Banks for one count of knowingly and willfully making false, fictitious, and fraudulent statements and representations to a Federal agency as to material facts, a Federal felony under 18 U.S.C. 1001.

As a result of this conviction, FDA served Ms. Banks by certified mail on September 26, 1996, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application, and offered her an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Ms. Banks was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Ms. Banks did not request a hearing. Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a) of the act, and under authority delegated to her (21 CFR 5.99(b)), finds that Ms. Norma D. Banks has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Ms. Norma D. Banks is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective August 28, 1997 (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Ms. Banks in any capacity, during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Ms. Banks, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications or abbreviated antibiotic drug applications submitted by or with the assistance of Ms. Banks during her period of debarment.

Any application by Ms. Banks for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 96N–0256 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 12, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–22856 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0298]

Distributor Medical Device Reporting; Draft Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft Compliance Policy Guide (CPG) entitled ''Distributor Medical Device Reporting.'' The purpose of the CPG is to provide guidance concerning the interpretation and applicability of some of the provisions in the Medical Device Distributor Reporting Regulation. FDA believes that the following guidance will improve the administration and efficiency of medical device distributor reporting as well as the quality of information received.

DATES: Written comments on the draft CPG may be submitted by November 26, 1997.

ADDRESSES: Submit written requests for single copies of the draft CPG to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597 or outside MD 1–800–638–2041. Send two self-addressed adhesive labels to assist that office in processing your requests, or FAX your request to 301–443–8818. Facsimiles of the draft CPG are available from DSMA. To receive the draft CPG on your fax machine, call the CDRH Facts-On-Demand system at 1–800–899–0381 or 301–827–0111 from a touch tone telephone. At the first voice prompt press ''1'' to access DSMA Facts, at the second voice prompt press ''2'' and then enter the document number, ''120'' followed by the pound sign, ''#''. Follow the remaining voice prompts to complete the request. Submit written comments on the draft CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Chester T. Reynolds, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4618, ext. 114.

SUPPLEMENTARY INFORMATION:

I. Background

Distributors of devices have been required, by statute, to report device related deaths, serious illnesses, serious injuries and malfunctions to FDA and the manufacturers of the devices since May 28, 1992. The regulations that implemented the statutory provisions can be found in parts 804 and 807 (21 CFR parts 804 and 807).

Since 1993, FDA has received thousands of Medical Device Reports (MDR's) submitted in response to part 804. As a result of this experience, FDA has developed a draft CPG to provide guidance concerning the interpretation and applicability of some of the provisions of the Distributor Medical Device Reporting Regulation. For practical purposes, FDA intends to interpret the reporting standards for both domestic distributors and importers to be the same. In exercising its enforcement discretion, the agency does not plan to initiate regulatory action involving distributor requirements for staff training and education. Additionally, FDA encourages distributors to voluntarily use the reporting form MEDWATCH FDA Form 3500A. The agency believes that using this form will reduce the paperwork and level of effort for distributors, manufacturers, and FDA. This draft guidance document represents the agency's current thinking on distributor medical device reporting. 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.

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft

CPG entitled ''Distributor Medical Device Reporting.'' 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 agency will review all comments, but in issuing a final CPG, need not specifically address every comment. The agency will make changes to the CPG in response to comments, as appropriate. A copy of the draft CPG and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of the draft CPG may also be downloaded to a personal computer with access to the World Wide Web (www). The Office of Regulatory Affairs (ORA) and CDRH Home Pages include the draft CPG and may be accessed at ''http://www.fda.gov/ora'' or ''http://www.fda.gov/cdrh'' respectively. The draft CPG will be available on the Compliance References or Compliance Information pages for ORA and CDRH respectively.

Dated: August 15, 1997.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 97–22702 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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: Food Advisory Committee.

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

Date and Time: The meeting will be held on September 25 and 26, 1997, 8:30 a.m. to 5 p.m.

Location: Holiday Inn—Eisenhower Metro Center, Eisenhower Station Ballroom, 2460 Eisenhower Ave., Alexandria, VA.

Contact Person: Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4727, or Catherine M. DeRoever, Advisory Committee Staff (HFS–22), 202–205–4251, FAX 202–205–4970, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will be conducting an informational meeting during which it will be receiving updates on past issues that were referred to the committee and on other activities related to food safety. There will also be briefings by the current working groups formed to discuss the Final Report from the Keystone National Policy Dialogue on Food, Nutrition, and Health, as well as simultaneous working group sessions. Two working groups are expected to have work products for committee discussion.

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 September 17, 1997. Oral presentations from the public will be scheduled between approximately 4 p.m. and 5 p.m. on September 25, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 17, 1997, 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: August 21, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–22854 Filed 8–27–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Mammography Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Mammography Workshop. The topics to be discussed are: Update on the Mammography Quality Standards Act (MQSA), State regulations on mammography, the medical physicist's responsibilities, FDA's MQSA compliance, the radiographic processor, and preparation for the MQSA inspection.

Date and Time: The public workshop will be held on Tuesday, September 23, 1997, 8:30 a.m. to 5 p.m.; registration, 8 a.m. to 8:30 a.m. Registration will close on September 16, 1997.

Location: The public workshop will be held at the Medical Forum Bldg., 950 22d St. North, Birmingham, AL 35203, 205–458–8800.

Contact: Ralph T. Trout, Food and Drug Administration (HFR–SE19), 60 Eighth St. NE., Atlanta, GA 30309, 404–347–4001, ext. 5248, FAX 404–347–4349.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Tuesday, September 16, 1997. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Ralph T. Trout at least 7 days in advance.

SUPPLEMENTARY INFORMATION: This workshop is being sponsored by FDA's Southeast Region and the radiological health programs of the States of the Southeast Region. These States are Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee, and the Commonwealth of Puerto Rico and the Virgin Islands. The purpose of this workshop is to provide mammography facilities with an update on MQSA and technical training in the area of mammography.

Dated: August 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–22980 Filed 8–25–97; 4:44 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medicated Feed Good Manufacturing Practices (GMP's) Training Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Pacific Region is announcing a training workshop to