failed to submit reports required under § 314.81.

In accordance with section 505 of the act and 21 CFR part 314, the applicants are hereby provided an opportunity for a hearing to show why the applications listed above should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file:

(1) On or before April 15, 1996, a written notice of participation and request for a hearing, and (2) on or before May 14, 1996, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: February 28, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–6174 Filed 3–14–96; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETINGS: The following advisory committee meetings are announced:

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. April 1, 1996, 8:30 a.m., Holiday Inn—Gaithersburg, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–948–8900 or 1–800–465–4329, and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Alice Hayes, Sociometrics, Inc., 8300 Colesville Rd., suite 550, Silver Spring, MD 20910, 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior notification is received.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 22, 1996, 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 required to make their comments.

Open committee discussion. The Division of Ophthalmic Devices will present the proposed draft guidance document for Photorefractive Keratectomy (PRK) Laser Systems and request comments and recommendations from the Panel on designated sections. The scope of the discussion will include a proposal from the Division to expand the guidance to address high myopia, hyperopia, astigmatism, and Laser Assisted In Situ Keratomileusis (LASIK). Single copies of the proposed outline for the discussion are available from the contact person (see above).

Technical Electronic Product Radiation Safety Standards Committee

Date, time, and place. April 9 and 10, 1996, 8:30 a.m., Corporate Bldg., 9200 Corporate Blvd., rm. 020B, Rockville, MD.

Type of meeting and contact person. Open committee discussion, April 9, 1996, 8:30 a.m. to 3:30 p.m.; open public hearing, 3:30 p.m. to 4:30 p.m., unless public participation does not last that long; open committee discussion, April 10, 1996, 8:30 a.m. to 11 a.m.; open public hearing, 11 a.m. to 11:30 a.m., unless public participation does not last that long; open committee discussion, 11:30 a.m. to 3:30 p.m.; open public hearing, 3:30 p.m. to 4:15 p.m., unless public participation does not last that long; Orhan H. Suleiman, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3533, or call the FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Technical Electronic Product Radiation Safety Standards Committee, code 12399.

General function of the committee. The committee advises on technical feasibility, reasonableness, and practicability of performance standards for electronic products to control the emission of radiation under 42 U.S.C. 263f(f)(1)(A).

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before March 22, 1996, 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 required to make their comments.

Open committee discussion. A brief overview and update of issues associated with the Radiation Control for Health and Safety Act (Pub. L. 90–602) will be presented by FDA staff. The committee will specifically discuss draft amendments to the following performance standards for ionizing radiation emitting products: (1) Radiographic dental equipment (21 CFR 1020.30); (2) mammography equipment (21 CFR 1020.30); and (3) laser products (21 CFR 1040.10). In addition, radiation exposure to patients during extended fluoroscopy procedures will be discussed.

Oncologic Drugs Advisory Committee

Date, time, and place. April 19, 1996, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 4:30 p.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of cancer.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 12, 1996, 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 required to make their comments.

Open committee discussion. The committee will discuss: (1) New drug application (NDA) 20–671, Hycamtin™ injection (topotecan HCl, SmithKline Beecham) for treatment of ovarian cancer after failure of first-line therapy; and (2) an update for the Committee on FDA Oncology activities, including the Cancer Liaison Program.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. April 23, 24, and 25, 1996, 9 a.m., Sheraton Hotel—Reston, rooms One and Two, 11810 Sunrise Valley Dr., Reston, VA. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 703–620–9000 and reference the FDA committee meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, April 23, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, April 24, 1996, 9 a.m. to 1:15 p.m.; open subcommittee discussions, 1:15 p.m. to 5 p.m.; open committee discussion, April 25, 1996, 9 a.m. to 5 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before April 16, 1996, 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 required to make their comments.

Open committee discussion. On April 23, 24, and 25, 1996, the committee will discuss the proposed regulations under the Mammography Quality Standards Act (the MQSA) of 1992. Copies of the proposed regulations will publish in the Federal Register in the near future and may be obtained by submitting a written request to the MQSA, c/o SciComm, P.O. Box 30224, Bethesda, MD, 20824–9998, or faxing a request to 301–986–8015. On April 25, 1996, the committee will discuss the ongoing work of the three subcommittees: Access to Mammography Services, Physicists Availability, and Cost Benefit of Compliance.

Open subcommittee discussion. On April 24, 1996, the three subcommittees will meet concurrently. The subcommittees will discuss information which is necessary to make the determinations and subsequently prepare the reports as mandated in the MQSA. Upon completion, the subcommittee reports will be reviewed by the committee prior to submission to the Secretary of Health and Human Services and Congress.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee

meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: March 11, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–6373 Filed 3–14–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Statement of Organization, Functions, and Delegations of Authority, Denver Regional Office

Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Health Care Financing Administration (HCFA), (Federal Register, Vol. 60, No. 148, pp. 39404–39409, dated Wednesday, August 2, 1995) is amended to reflect a reorganization in the Denver Regional Office.

The Denver Regional Office (RO) proposes an organizational change, as a demonstration of a streamlined customer-focused organization, for up to 18 months. The new structure will eliminate one layer of management, reduce the number of management positions by nearly half, create customer-focused teams, and significantly empower staff.

The specific amendments to part F are described below:

Section F.10.D.6., (Organization) is amended to read as follows:

e1. State Team 1 (FLD8D)
e2. State Team 2 (FLD8E)
e3. State Team 3 (FLD8F)
e4. State Team 4 (FLD8G)

Section F.20.D.6.e., (Functions) will read as follows:

e.1.–4. State Team 1–4 (FLD8(D–G))

- State Teams will administer the full range of HCFA program responsibilities in the field. Teams are comprised of a multi-disciplinary work force which conducts all statutory, regulatory and administrative functions to manage the Medicare and Medicaid benefits for those enrolled in HCFA's programs with the six Regional VIII States—Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming.

Operations

- Assures that health care services provided under the Medicare, Medicaid and CLIA programs are furnished in the most effective and efficient manner consistent with recognized professional standards of care.
- Evaluates services to ensure protection of beneficiaries receiving health care services under the Medicare, Medicaid, and CLIA programs.
- Determines program eligibility for all providers and suppliers under the Medicare program, and executes required agreements.
- Initiates, implements, and coordinates State related adverse actions and alternative remedies, including civil money penalties, and Federal activities against health care facilities not in compliance with Medicare or CLIA requirements.
- Establishes and maintains an extensive data and information gathering system involving all aspects of the certification program and CLIA.
- Responds to beneficiary, Congressional, provider, and public inquiries concerning Medicaid issues, including Freedom of Information Act requests.
- Develops and conducts training programs for the State survey agencies.
- Monitors and evaluates State activities related to Medicare and Medicaid survey and certification.
- Plans, manages and provides Federal leadership to State agencies in program development, implementation, maintenance, and the regulatory review of State Medicaid program management activities under title XIX of the Social Security Act.
- Plans, directs, coordinates, and approves Medicaid State agency data processing systems, proposals, modifications, operations, contracts and reviews. Assists Medicaid State agencies in developing innovative automated data processing health care systems. Assures the propriety of Federal expenditures.
- Maintains day-to-day liaison with State agencies and monitors their Medicaid program activities and practices by conducting periodic program management and financial reviews to assure State adherence to Federal Law and regulations.
- Reviews, approves, recommends disapproval, and maintains official State plans and plan amendments for medical assistance.