

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<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping <sup>2</sup>	Total Annual Records	Hours per Recordkeeper <sup>3</sup>	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

<sup>1</sup> 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))

<sup>2</sup> Based on an estimated 280 working days per year.

<sup>3</sup> Estimated average time per 8 hour work day unless one time response.

Dated: July 21, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## 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