and Application Review.'' This document provides guidance to industry on FDA's fast track program, which seeks to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that have the potential to address unmet medical needs for such conditions. The guidance document is also intended to meet the requirement of section 112(b) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments on the guidance document may be submitted by February 16, 1999. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–540), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on this guidance document to the Dockets Management Branch (HFD–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041; or Bette A. Goldman, Center for Biologics Evaluation and Research (HFM–500), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5098.

SUPPLEMENTARY INFORMATION:

FDA is announcing the availability of a guidance for industry entitled ''Fast Track Drug Development Programs: Designation, Development, and Application Review.'' This guidance document is intended to meet the requirement of section 112(b) of the Modernization Act (Pub. L. 105–115), which amends the Federal Food, Drug, and Cosmetic Act (the act) by adding new section 506 (21 U.S.C. 356) and directs FDA to issue guidance describing its policies and procedures pertaining to fast track products.

FDA's fast track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs (fast track products). In this guidance document, FDA discusses the regulations, policies, and procedures of the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) that are related to fast track products. This guidance document describes and clarifies the criteria and processes for designating a new drug as a product in a fast track drug development program and describes the diverse activities and programs that can facilitate the development and expedite the review of drugs that demonstrate the potential to advance the treatment of serious and life-threatening illnesses.

This guidance document is being issued as a Level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It is being implemented without prior public comment because the guidance document is needed to implement the Modernization Act. The agency understands the need for this document to be available immediately in order for there to be clear guidance to industry, the public, and agency reviewers about this very significant program. However, FDA also understands that many interested persons may wish to provide comments and suggest revisions to this guidance. FDA is, therefore, emphasizing that it is soliciting comment from all interested persons and is providing a 90-day comment period and establishing a docket for receipt of comments. The agency will give full consideration to all comments received and make any appropriate changes to the guidance in a timely manner.

This guidance document represents the agency's current thinking on its policies and procedures relating to products in fast track drug development programs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

This guidance document contains collections of information that require clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction of 1995. In a notice published in the **Federal Register** of October 21, 1998 (63 FR 56195), FDA announced that this collection of information has been submitted to OMB for emergency processing. The notice also solicited comments on the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless a currently valid OMB control number has been displayed.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 11, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30811 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.'' This draft guidance announces that FDA now believes it is necessary to evaluate the human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals when approving such drugs.

DATES: Written comments should be submitted by December 18, 1998.

ADDRESSES: Submit written requests for single copies of this draft guidance to

the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville MD 20852. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section of this document for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Margaret A. Miller, Office of New Animal Drug Evaluation (HFV–100), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1620.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's ''Good Guidance Practices'' (GGP's) require the agency to publish, as Level 1 guidance, a change in interpretation or policy that is of more than a minor nature (62 FR 8961, February 27, 1997). Therefore, FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Evaluation of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.'' The draft guidance describes the agency's current thinking on this subject.

Since the 1970's, FDA has evaluated the effects of an antimicrobial drug product on enteric bacteria of food-producing animals in determining whether certain feed uses of an antimicrobial new animal drug are safe under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b). Under section 512 of the act, an application for approval of a new animal drug must ''include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use * * *'' (21 U.S.C. 360b(d)(1)(A)) . Section 201(u) of the act (21 U.S.C. 321(u)) states that when ''safe' is used in section 512, the term ''has reference to the health of man or animal''. In addition, section 512(d)(2) of the act states that, when determining the safety of a new animal drug, the agency ''shall consider, among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, [and] (B) the cumulative effect on man * * * of such drug, taking into account any chemically or pharmacologically related substance * * *'' (21 U.S.C. 360b(d)(2)).

In the past, FDA evaluated the human health impact of the microbial effects of only certain uses of antimicrobial new animal drugs in animal feeds (Ref. 1). However, based on scientific evidence referenced in the draft guidance, the agency now believes that sponsors of all antimicrobial new animal drugs intended for use in food-producing animals should provide information that will allow the agency to evaluate the human health impact of the intended use.

