RECORD ACCESS PROCEDURES:

Requests from individuals for access to their records should be addressed to the system manager.

CONTESTING RECORD PROCEDURES:

GSA rules for access to systems of records, contesting the contents of systems of records, and appealing initial determinations are published in the **Federal Register**, 41 CFR part 105–64.

RECORD SOURCE CATEGORIES:

Information is provided by individuals who wish to participate in the GSA personal property sales program, and system transactions designed to gather and maintain data and to manage and evaluate the Federal personal property disposal program.

Dated: October 18, 2000.

Daniel K. Cooper,

Director, Information Management Division.

[FR Doc. 00–27909 Filed 10–30–00; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Office of the Secretary will periodically publish summaries of proposed information collections projects and solicit public comments in compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690–6207.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects 1. Annual Report for OPA Title X Family Planning Program Grantees—0990–0221—Revision—The Office of Population Affairs (OPA) collects annual data from Title X grantees to assure compliance with legislative and regulatory requirements and identify areas where grantees may require assistance. *Respondents:* Title X Family Planning Program Grantees; *Annual Number of Respondents:* 85; *Average Burden per Response:* 22 hours; *Total Burden:* 1,870 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: October 19, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 00–27834 Filed 10–30–00; 8:45 am]

BILLING CODE 4150–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Citizens Advisory Committee on Public Health Service (PHS) Activities and Research at Department of Energy (DOE) Sites: Oak Ridge Reservation Health Effects Subcommittee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

Name: Citizens Advisory Committee on PHS Activities and Research at DOE Sites: Oak Ridge Reservation Health Effects Subcommittee (ORRHES).

Times and Dates:

8 a.m.–5 p.m., November 16, 2000

8 a.m.–5 p.m., November 17, 2000

Place: YWCA, 1660 Oak Ridge Turnpike, Oak Ridge, Tennessee, 37830. Telephone 865/482–9922.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 150 people.

Background: Under a Memorandum of Understanding (MOU) signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles. In addition, under an MOU signed in December 1990 with DOE and replaced by an MOU signed in 1996, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS has delegated program responsibility to CDC.

Purpose: This subcommittee is charged with providing advice and recommendations to the Director, CDC, and the Administrator, ATSDR, pertaining to CDC's and ATSDR's public health activities and research at this DOE site. Activities shall focus on providing the public with a vehicle to express concerns and provide advice and recommendations to CDC and ATSDR. The purpose of this meeting is to receive updates from ATSDR and CDC, and to address other issues and topics, as necessary.

Matters to be Discussed: Agenda items include a presentation and discussion on the purpose, function, and structure of the Subcommittee, discussion on defining operational guidelines, and agency updates. Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Loretta Bush, Executive Secretary ORRHES, or Marilyn Palmer, Committee Management Specialist, Division of Health Assessment and Consultation, ATSDR, 1600 Clifton Road, NE, M/S E–56, Atlanta, Georgia 30333, telephone 1–888–42–ATSDR(28737), fax 404/639–6075.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: October 25, 2000.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 00–27871 Filed 10–30–00; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1571]

Enrofloxacin for Poultry; Opportunity For Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is proposing to withdraw approval of the new animal drug application (NADA) for use of the fluoroquinolone enrofloxacin in poultry. This action is based on CVM's determinations that the use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant *Campylobacter*, a human pathogen, in poultry; this resistant *Campylobacter* is transferred to humans and is a significant cause of the development of resistant *Campylobacter* infections in humans; and resistant *Campylobacter* infections are a human health hazard. Therefore, CVM is proposing to withdraw the approval of the new animal drug application for use of enrofloxacin in poultry on the grounds that new evidence shows that the product has not been shown to be safe as provided for in the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written appearances and a request for a hearing by November 30, 2000. Submit all data and analysis upon which a request for a hearing relies by January 2, 2001.

ADDRESSES: Written appearances, requests for a hearing, data and analysis, and other comments are to be identified with Docket No. 00N–1571 and must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Linda R. Tollefson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6647.

