Dated: August 12, 2002.

Sandra R. Manning,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 02–20947 Filed 8–16–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects

Title: National Survey of Child and Adolescent Well-Being.

OMB No.: 0970–0202.

Description: This longitudinal survey provides national estimates on the characteristics related to children and fami8lies who enter the child welfare system. It has collected data from a cohort of 6,100 children who entered the child welfare system as a result of a CPS investigation between October 1999 and April 2001. Data were collected from the children themselves, their caregivers, their teachers, and their caseworkers at baseline, with follow-ups at 12 and 18 months post-baseline. The current request is to pursue a 36-month follow-up, essentially replicating the measure that were used at baseline and at the 18-month follow-up.

Respondents: Children who are clients of the child welfare system, their primary caregivers, caseworkers, and teachers.

Annual Burden Estimates:

Instrument	Responses	Number of responses per respondent	Average burden hours per respondent	Total burden hours
Child interview	5,491	1	1.63	8,950
Caregiver interview	5,491	1	1.50	8,237
Caseworker Interview	2,366	1	0.80	1,893
Caseworker Interview	2,491	1	0.75	1,868

Estimated Total Annual Burden Hours: 20,948.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 650 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Act, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: August 13, 2002.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 02–20936 Filed 8–16–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0355]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical device recall authority.

DATES: Submit written or electronic comments on the collection of information by October 18, 2002.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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: (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.

Medical Device Recall Authority—21 CFR Part 810 (OMB Control Number 0910–0432—Extension)

This collection implements medical device recall authority provisions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) and part 810 (21 CFR part 810). Section 518(e) of the act gives FDA the authority to issue an order requiring the appropriate person, including manufacturers, importers, distributors, and retailers of a device to immediately cease distribution of such device, to immediately notify health professionals and device-user facilities of the order, and to instruct such professionals and facilities to cease use of such device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death.

Section 518(e) of the act sets out a three-step procedure for issuance of a mandatory device recall order. First, if there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately: (a) Cease distribution of the device, (b) notify health professionals and device user facilities of the order, and (c) instruct those professionals and facilities to cease use of the device. Second, FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device. Third, after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the agency determines that such an order is necessary.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market.

The respondents to this proposed collection of information are manufacturers, importers, distributors, and retailers of medical devices.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a) through (b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a) through (d)	2	1	2	16	32
810.15(e)	10	1	10	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Totals					1,082

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

Explanation of Report Burden Estimate:

The following estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntary.

21 CFR 810.10(d)—FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section. The total annual burden is 16 hours.

21 CFR 810.11(a)—Based on its experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately one staff day (8 hours) to prepare this request.

21 CFR 810.12(a) through (b)—Based on its experience in similar situations, FDA expects that there will be only one written request for a review of cease distribution and notification order per year and that it will take approximately one staff day (8 hours) to prepare this request.

21 CFR 810.14——Based on its experience with voluntary recalls, FDA estimates that it will take approximately two staff days (16 hours) to develop a strategy for complying with this order.

21 CFR 810.15 (a) through (d)—Based on its experience with voluntary recalls, FDA estimates that it will take approximately 2 staff days (16 hours) to notify each health professional, user facility, or individual of the order.

21 CFR 810.15 (e)—Based on its experience with voluntary recalls, FDA estimates that there will be approximately five consignees per recall (10 per year) who will be required to notify their consignees of the order. FDA estimates it will take them about 1 hour to do so.

21 CFR 810.16—FDA estimates that it would take no more than one staff week (40 hours) to assemble and prepare a written status report required by a recall (§ 810.16). The status reports are prepared by manufacturers 6 to 12 times each year. Therefore, each manufacturer would spend no more than 480 hours each year preparing status reports (40 x

12). If there were two FDA invoked recalls each year, the total burden hours would be estimated at 960 hours each year (480 x 2).

21 CFR 810.17—Based on its experience with similar procedures, FDA estimates it would take one staff day (8 hours) to draft a written request for termination of a cease distribution and notification or mandatory recall order.

Dated: August 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–20916 Filed 8–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0052]

Agency Information Collection Activities; Announcement of OMB Approval; Temporary Marketing Permit Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

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 the **Federal Register** of May 30, 2002 (67 37835), 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 0910–0133. The approval expires on July 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–20914 Filed 8–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0054]

Agency Information Collection Activities; Announcement of OMB Approval; Labeling Requirements for Color Additives (Other Than Hair Dyes) and Petitions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Labeling Requirements for Color Additives (Other Than Hair Dyes) and Petitions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of June 14, 2002 (67 40947), 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 0910–0185. The approval expires on July 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: August 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–20918 Filed 8–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0354]

Agency Emergency Processing under OMB Review; The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the evaluation of approximately 1,200 people involved in the decontamination/cleanup (''remediation'') of various facilities contaminated with anthrax spores during a terrorist event in the fall of 2001. The 1,200 decontamination workers have been on continuous prophylactic antibiotics for greater than 60 days and FDA wants to evaluate these workers for adverse events that may have occurred in light of this prolonged drug exposure.

DATES: Submit written comments on the collection of information by September 3, 2002.

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: Stuart Shapiro, Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

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: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). The information is critical to the agency's mission in protecting the public health and is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations (5 CFR part 1320). As a result of recent terrorist events, a number of individuals