DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Clinical Laboratory Improvement Advisory Committee: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Clinical Laboratory Improvement Advisory Committee, of the Centers for Disease Control and Prevention (CDC), of the Department of Health and Human Services, has been renewed for a 2-year period extending through February 19, 2004.

FOR FURTHER INFORMATION CONTACT: Edward L. Baker, M.D., Executive Secretary, Clinical Laboratory Improvement Advisory Committee, CDC, 4770 Buford Hwy, NE, m/s K–36, Atlanta, Georgia 30333. Telephone 770/488–2402, fax 770/488–2420, e-mail *elb1@cdc.gov*.

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: February 13, 2002.

Alvin Hall,

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

[FR Doc. 02–4024 Filed 2–19–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors Meeting, National Institute for Occupational Safety and Health: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH).

Time and Date: 9 a.m.—3 p.m., March 7, 2002.

Place: Washington Court Hotel on Capitol Hill, 525 New Jersey Avenue, NW., Washington, DC 20001, telephone 202/628–2100, fax 202/879–7938.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

Purpose: The Secretary, the Assistant Secretary for Health, and by delegation the Director, Centers for Disease Control and Prevention, are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health. The Board of Scientific Counselors shall provide guidance to the Director, National Institute for Occupational Safety and Health, on research and preventions programs. Specifically, the Board shall provide guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings and disseminating results. The Board shall evaluate the degree to which the activities of the National Institute for Occupational Safety and Health: (1) Conform to appropriate scientific standards, (2) address current, relevant needs, and (3) produce intended results.

Matters to be Discussed: Agenda items include a report from the Acting Director of NIOSH; Update on NIOSH/NCI Diesel Exposure Study; Final Report from the BSC Beryllium Subcommittee; Workplace Violence Prevention Research and Planning; Update on the National Personal Protective Technologies Laboratory.

Agenda items are subject to change as priorities dictate.

FOR MORE INFORMATION CONTACT: Roger Rosa, Executive Secretary, BSC, NIOSH, CDC, 200 Independence Avenue, SW., Room 715H, Washington, DC 20201, telephone: 202/205–7856, fax: 202/260–4464.

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: February 13, 2002.

Alvin Hall,

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

[FR Doc. 02–4023 Filed 2–19–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Public Meeting Between CDC and the Cruise Ship Industry, Private Sanitation Consultants and Other Interested Parties

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Current Status of the Vessel Sanitation Program (VSP) and Experience to Date with Program Operations—Public meeting between CDC and the cruise ship industry, private sanitation consultants, and other interested parties.

Time and Date: 9 a.m.–1 p.m., April 17, 2002.

Place: Auditorium, Port Everglades Administration Building, 1850 Eller Drive, Fort Lauderdale, Florida 33316. Telephone (954)356–6650; Fax (954)356–6671.

Status: Open to the public, limited by the space available. The meeting room accommodates approximately 100 people.

Purpose: During the past 15 years, as part of the revised VSP, CDC has conducted a series of public meetings with members of the cruise ship industry, private sanitation consultants, and other interested parties.

This meeting is a continuation of that series of public meetings to discuss current status of the VSP and experience to date with program operations.

Matters to be Discussed: Agenda items will include VSP Program Update; 2001 Program Review; Update on the implementation of the VSP Program Operations Manual 2000; Update on Disease Surveillance and Outbreak Investigations; and VSP Training Seminars.

For a period of 15 days following the meeting, through May 2, 2002, the official record of the meeting will remain open so that additional materials or comments may be submitted to be made part of the record of the meeting. Advanced registration for the meeting is encouraged. Please provide the following information: Name, title, company name, mailing address, telephone number, facsimile number and e-mail address to Dorothy Johnson, facsimile (770)488–4127 or e-mail: *DJJohnson@cdc.gov*.

FOR MORE INFORMATION CONTACT: Dave Forney, Chief, VSP, NCEH, CDC, 4770 Buford Highway, NE, M/S F–16, Atlanta, Georgia 30341–3724, telephone (770)488–7333, e-mail: *DForney@cdc.gov*.

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: February 13, 2002.

Alvin Hall,

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

[FR Doc. 02–4022 Filed 2–19–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1571]

Enrofloxacin for Poultry; Notice of Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a hearing on a proposal to withdraw approval of a new animal drug application (NADA). In the **Federal Register** of October 31, 2000 (65 FR 64954), the Director of FDA's Center for Veterinary Medicine (CVM) issued a notice of opportunity for a hearing (NOOH) proposing to withdraw approval of NADA 140–828 for enrofloxacin (Baytril 3.23% Concentrate Antimicrobial Solution). Bayer Corp., the sponsor of the new animal drug, responded by filing a request for a hearing on November 29, 2000.

