file required annual reports on these NDA's.

EFFECTIVE DATE: May 24, 1996.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1038.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs or antibiotic drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81).

In the Federal Register of July 13, 1990 (55 FR 28829), FDA offered an opportunity for a hearing on a proposal to withdraw approval of five NDA's because the firms had failed to submit the required annual reports for these NDA's.

The agency had two responses to the notice of opportunity for hearing: From Astra Pharmaceutical Products, Inc.; and from The Purdue Frederick Co. Both responses indicated that the sponsors had previously submitted letters requesting voluntary withdrawal of their NDA's (NDA 13–077 and NDA 11–160, respectively). In the Federal Register of March 27, 1996 (61 FR 13506 at 13507), FDA published a notice that withdrew these applications.

The other three firms did not respond to the notice of opportunity for hearing. Failure to file a written notice of participation and request for a hearing as required by 21 CFR 314.200 constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Drug Evaluation and Research, is withdrawing approval of the NDA's listed in the table in this document.

Application no.	Drug	Applicant
NDA 9–394	Kasdenol Mouthwash or Gargle	The Kasdenol Corp., Huntington, NY 11743.
NDA 10–094	Pepsodent Antiseptic Mouthwash	Lever Brothers Co., Inc., 390 Park Ave., New York, NY 10022.
NDA 13–397	Ampar SRC	United Pharmaceutical Inc., 1500 North Wilmut, Tucson, AZ 85712.

The Director, Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority of 21 CFR 5.82, finds that the holders of the applications listed above have repeatedly failed to submit reports required by § 314.81. Therefore, pursuant to this finding, approval of the NDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective May 24, 1996.

Dated: April 9, 1996.

Murray M. Lumpkin,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 96–10022 Filed 4–23–96; 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:

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. May 2, 1996, 8:30 a.m., and May 3, 1996, 9 a.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. 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, May 2, 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, May 3, 1996, 9 a.m. to 4:30 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211; or Valerie M. Mealy, Advisors and Consultants Staff (HFD–21), 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533. Please call the hotline for information concerning any possible changes.

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 April 19, 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 May 2, 1996, the committee will discuss: (1) New drug application (NDA) 20–297, Supplement 1, Coreg® (carvedilol), SmithKline Beecham, to be indicated for use in congestive heart failure; and (2) NDA 20–405, Lanoxin® (digoxin)

tablets, Glaxo-Wellcome, for congestive heart failure, and control of ventricular rate in atrial fibrillation. On May 3, 1996, the committee will discuss product license application 95–1167, reteplase, Boehringer Mannheim, for management of acute myocardial infarction (AMI) in adults, lysis of thrombi obstructing coronary arteries, improvement of ventricular function following AMI, reduction of the incidence of congestive heart failure, and reduction of mortality associated with AMI.

FDA regrets that it was unable to publish this notice 15 days prior to the May 2, 1996, Cardiovascular and Renal Drugs Advisory Committee meeting. Because the agency feels that the issue needs to be brought to public discussion urgently, and qualified members of the Cardiovascular and Renal Drugs Advisory Committee were available at this time, the agency decided that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Arthritis Advisory Committee

Date, time, and place. May 7, 1996, 8 a.m., Holiday Inn—Gaithersburg, Whetstone and Walker Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, FAX 301–443–0699, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Arthritis Advisory Committee, code 12532. Please call the hotline for information concerning any possible changes.

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

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 May 1, 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 hear presentations and discuss data submitted regarding the safety and efficacy of NDA 20–395, Enable® (tenidap sodium), Pfizer, Inc., for use in the treatment of rheumatoid arthritis and osteoarthritis.

FDA regrets that it was unable to publish this notice 15 days prior to the May 7, 1996, Arthritis Advisory Committee meeting. Because the agency feels that the issue needs to be brought to public discussion urgently, and qualified members of the Arthritis Advisory Committee were available at this time, the agency decided that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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: April 18, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–10047 Filed 4–23–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for