within 30 days after the close of the meeting.

Location: The meeting will be held at the Hyatt Dulles International Airport, 2300 Dulles Corner Blvd., Herndon, VA, 1–800–233–1234 or 703–713–1234.

Comments and Electronic Access: Interested persons may submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with docket number found in brackets in the heading of this document. A copy of the received comments will be available for public examination in the Dockets Management Division between 9 a.m.