Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 2001 (66 FR 1142), 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 0910–0370. The approval expires on July 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov.ohrms/dockets.

Dated: July 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17975 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1503]

Agency Information Collection Activities; Announcement of OMB Approval; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled Orphan Drugs has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 1, 2001 (66 FR 21769), 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 0910–0167. The approval expires on July 31, 2004. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: July 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17978 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0178]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Premarket Notification 510(k) Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below 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 17, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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.

Premarket Notification 510(k) Submissions (21 CFR Part 807) (OMB Control No. 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) requires a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. The definition of ''person'' has been expanded to include hospitals who reuse or remanufacture single-use medical devices. The estimated submissions below include those submitted by hospitals remanufacturing single-use medical devices.

Section 510(k) of the act allows for exemptions to the 510(k) submissions (i.e., a premarket notification submission would not be required if FDA determines that premarket notification is not necessary for the protection of the public health, and they are specifically exempted through the regulatory process). Under 21 CFR 807.85, ''Exemption from premarket notification,'' a device is exempt from premarket notification if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling and advertising by the manufacturer, importer, or distributor for commercial distribution. In addition, the device must meet one of the following conditions: (1) It is intended for use by a patient or dentist (or other specially qualified persons), or (2) it is intended solely for use by a physician or dentist and is not generally available to other physicians or dentists.

A commercial distributor who places a device into commercial distribution for the first time under their own name and a repackager who places their own name on a device, and does not change any other labeling or otherwise affect the device, shall be exempted from premarket notification if the device was legally in commercial distribution before May 28, 1976, or a premarket notification was submitted by another person.

The information collected in a premarket notification is used by the medical, scientific, and engineering staffs of FDA in making determinations as to whether or not devices can be allowed to enter the U.S. market. The premarket notification review process allows for scientific and/or medical review of devices, subject to section 510(k) of the act, to confirm that the new devices are as safe and as effective as legally marketed predicate devices. This review process, therefore, prevents potentially unsafe and/or ineffective devices, including those with fraudulent claims, from entering the U.S. market. This information will allow FDA to collect data to ensure that the use of the device will not present an unreasonable risk for the subject's rights. The respondents to this information collection will primarily be medical device manufacturers and businesses.

FDA form 3514 was developed to assist respondents in organizing 510(k) data for submission to FDA. This form also assists respondents in organizing and submitting data for other FDA medical device programs such as premarket approval applications, investigational device exemptions, and humanitarian device exemptions.

In the **Federal Register** of April 30, 2001 (66 FR 21398), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Form No.	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
807.81 and 807.87 (part 807, subpart E)		4,000	1	4,000	80	320,000
	FDA 3514	2,000	1	2,000	.5	1,000
Total						321,000

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	No. of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours
807.93	2,000	10	20,000	0.5	10,000
Total					10,000

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2 of this document. The total burden for using voluntary FDA form 3514 is estimated to be approximately 1,000 hours and has been included in this information collection. Once this information collection has been approved, the burden for FDA form 3514 will be reported and approved in each of the following OMB information collections: 0910–0078, investigational device exemption reports and records; 0910–0231, premarket approval of medical devices; and 0910–0332, medical devices, humanitarian devices.

Dated: July 12, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–17977 Filed 7–17–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0359]

Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments concerning the establishment of program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for fiscal year (FY) 2002. As part of its annual planning, budgeting, and resource allocation process, CFSAN is reviewing its programs to set priorities and establish work product expectations. This notice is being published to give the public an opportunity to provide input into the priority-setting process.

DATES: Submit written or electronic comments by September 17, 2001.

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

FOR FURTHER INFORMATION CONTACT: Donald J. Carrington, Center for Food Safety and Applied Nutrition (HFS–666), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–260–5290, e-mail: DCarring@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On January 9, 2001, CFSAN released a document entitled ''2001 CFSAN Program Priorities.'' The document, a copy of which is available on CFSAN's Web page (www.cfsan.fda.gov), constitutes the Center's priority workplan for FY 2001, i.e., October 1, 2000, through September 30, 2001. (Copies are also available from the contact person listed above.) The 2001 workplan is based on input we received from our stakeholders (see 65 FR 39415, June 26, 2000), as well as input generated internally. Throughout the priority-setting process, we focused on one central question: ''Where do we do the most good for consumers?''

The paramount theme for the FY 2001 workplan has been program continuity. We continue to place our highest emphasis on the food safety initiative, food additives, dietary supplements,