Estimated Total Annual Burden Hours: 2,240.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, Division of Resource Management Services, 370 L'Enfant Promenade, SW, Washington, DC 20447, Attn: Reports Clearance Officer. This information collection and an electronic comment form are also available at the following Child Care Bureau Web Site: *http://www.acf.dhhs.gov/programs/ccb/systems/index.htm.*

The Department specifically requests comments on: (a) Whether the proposed revised collection of information is necessary for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 20, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–33384 Filed 12–22–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals (GFI #78); Availability; Republication

Editorial Note: FR Doc. 99–32324 was originally published at page 70716 in the **Federal Register** of Friday, December 17, 1999. The companion Framework document was inadvertently not published. At the request of the agency, FR Doc. 99–32324 is republished below in its entirety together with the companion Framework document.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78). After the agency considered public comments on a draft of this guidance, announced in the **Federal Register** of November 18, 1998, it determined that revision of the draft guidance was necessary. GFI #78 addresses how under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b) FDA intends to consider the potential 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. For additional information regarding the subject matter dealt with in GFI #78, see the notice of availability of the document entitled ''FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' that appears elsewhere in this issue of the **Federal Register**.

DATES: Submit comments at any time.

ADDRESSES: Submit written comments on GFI #78 to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

FDA will also accept electronic comments. Persons who wish to submit electronic comments should go to the FDA home page at www.fda.gov and select ''Dockets'' and follow the instructions.

Submit written requests for single copies of the document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78) to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See section III. Electronic Access of this document for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sharon Thompson, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1798, e-mail: sthompso@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 18, 1998 (63 FR 64094), FDA announced 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'' (GFI #78). This draft guidance announced that FDA believed that 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. The publication of the draft of GFI #78 was the first step in the agency's consideration of the issues related to the use of antimicrobial new animal drugs in food-producing animals. The draft of GFI #78 laid out the agency's rationale for its current thinking about its authority under section 512 of the act to consider the human health impact of the microbial effects associated with the use of antimicrobial new animal drugs in food-producing animals.

In the **Federal Register** of January 6, 1999 (64 FR 887), FDA announced 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'' (Framework Document). The Framework Document was the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA made the Framework Document 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. The Framework Document is related to GFI #78 in that it sets out a conceptual risk-based framework for evaluating the microbial safety (related to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals.

After considering comments received by the public for both the draft of GFI #78 and the Framework Document, FDA determined that it was necessary to make some revisions to GFI #78. The revisions are intended to make GFI #78

more clearly reflect the agency's intentions regarding this issue. For example, the words ''evaluate'' and ''evaluation'' have been changed to ''consider'' and ''consideration,'' and other changes have been made to indicate that additional testing would not always be needed to determine the potential human health impact of the microbial effects associated with antimicrobial new animal drugs intended for use in food-producing animals.

GFI #78 represents the agency's current thinking on how under section 512 of the act it intends to consider the potential 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. It does not create or confer any right 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.

II. Comments

Interested persons may, at any time, submit written or electronic comments on GFI #78 to the Dockets Management Branch (address above). Two copies of written comments are to be submitted, except that individuals may submit one copy. All comments are to be identified with the docket number found in brackets in the heading of this document. GFI #78 and written and electronic comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain copies of ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78) at http://www.fda.gov/cvm.

Dated: December 8, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

Editorial Note: FR Doc. 99–32324 was originally published at page 70716 in the **Federal Register** of Friday, December 17, 1999. The companion Framework document was inadvertently not published. At the request of the agency, FR Doc. 99–32324 is republished in its entirety together with the companion Framework document.

[FR Doc. 99–32324 Filed 12–14–99; 4:09 pm]

BILLING CODE 1505–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0969]

FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food 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 of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals.'' The comments were received in response to a document entitled ''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' '' (the Framework Document) that FDA made public and discussed at the Veterinary Medicine Advisory Committee (VMAC) meeting in January 1999. FDA intends to revise the Framework Document in response to the comments. Specific aspects of the Framework Document are to be discussed at two workshops scheduled for December 9 and 10, 1999, and February 22 and 23, 2000, and at later workshops currently being considered. For additional information, see the notice of availability of the guidance document entitled ''Guidance for Industry: Consideration of the Human Health Impact of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' (GFI #78) that appears elsewhere in this issue of the **Federal Register**.

DATES: Submit comments at any time.

ADDRESSES: Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

FDA will also accept electronic comments. Persons who wish to submit electronic comments should go to the FDA home page at http://www.fda.gov, select ''Dockets'', and follow the instructions for submitting electronic comments.

Submit written requests for single copies of the guidance document entitled ''FDA Response to Comments on a Proposed Framework for Evaluating and Assuring the Human Food Safety of the Microbial Effects of Antimicrobial New Animal Drugs Intended for Use in Food-Producing Animals'' and other documents discussed in the **SUPPLEMENTARY INFORMATION** section of this **Federal Register** notice to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Enclose one self-addressed adhesive label to assist that office in processing your requests. See section **III. Electronic Access** of this document for information on electronic access to the guidance document and its related documents.

FOR FURTHER INFORMATION CONTACT: Marcia R. Larkins, Center for Veterinary Medicine (HFV–230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0137, e-mail: mlarkins@cvm.fda.gov.

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 document 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'' (GFI #78). The publication of this draft guidance for industry (GFI #78) was the first step in the agency's consideration of the issues related to the use of antimicrobial new animal drugs in food-producing animals. GFI #78 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. Elsewhere in this issue of the **Federal Register** is a notice of availability of the final revised guidance.

In the **Federal Register** of January 6, 1999 (64 FR 887), FDA announced the availability of a discussion paper called the Framework Document, which was the second step in the agency's consideration of issues related to the use of antimicrobial new animal drugs in food-producing animals. FDA made the Framework Document available to the public to initiate discussions with the scientific community and other interested parties on the agency's thinking about appropriate underlying