To assess the human health impact, the following two separate, but related aspects, should be evaluated: (1) The quantity of resistant enteric bacteria formed in the animal's intestinal tract following exposure to the antimicrobial new animal drug (resistance) and (2) changes in the number of enteric bacteria in the animal's intestinal tract that can cause human illness (pathogen load). In some cases, a preapproval study or studies may be needed. FDA recognizes that there is no standardized protocol established for determining the human health impact of the microbial effect(s) of an antimicrobial product, and that one standard study is likely to be inappropriate for all intended uses.

This draft guidance represents the agency's current thinking only about its authority under the act to consider the human health impact of the microbial effects associated with all uses of all classes of antimicrobial new animal drugs intended for use in food-producing animals. It does not provide technical guidance regarding the design of studies or types of information required to satisfy the requirements to demonstrate safety. The agency intends to solicit public comments on this issue at a meeting of the Veterinary Medicine Advisory Committee in Rockville, MD, on December 10 and 11, 1998, and possibly later at other public meetings that involve experts in public health.

The draft document does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

References that are cited in the draft guidance have been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

II. Comment

Interested persons may, on or before December 18, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance using the World Wide Web (WWW). For WWW access, connect to CVM at ''http://www.fda.gov/cvm''.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration, ''Human Health Safety Criteria,'' Center for Veterinary Medicine, Guideline 18.

2. Food and Drug Administration, ''Penicillin Use in Animal Feeds,'' 42 FR 43769–43793, August 30, 1977.

3. Endtz, H., G. Ruijjs, et. al., ''Quinolone Resistance in *Campylobacter* Isolated From Man and Poultry Following the Introduction of Fluoroquinolones in Veterinary Medicine,'' *Journal of Antimicrobial Chemotherapy*, 27, 199–208, 1991.

4. Aserkoff, B., and J. V. Bennett, ''Effect of Antibiotic Therapy in Acute Salmonellosis on the Fecal Excretion of *Salmonella*,''*New England Journal of Medicine*, 281, 636–640, 1969.

5. Seyfarth, A. M., H. C. Wegener, and N. Frimodt-Moller, ''Antimicrobial Resistance in *Salmonella enterica* subsp. *enterica* serovar *typhimurium* from Humans and Production Animals,'' *Journal of Antimicrobial Chemotherapy*, 40, 67–75, 1997.

6. D'Aoust, J-Y., *Salmonella Species*, In: Food Microbiology Fundamentals and Frontiers, edited by Doyle, M. P., L. R. Beuchat, and T. J. Montville, ASM Press, Washington, DC, pp. 129–158, 1997.

7. Nachamkin, I., *Campylobacter jejuni*, In: Food Microbiology Fundamentals and Frontiers, edited by Doyle, M. P., L. R. Beuchat, T. J. Montville, ASM Press, Washington, DC, pp. 159–170, 1997.

8. Bates, J., J. Z. Jordens, and D. T. Griffiths, ''Farm Animals as a Putative Reservoir for Vancomycin-resistant Enterococcal Infection in Man,'' *Journal of Antimicrobial Chemotherapy*, 34, 507–514, 1994.

9. Department of Agriculture, Food Safety Inspection Service, ''Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems; Final Rule,'' 61 FR 38805–38989, July 25, 1996.

10. Department of Agriculture, ''Nationwide Beef Microbiological Baseline: Steers and Heifers,'' October 1992–September 1993; ''Nationwide Broiler Chicken Microbiological Baseline,'' July 1994–June 1995; and ''Nationwide Pork Microbiological Baseline: Market Hogs,'' April 1995–March 1996: Food Safety Inspection Service, Data Collection Programs, Microbiology Division.

11. U.S. Food and Drug Administration, ''Microbiological Testing of Antimicrobial Drug Residues in Food,'' Center for Veterinary Medicine, Guideline 52.

Dated: November 10, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30747 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Services

North American Wetlands Conservation Council; Membership

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of policy and request for comments.

SUMMARY: The purpose of this action is to notify the public regarding an existing term rotation policy for membership of charitable and non-profit organizations of the North American Wetlands Conservation Council. This policy will assure broad representation from such organizations in keeping with the purposes of the North American Wetlands Conservation Act.

