

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 4 and 5, 1999, 8:30 a.m. to 5 p.m.

Location: CDER Advisory Committee Conference Room 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Igor Cerny, or Tony Slater, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or by e-mail at CERNY@CDER.FDA.GOV, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12440. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss and provide FDA with advice about the agency's development and publication of a list of bulk drug substances that may be used in pharmacy compounding that do not have a United States Pharmacopeia or National Formulary monograph and are not components of FDA-approved drugs. Specifically, the committee is likely to address the following drug substances as candidates for the bulk drugs list: 4-aminopyridine, 3,4-diaminopyridine, betahistine dihydrochloride, cyclandelate, dinitrochlorobenzene, diphenylcyclopropanone, hydrazine sulfate, mild silver protein, pentylentetrazole, and squaric acid dibutyl ester. The committee may also review drug products to be included on a list which have been withdrawn or removed from the market for reasons of safety or efficacy which may not be used in compounding that qualifies for the applicable statutory exemptions.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 21, 1999. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 21, 1999, and submit a brief statement of the general nature of the evidence or arguments

they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99-154 Filed 1-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-1146]

Discussion Paper: "A Proposed Framework for Evaluating and Assuring the Human Safety 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 discussion paper entitled "A Proposed Framework for Evaluating and Assuring the Human Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals" (discussion paper). This discussion paper is the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA is making the discussion paper available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop microbial safety policies protective of the public health.

DATES: Written comments on the discussion paper should be submitted by April 6, 1999.

ADDRESSES: Submit written requests for single copies of the discussion paper 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 on the discussion paper 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 discussion paper 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 discussion paper.

FOR FURTHER INFORMATION CONTACT:

Sharon R. Thompson, Office of the Director (HFV-1), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1798.

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.

Linda R. Tollefson, Office of Surveillance and Compliance (HFV-200), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6644.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1998 (63 FR 64094), FDA published a notice of 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 release of this draft guidance was the first step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. The draft guidance lays out the agency's rationale for its current thinking about its authority under the Federal Food, Drug, and Cosmetic Act to consider the human health impact of the microbial effects associated with the use of antimicrobial new animal drugs in food-producing animals. Since the 1970's, and until scientific evidence indicated that a change was necessary, the agency had evaluated the human health impact of the microbial effects of only certain uses of antimicrobial new animal drugs in animal feeds. The draft guidance provides that the agency now believes that sponsors of all antimicrobial new animal drugs intended for use in food-producing animals need to provide information that will allow the agency to evaluate the human health impact of the microbial effects of the intended uses. In assessing the human health impact of such uses, the draft guidance states that two separate but related factors should be evaluated: (1) The quantity of antimicrobial drug-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 cause human illness (pathogen load).

The discussion paper that is the subject of this notice is the second step of the agency's consideration of these issues. It augments the draft guidance made available in November 1998 by setting out a conceptual risk-based framework for evaluating the microbial safety (relating to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals. FDA is making the discussion paper available to the public in order to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying concepts to be used to develop policies that are protective of the public health. The agency is seeking comment from the public in two areas. The first is whether the concepts set out in this document, if implemented, will accomplish the goal of protecting the public health by ensuring that significant human antimicrobial therapies are not lost as a result of use of antimicrobial new animal drugs in food-producing animals, while providing for the safe use of antimicrobials in food-producing animals. The second is to obtain input on important areas of scientific complexity outlined in the discussion paper.

This will not be the only opportunity for public comment on these issues. The agency intends to solicit further public comments at the next meeting of FDA's Veterinary Medicine Advisory Committee in Rockville, MD, which is scheduled to be held on January 25 and 26, 1999. Also, comments regarding the 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" may be submitted at any time.

II. Comments

Interested persons may, on or before April 6, 1999, submit to the Dockets Management Branch (address above) written comments regarding this discussion paper. 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 discussion paper 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 discussion paper using the World Wide Web (WWW). For WWW access, connect to CVM at "http://www.fda.gov/cvm".

Dated: December 30, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-34842 Filed 12-31-98; 12:04 pm]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0046]

Quarterly List of Guidance Documents at the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a quarterly update of all guidance documents issued and withdrawn since the compilation of the quarterly list that published on July 6, 1998. FDA committed to publishing quarterly updates in its February 1997 "Good Guidance Practices" (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. This list is intended to inform the public of the existence and availability of guidance documents issued during this quarter. This list also includes some guidance documents that were inadvertently not included on previously published lists.

DATES: General comments on this list and on agency guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch

(HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Information on where to obtain single copies of listed guidance documents is provided for each agency center individually in the specific center's list of guidance documents.

FOR FURTHER INFORMATION CONTACT: Lisa L. Barclay, Office of Policy (HF-22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 27, 1997 (62 FR 8961), FDA published a notice announcing its "Good Guidance Practices" (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents. The agency adopted the GGP's to ensure public involvement in the development of guidance documents and to enhance public understanding of the availability, nature, and legal effect of such guidance.

As part of FDA's effort to ensure meaningful interaction with the public regarding guidance documents, the agency committed to publish an annual comprehensive list of guidance documents and quarterly **Federal Register** notices that list all guidance documents that were issued and withdrawn during that quarter, including "Level 2" guidance documents. The following list of guidance documents represents all guidances issued or withdrawn by FDA since the compilation of the July 6, 1998 (63 FR 36413) quarterly list and any guidance documents inadvertently not included on previously published lists. The guidance documents are organized by the issuing Center or Office within FDA, and are further grouped by the intended users or regulatory activities to which they pertain. Dates provided in the following list refer to the date of issuance or, where applicable, the date of last revision of the document. Document numbers are provided where available.

II. Guidance Documents Issued by the Center for Biologics Evaluation and Research (CBER)