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

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 effects (related to human health impact) of antimicrobial new animal drugs intended for use in food-producing animals.

The agency invited comment on both GFI #78 and the Framework Document. FDA received more than 50 comments to these documents. These comments originated from a number of sources including individual members and committees of Congress (3); individual physicians, microbiologists, and hospitals (6); individual citizens and organizations representing consumers (16); animal drug and feed industries (3); individual veterinarians and organizations representing veterinarians (5); environmental organizations (3); individual producers and organizations representing producers (14); and another Federal agency (1).

In addition to requesting comment from the public, the agency also consulted with the VMAC on this issue. In a meeting held on January 25 and 26, 1999, the VMAC provided input on the Framework Document and addressed five specific questions from the agency regarding its contents. The goal of the meeting was ''to find the balance that protects human health and gives veterinarians the tools they need to treat animals.'' A transcript of this meeting is available on the CVM home page at the Internet address provided below in section **III. Electronic Access**.

FDA stated it would review the transcript of the VMAC meeting and any comments on GFI #78 and the Framework Document that were submitted to the agency, publish the analysis, and then appropriately revise GFI #78 and the Framework Document. This 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'' contains the analysis of the transcript, the comments received regarding GFI #78 and the Framework Document, and provides responses to the comments.

In the **Federal Register** of September 27, 1999 (64 FR 52099), the agency announced a general public meeting and two public workshops to discuss issues related to antimicrobial resistance in food-producing animals. The general public meeting was held on October 4, 1999. The first workshop called the ''Risk Assessment and the Establishment of Resistance Thresholds Workshop'' is scheduled for December 9 and 10, 1999. The second workshop called ''Preapproval Studies in Antimicrobial Resistance'' is scheduled for February 22 and 23, 2000. The agency intends for 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,'' along with the Framework Document, to serve as a basis for discussion at the two workshops and at future workshops.

II. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written or electronic comments regarding this response to comments. Two copies of any 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. A copy of the response to comments and all received electronic and written comments may be seen in the office above between 9 a.m. and 5 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain copies 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,'' the Framework Document, GFI #78, and transcripts from the VMAC meeting at http://www.fda.gov/cvm.

Dated: December 8, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–33386 Filed 12–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–5002]

Acupuncture Devices and Accessories; Revocation of Compliance Policy Guide 7124.11

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the Compliance Policy Guide (CPG) entitled ''Sec. 305.100 Acupuncture Devices and Accessories (CPG 7124.11)'' to eliminate obsolete compliance policy. In general, this CPG no longer reflects current agency policy because acupuncture needles have been reclassified from class III to class II (special controls).

DATES: Effective January 24, 2000.

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411 or FAX your request to 301–827–0482. A copy of the CPG may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0411.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued the CPG entitled ''Sec. 305.100 Acupuncture Devices and Accessories (CPG 7124.11)'' on June 15, 1976. This CPG considered acupuncture devices and accessories as investigational devices subject to the investigational device exemptions (IDE) regulations (21 CFR part 812). As such, these class III devices were permitted to be distributed only for the purpose of conducting clinical studies to establish their safety and effectiveness. In the absence of an approved premarket approval application, the sale, promotion, and commercial distribution of these acupuncture devices and accessories were prohibited.

In response to a reclassification petition that was submitted to FDA by the Acupuncture Coalition, the agency reclassified acupuncture needles from class III to class II (special controls) in the **Federal Register** of December 6, 1996 (61 FR 64616). The classification regulation (21 CFR 880.5580) for solid, stainless steel, acupuncture needles requires that these class II devices must comply with special controls for single use labeling, prescription labeling, biocompatibility, and sterility.

Currently, an acupuncture needle that is intended to pierce the skin in the practice of acupuncture may be