This notice of hearing (NOH) provides factual and legal information concerning CVM's proposal to withdraw the NADA and identifies the factual issues that will be the subject of the evidentiary hearing.

DATES: A prehearing conference will be held on April 8, 2002, beginning at 10 a.m. Any person wishing to participate in this hearing shall submit a written notice of participation by March 22, 2002. Disclosure of data and information as required by part 12 (21 CFR part 12) must be made by April 22, 2002.

ADDRESSES: The prehearing conference will be held in conference room. F, 5600 Fishers Lane, Rockville, MD 20857. You must submit written notices of participation and disclosure of data and information to Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All submissions must reference docket number 00N–1571.

FOR FURTHER INFORMATION CONTACT: Robin Thomas Johnson, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION:

I. Background

Enrofloxacin belongs to the class of antimicrobial drugs called fluoroquinolones. Fluoroquinolones are used in humans and animals for therapeutic purposes. Bayer Corp., P.O. Box 390, Shawnee Mission, KS 66201–0390, sponsor of NADA 140–828 for enrofloxacin (also known under Bayer's product name ''Baytril'') was approved for use in poultry on October 4, 1996, and published on November 5, 1996 (61 FR 56892). The new animal drug is indicated for the control, in chickens, of mortality associated with *Escherichia coli (E. coli)* susceptible to enrofloxacin. It is indicated for the control, in turkeys, of mortality associated with *E. coli* and *Pasteurella multocida (P. multocida)* susceptible to enrofloxacin.

II. Statutory Grounds Proposed for Withdrawal of the NADA for Enrofloxacin

In the NOOH published on October 31, 2000 (as revised on January 22, 2001), CVM proposed to withdraw approval of NADA 140–828 for use in poultry under section 512(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S. C. 360b(e)(1)(B)) . Section 512(e)(1)(B) states:

> (e)(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds —
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> * * * * *
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> (B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) applies to such drug.

CVM must provide a reasonable basis from which serious questions about the ultimate safety of the drug may be inferred. '''Serious questions' can be raised where the evidence is not conclusive, but merely suggestive of an adverse effect.'' (See 44 FR 54852 at 54861, September 21, l979 (Commissioner's DES Decision.) Once CVM provides a basis for questioning the safety of enrofloxacin, the sponsor will have the ultimate burden of showing the drug's safety. *See Rhone-Poulenc, Inc., Hess & Clark Div.* v. *FDA*, 636 F.2d 750 (D.C. Cir. 1980); 21 CFR 12.87(d); 44 FR 54852 at 54861, September 21, l979 (Commissioner's DES Decision); 49 FR 34965, September 4, 1984 (Notice of Hearing for Nitrofurazone); and, 56 FR 41902, August 23, 1991 (Commissioner's Nitrofurans Decision).

III. Summary of the Evidence

In accordance with FDA's procedural regulations (§ 12.85) CVM has placed on file with the Dockets Management Branch (address above) copies of all documents in the CVM Director's files containing factual information relating to the issues involved in the hearing, and a narrative statement summarizing the evidence CVM plans to introduce at the hearing. For the benefit of those who are unable to inspect those documents, the information placed on file by CVM is summarized below.

The primary factual issues at the hearing will be whether there is a reasonable basis from which serious questions about the safety of enrofloxacin use in poultry may be inferred, and, if so, whether the use of enrofloxacin under the approved conditions of use in poultry has been shown to be safe. This action is based on CVM's determination that the use of fluoroquinolones in poultry causes the development of fluoroquinolone-resistant *Campylobacter* spp., a human pathogen, in poultry; that this fluoroquinolone-resistant *Campylobacter* spp. is transferred to humans and is a significant cause of the development of fluoroquinolone-resistant *Campylobacter* infections in humans; and thatfluoroquinolone-resistant *Campylobacter* infections in humans are a human health hazard. (See 65 FR 64954.)

CVM has concluded, based on data from surveillance programs, published literature, and other sources, that the use of fluoroquinolones in poultry is a significant cause of fluoroquinolone-resistant *Campylobacter* on poultry carcasses and therefore a significant cause of fluoroquinolone-resistant *Campylobacter* infections in humans. This conclusion is supported by data establishing a temporal association between approval of fluoroquinolones for use in poultry and an increase influoroquinolone-resistant *Campylobacter* infections in humans; by a comparison of fluoroquinolone use in poultry with other possible cause of fluoroquinolone-resistant human infections; and a risk assessment that determined that in 1999, a mean estimate of 9,261 persons infected with campylobacteriosis and prescribed a