fifteen percent of their time enforcing the Maine Act. Debt collector licensing is also the primary responsibility of the Superintendent and Deputy Superintendent of the Bureau of Consumer Credit Protection.

The Maine Bureau reviews the financial posture of collection firms applying for licenses and handles numerous written debt collector complaints each year, along with hundreds of telephone complaints and questions. Three additional individuals in the office (consumer assistance specialists) are trained to respond to these inquiries about the activities of debt collectors, with regard to both federal and state debt collection law; they also routinely petition the administrator to initiate enforcement proceedings to deal with suspected violations of the Maine Act. The agency has been involved in at least four court actions in the past two years relating to unlicensed practice or license revocation. In addition, the Maine Bureau has obtained voluntary Assurances of Discontinuance from ten debt collectors during the same time period. The Maine Bureau publishes its enforcement actions and mails the information to all licensed companies as a deterrent to further violative practices.

All license fees and examination reimbursement costs accrue to the agency as dedicated revenue within the State's budget process. In addition, a portion of creditor and lender ''volume fees'' based upon the amount of consumer credit extended is also dedicated to enforcement activities of the Maine Bureau, on the theory that the hiring of collection agencies by consumer creditors justifies the funding by those creditors of a portion of the cost of regulating them. Approximately $100,000 of the Maine Bureau's total budget of $800,000 is derived from sources of revenue related to debt collection activity and directed toward enforcement of the Maine Act.

Thus, the personnel, facilities and funding devoted to administering and enforcing the Maine Act are comparable to the resources expended by the Commission in enforcing the FDCPA. The fact that these resources will be directed at the activities of debt collectors in one state supports Maine's contention that it will have a greater enforcement presence in the State of Maine under the Maine Act than the Commission does nationally under the FDCPA.

C. Conclusion

After consideration of the facilities, personnel and funding devoted to administrative enforcement of the Maine Act and the Maine Act's provisions for civil liability and appropriate statutes of limitations for both private and governmental actions, the Commission finds that provisions for enforcement of the Maine Act are adequate, as required by Section 901.4(b) of the Procedures.

Action Taken

Based on the submissions of the Maine Bureau of Consumer Credit Protection in support of its request for an exemption and upon the comments received, the Commission concludes that the Maine Act is substantially similar to, and in some instances provides greater protection than, the FDCPA and contains provisions for adequate enforcement. As such, it meets all of the criteria set forth in Section 901.4 (a) and (b) of the Procedures. The Commission has granted to the State of Maine an exemption from Sections 803–812 of the FDCPA for debt collection practices conducted within the State on that basis, in accordance with Section 817 of the FDCPA. The exemption will remain in effect as long as state law continues to afford substantially equivalent protection to that of the FDCPA.

To ensure that the conditions for an exemption continue to be met, the State of Maine must provide notice to the Commission of any change in its law, policies or procedures, including court decisions, that would significantly affect whether the state law continues to afford substantially equivalent protection and whether the State is effectively enforcing the Maine Act. In any event, the State of Maine must provide a report to the Commission not later than two years after the date this exemption becomes effective, and every two years thereafter, concerning the manner in which the State has enforced its law. The Commission reserves the right to revise this reporting requirement at a later date if circumstances warrant or to request additional information as needed.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 95–31316 Filed 12–26–95; 45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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:

Allergenic Products Advisory Committee

Date, time, and place. January 22, 1996, 3 p.m., Food and Drug Administration, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 4:40 p.m.; closed committee deliberations, 4:40 p.m. to 5:30 p.m.; William Freas or Sheila D. Langford, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or

FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Allergenic Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of allergenic biological products intended for use in the diagnosis, prevention, or treatment of human disease.

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 January 16, 1996, then submit a brief statement of the general nature of the evidence or arguments they wish to present, the name and addresses of the proposed participants, and the indication of the approximate time to make comments.

Open committee discussion. The committee will discuss issues relevant to an extension of the deadline for the distribution of standardized and nonstandardized grass pollen extracts.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to three investigational new drug applications. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. January 29, 30, and 31, l996, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Closed committee deliberations, January 29, 1996, 8 a.m. to 9 a.m.; open committee discussion, 9 a.m. to 6:30 p.m.; open public hearing, January 30, l996, 8 a.m. to 8:30 a.m., unless public participation does not last that long; open committee discussion, 8:30 a.m. to 3 p.m.; open public hearing, 3 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5:30 p.m.; closed committee deliberations, January 31, l996, 8 a.m. to 10 a.m.; open public hearing, 10 a.m. to 10:15 a.m., unless public participation does not last that long; open committee discussion, 10:15 a.m. to 1 p.m.; Nancy T. Cherry or Sandy M. Salins, Scientific Advisors and Consultants Staff (HFM–21), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

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 January 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. On January 29, 1996, the committee will review safety and efficacy data relating to a product licensing application for a rabies vaccine by Behringwerke A. G. and a product licensing application for a combined diphtheria, tetanus, and acellular pertussis (whooping cough) vaccine with infant indication from Connaught Laboratories. On January 30, l996, the committee will discuss the influenza virus vaccine formulation for 1996–1997 and sequential schedules of inactivated polio vaccines and oral polio vaccines. On January 31, l996, the committee will review safety and efficacy data relating to a product licensing application from Merck for an inactivated Hepatitis A vaccine.

Closed committee deliberations. On January 29 and 31, l996, the committee will review trade secret and/or confidential commercial information relevant to pending product licensing applications. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C 552b(c)(4)).

Each public advisory committee meeting listed above 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. The dates and times reserved for the separate 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

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: December 18, 1995.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 95–31292 Filed 12–26–95; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting 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.

MEETING: The following advisory committee meeting is announced:

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. January 25, 1996, 8:30 a.m., and January 26, 1996, 9 a.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD 20892. Parking in the Clinical Center Visitor area is reserved for clinical center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times.

Type of meeting and contact person. Open public hearing, January 25, 1996, 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 5:30 p.m.; open committee discussion, January 26, 1996, 9 a.m. to 4:30 p.m.; Joan C. Standaert (HFD–110), 419–259–6211; or Valerie M. Mealy (HFD–21), Center for Drug Evaluation and Research, 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) Cardiovascular Drugs Advisory Committee, code 12533.

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 cardiovascular and renal disorders.

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 January 13, 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 January 25, 1996, the committee will discuss a Current Controversy: Calcium Channel Blockers. On January 26, 1996, the committee will review the Center for Biologics Evaluation and Research's product license application 95–1210, imciromaba pentetate (Myoscint, Centocor), a monoclonal antibody for use as an imaging agent for diagnosis of cardiac necrosis.

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,