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.

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.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910–0363)—Extension

The veterinary feed directive (VFD) drugs section of the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) established a new class of restricted feed use drugs that may be distributed without invoking State pharmacy laws. In order to implement the VFD drugs section of the ADAA, FDA issued regulations (65 FR 76924, December 8, 2000) that impose reporting and recordkeeping requirements on veterinarians, distributors of animal feeds containing VFD drugs, and clients using medicated feeds containing VFD drugs. All distributors of animal feed containing VFD drugs must notify FDA of their intent to distribute animal feed containing a VFD drug, and must maintain records of the distribution of all animal feeds containing VFD drugs (21 CFR 558.6).

In the **Federal Register** of April 30, 2002 (67 FR 21252), the agency requested comments on the proposed collection of information. FDA received one comment.

The comment asked if the proposed collection of information was necessary for the proper performance of FDA functions and whether the information will have practical utility. The answer is yes. As detailed, the VFD regulation ensures protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

Respondents to this collection of information are veterinarians, distributors of animal feeds containing VFD drugs, and clients using medicated feeds containing VFD drugs.

FDA estimates the burden for this collection of information 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
558.6(a)(3) through (a)(5)	15,000	25	375,000	0.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	1,500	1	500	0.25	125
558.6(d)(1)(iv)	20	1	20	0.25	5
558.6(d)(2)	1,000	5	5,000	0.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total					95,133

[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 per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(3)	5,000	75	375,000	.0167	6,263
Total					25,051

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

These estimates are based on agency communication with industry. Other information needed to calculate the total burden hours are derived from agency records and experience.

Dated: August 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–20917 Filed 8–16–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program; Notice of a Meeting of the NTP Board of Scientific Counselors

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors on September 17–18, 2002, at the Radisson Governors Inn, 1–40 at Davis Drive, Exit 280, Research Triangle Park, North Carolina.

The NTP Board of Scientific Counselors (the Board) is composed of scientists from the public and private sector and provides primary scientific oversight to the NTP.

Agenda

The meeting being held on September 17–18, 2002, is open to the public from 8:30 a.m. to adjournment each day with attendance limited only by the space available. Persons needing special assistance should contact the NTP Executive Secretary (contact information below). A draft agenda with tentative schedule is provided below. Primary agenda topics include: (1) A draft format for the NTP brief that will be part of the NTP–CERHR Monograph prepared on each chemical reviewed by the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR); (2) a discussion of the proposed NTP