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

commercially distributed if it is the subject of a cleared premarket notification (510(k)), complies with the special controls, and meets all other applicable statutory and regulatory requirements.

Given the reclassification of acupuncture needles, FDA is revoking CPG 7124.11, in its entirety, to eliminate obsolete compliance policy.

II. Electronic Access

Prior to January 24, 2000, a copy of the CPG may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs (ORA) Home Page includes the referenced document that may be accessed at http://www.fda.gov/ora/compliance__ref/cpg/cpgdev/cpg305–100.html.

Dated: December 7, 1999.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 99–33282 Filed 12–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1109–N]

Medicare Program; January 12, 2000, Meeting of the Competitive Pricing Advisory Committee

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces a meeting of the Competitive Pricing Advisory Committee (the CPAC) on January 12, 2000. The Balanced Budget Act of 1997 (BBA) requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. The BBA requires the Secretary to create the CPAC to make recommendations on demonstration area designation and appropriate research designs for the project. The CPAC meetings are open to the public.

DATES: The meeting is scheduled to meet on January 12, 2000, from 1 p.m. until 5 p.m., e.s.t.

ADDRESSES: The meeting will be held at the Embassy Suites, 1250 22nd Street, NW., Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Sharon Arnold, Ph.D., Executive Director, Competitive Pricing Advisory Committee, Health Care Financing Administration, 7500 Security Boulevard, C4–14–17, Baltimore, Maryland 21244–1850, (410) 786–6451.

SUPPLEMENTARY INFORMATION: Section 4011 of the Balanced Budget Act of 1997 (BBA) (Public Law 105–33), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish a demonstration project under which payments to Medicare+Choice organizations in designated areas are determined in accordance with a competitive pricing methodology. Section 4012(a) of the BBA requires the Secretary to appoint a Competitive Pricing Advisory Committee (the CPAC) to meet periodically and make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research design for implementing the project. The CPAC has previously met on May 7, 1998, June 24 and 25, 1998, September 23 and 24, 1998, October 28, 1998, January 6, 1999, May 13, 1999, July 22, 1999, September 16, 1999, and October 29, 1999.

The CPAC consists of 15 individuals who are independent actuaries, experts in competitive pricing and the administration of the Federal Employees Health Benefit Program; and representatives of health plans, insurers, employers, unions, and beneficiaries. The CPAC members are: James Cubbin, Executive Director, General Motors Health Care Initiative; Robert Berenson, M.D., Director, Center for Health Plans and Providers, HCFA; John Bertko, Actuary Principal, Humana Inc.; David Durenberger, Vice President, Public Policy Partners; Gary Goldstein, M.D., Healthcare Consultant; Samuel Havens, Healthcare Consultant; Margaret Jordan, Healthcare Consultant; Chip Kahn, President, The Health Insurance Association of America; Cleve Killingsworth, President and CEO, Health Alliance Plan; Nancy Kichak, Director, Office of Actuaries, Office of Personnel Management; Len Nichols, Principal Research Associate, The Urban Institute; Robert Reischauer, President, The Urban Institute; John Rother, Director, Legislation and Public Policy, American Association of Retired Persons; Andrew Stern, President, Service Employees International Union, AFL-CIO; and Jay Wolfson, Director, The Florida Information Center, University of South Florida. The chairperson is James Cubbin and the co-chairperson is Robert Berenson, M.D. In accordance with section 4012(a)(5)of the BBA, the CPAC will terminate on December 31, 2004.

The agenda for the January 12, 2000, meeting will include an overview and discussion of the recent legislation that affected the Medicare competitive pricing demonstration, Public Law 106–113, referred to as the Appropriations Act for FY 2000.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issue should contact the Executive Director, by 12 noon, January 7, 2000, to be scheduled. The number of oral presentations may be limited by the time available. A written copy of the oral remarks should be submitted to the Executive Director, no later than 12 noon, January 10, 2000. Anyone who is not scheduled to speak, may submit written comments to the Executive Director, by 12 noon, January 10, 2000.

The meeting is open to the public, but attendance is limited to the space available.

(Section 4012 of the Balanced Budget Act of 1997, Public Law 105–33 (42 U.S.C.1395w–23 note) and section 10(a) of Public Law 92–463 (5 U.S.C. App. 2, section 10(a))

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 15, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 99–33260 Filed 12–22–99; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.