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]

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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

were potentially exposed to anthrax at various facilities. The Federal Government contracted to have the subject facilities decontaminated of residual anthrax spores. This cleanup work has been ongoing, at the affected sites, since late 2001. The workers employed in the decontamination effort were placed on long-term prophylactic antibiotics. Although FDA is interested in collecting data regarding adverse events on all 1,200 decontamination workers; there are approximately 400 decontamination workers at the Brentwood Post Office facility in Washington, DC, who continue to receive antibiotics. These 400 workers are scheduled for a final medical examination 10 days after the final antibiotic is taken. FDA needs to have OMB authorization in place in time to administer the survey to these workers when they present for their final medical examination. It is estimated that most of the cleanup work will be completed by the end of September 2002. FDA will also be administering the same survey to the remaining 800 decontamination workers who were not offered final medical examinations. Many of these workers have already left the decontamination site. FDA is requesting that emergency OMB approval to administer the survey be granted because the longer the timespan between a worker's having stopped taking an antibiotic and the time the questionnaire is administered, the less reliable the answers provided become and the more difficult it is to locate a former worker.

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.

The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities

Due to a terrorist event during the fall of 2001, approximately 1,200 decontamination workers were placed on long-term antibiotic therapy to protect them from environmental anthrax spores. Through the services of a contractor FDA plans to administer a survey to all 1,200 decontamination workers. For those decontamination workers that are still on site at the Brentwood Postal Facility, the contractor shall work with the medical service subcontractor to establish a toll free 800 telephone number that a worker can call as part of their post-antibiotic followup visit. The Government estimates that approximately 400 decontamination workers will place calls to an 800 number. The contractor shall have a qualified interviewer available to administer the assessment tool to these individuals during the telephone calls. Whereas approximately 20 percent of the decontamination workers are Spanish speaking, the contractor shall be able to conduct interviews in both English and Spanish. For those decontamination workers that have left the Brentwood Postal Facility, and for all other sites (about 800 total), the contractor shall administer the same survey via the telephone, but the contractor shall initiate these calls. If the contractor is not able to contact the decontamination worker on the initial telephone call or the worker is nonresponsive, the contractor shall attempt to followup with these workers up to three additional times.

Failure of FDA to adequately followup on these workers will reduce the agency's ability to apply lessons learned from the current situation to provide guidance during future public health emergencies should they occur. This could result, not only, in the loss of time and dollars but also in the loss of human life if patients stop taking their medicines because they think the drug therapy is responsible for a health problem when in fact it is not. Because the stress of exposure from a terrorist act can in itself cause many symptoms that are similar to adverse events that might be caused by various therapies, it is extremely important that FDA obtain information on individuals who took these antibiotics but were not subjected to the anxiety and stress associated with a terrorist event. This type of population is likely to never be available for assessment again until a future terrorist event occurs. It would be unacceptable for FDA not to obtain drug experience information from this group to assist in any future public health response to a terrorist attack.

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

TABLE 1.— ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Telephone	1,200	1	1,200	.25	300
Total					300

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

The estimated annual reporting burden is based on CDC's administration, in 2001 and 2002, of a similar questionnaire to individuals who were exposed to anthrax spores dispersed during a terrorist event.

Dated: June 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–20915 Filed 8–16–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0116]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the 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 (the PRA).

DATES: Submit written comments on the collection of information by September 18, 2002.