SUPPLEMENTARY INFORMATION:

I. Fluoroquinolones Approved for Poultry Use

The following are approved uses for fluoroquinolones in poultry:

A. Sarafloxacin Hydrochloride

NADA 141–017, SaraFlox® WSP, approved August 18, 1995, for the control of mortality in growing turkeys and broiler chickens associated with *Escherichia coli* organisms, Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064.

NADA 141–018, SaraFlox® Injection, approved October 12, 1995, for the control of early chick mortality associated with *E. coli* organisms in chickens and turkeys, Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064.

B. Enrofloxacin

NADA 140–828, Baytril® 3.23% Concentrate Antimicrobial Solution, approved October 4, 1996, for the control of mortality in chickens associated with *E. coli* organisms and control of mortality in turkeys associated with *E. coli* and *Pasteurella multocida* organisms, Bayer Corp., Agriculture Division, Animal Health, Shawnee Mission, KS 66201.

Abbott Laboratories has requested withdrawal of NADA's 141–017 and 141–018 for use of sarafloxacin hydrochloride in poultry. By doing so, the company has waived its right to a hearing. Therefore, only NADA 140–828 is covered by this notice.

II. Summary of the Bases for Withdrawing the Approval

CVM is providing notice of an opportunity for a hearing on a proposal to withdraw approval of the NADA for enrofloxacin for use in poultry and to revoke the new animal drug regulations reflecting the approval of the NADA (21 CFR 520.813). Enrofloxacin belongs to the class of antimicrobial drugs called fluoroquinolones. Fluoroquinolones also are approved for use in humans. Fluoroquinolones are considered to be one of the most valuable antimicrobial drug classes available to treat human infections because of their spectrum of activity, pharmacodynamics, safety and ease of administration. This class of drugs is effective against a wide range of human diseases and is used both in treatment and prophylaxis of bacterial infections in the community and in hospitals. Fluoroquinolones are essential to the treatment of foodborne diseases. These diseases have a major public health impact in the United States.

Enrofloxacin oral solution for each of its uses in poultry is a new animal drug as defined in section 201(v) of the act (21 U.S.C. 321(v)). As such, the drug cannot be legally marketed in interstate commerce in the absence of an approved NADA (sections 301, 501, and 512 of the act (21 U.S.C. 331, 351, and 360b)). The requirements for approval of NADA's are set out in section 512 of the act. Section 512 of the act requires that a new animal drug must be shown to be safe and effective for its intended uses. Section 201(u) of the act provides that ''safe'' as used in section 512 ''has reference to the health of man or animal.'' The determination of safety requires CVM to consider, among other relevant factors, ''the probable consumption of such drug and of any substance formed in or on food because of the use of such drug'' (section 512(d)(2)(A)). Accordingly, CVM must consider not only safety of the new animal drug to the target animal but also safety to humans of substances formed in or on food as a result of the use of the new animal drug.

FDA approved the NADA's for fluoroquinolones for use in poultry in 1995 and 1996 (see section V.A.3 of this document). After the approvals, CVM instituted several strategies intended to prevent or mitigate the development of resistance (see section V.A.4 of this document). However, resistance still quickly developed to the fluoroquinolones among the human foodborne pathogen, *Campylobacter* (see section V.B of this document). The resistance developed from use of fluoroquinolones in poultry under the approved, labeled conditions of use (see section V.B.1 of this document).

By 1998, Centers for Disease Control and Prevention (CDC) testing found that 13.6 percent of *Campylobacter* human isolates were resistant to fluoroquinolones. Fluoroquinolone resistance rose to 17.6 percent among *Campylobacter jejuni* and 30 percent among *Campylobacter coli* isolated from ill humans in 1999. In 1998, testing established that approximately 9.4 percent of the *C. jejuni* isolated from chicken carcasses at federally inspected slaughter plants in the United States were fluoroquinolone resistant. Higher levels of fluoroquinolone resistance are observed in retail chicken (see section V.B of this document).

After thoroughly analyzing all the data and evidence, CVM has determined the following: The primary cause of the emergence of domestically-acquired fluoroquinolone-resistant *Campylobacter* infections in humans is the consumption of or contact with contaminated food (see section IV.B of this document). Moreover, poultry is the most likely source of campylobacteriosis