DATES: Comments on this policy must be received by January 19, 1999.

ADDRESSES: Comments regarding this notice should be addressed to: Director (FSW/NAWWO), U.S. Fish and Wildlife Service, 110 ARLSQ, 1849 C ST., NW, Washington, D.C. 20240. Comments received on this notice will be available for public inspection during normal business hours in Room 110, Arlington Square Building, 4401 No. Fairfax Drive, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Mr. David A. Smith, Executive Director, or Mr. Douglas A. Ryan, Wildlife Biologist, North American Waterfowl and Wetlands Office, 703/358–1784; Facsimile 703/358–2282.

SUPPLEMENTARY INFORMATION:

Background

The North American Wetlands Conservation Council (Council) was established by the North American Wetlands Conservation Act (Act), 16 U.S.C. 4401–4412, Public Law 101–233, and is comprised of nine members. The Council reviews and recommends wetland conservation projects to the Migratory Bird Conservation Commission, following criteria given in the Act. Two permanent Council seats are occupied by the Director of the U.S. Fish and Wildlife Service and the Secretary of the Board of the National Fish and Wildlife Foundation. Four of the seven non-permanent seats are Directors of State Fish and Wildlife agencies representing the four migratory bird flyways. Individuals representing non-governmental organizations (NGOs) that are actively participating in carrying out wetland conservation projects under the Act, the Plan, or the Tripartite Agreement (among the U.S., Canada, and Mexico) occupy the other three non-permanent seats. Appointment of the non-permanent members is at the discretion of the Secretary of the Interior (Secretary). The term for non-permanent seats is three years. In addition, the Secretary appoints an alternate member and may appoint ex-officio non-voting members to the Council.

What is the Policy?

In the Spring of 1998, the Secretary adopted a term rotation policy of two consecutive terms or six consecutive years for organizations occupying the three NGO Council seats. An NGO that has completed two terms would be eligible for full reappointment to the next vacancy among the three NGO seats and also eligible for appointment to either the alternate seat or an ex-officio seat.

Why Was the Policy Adopted?

The Secretary adopted a two-term rotation policy for NGO members on the Council for the following reasons:

- The purpose of the Act is to encourage partnership among public agencies and other interests for the conservation of wetlands and migratory birds in North America. This policy is intended to build broad support for the Act by opening the door to a variety of organizations to take full advantage of opportunities available through Council participation.
- All organizations that meet the requirements for NGOs stated above in the Act should be given full and fair consideration for Council membership.
- Given the detailed approval process, and frequent consideration of complex issues associated with Council participation, appointing any NGO representative to serve two consecutive terms is appropriate, as it would allow that representative to become familiar with Council operations and to reach their full potential for contributing to the work of the Council.
- While the Act requires that NGOs on the Council be active participants in wetlands conservation, it does not restrict Council participation to only those NGOs that are most active (i.e., in terms of matching dollars and services, and grants received).
- Each NGO can only represent its own organization, unlike State agencies on the Council that have the responsibility and capability to represent the flyways, of which they are a part.
- Regardless of appointment status, those NGOs that have contributed substantially to Act-funded projects are encouraged to continue as instrumental participants in project development and implementation.

In summary, the purpose of this action is to notify the public and invite any comments regarding the Secretary's existing term rotation policy for charitable and non-profit organizations on the North American Wetlands Conservation Council, to fully implement the purpose of the North American Wetlands Conservation Act.

NEPA Consideration

Pursuant to the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4332(C)), and the Council on Environmental Quality's regulation for implementing NEPA (40 CFR parts 1500–1508), the Service has determined that the policy published in this document is categorically excluded from the NEPA process as provided by 516 DM 2, Appendix 1.10 of the Departmental Manual.

Authorship: The primary author of this notice is Mr. Douglas A. Ryan, U.S. Fish and Wildlife Service North American Waterfowl and Wetlands Office, Arlington, Virginia.

Dated: November 6, 1998.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 98–30766 Filed 11–17–98; 8:45 am]

BILLING CODE 4310–55–M