submitted only once and amended as necessary. Our experience is that a State will amend a Plan once every 4 years; approximately 12 per year.

Respondents: State governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case plan	51	1	15	180

Estimated Total Annual Burden Hours: 180.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: June 12, 1996.

Larry Guerrero,

Director, Office of Information Services.

[FR Doc. 96–16620 Filed 6–28–96; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 96M–0193]

Kaneka America Corp.; Premarket Approval of Liposorber LA–15 System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Kaneka America Corp., New York, NY, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Liposorber LA–15 System. After reviewing the recommendation of the Gastroenterology and Urology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of February 21, 1996, of the approval of the application.

DATES: Petitions for administrative review by July 31, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Linda L. Dart, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220.

SUPPLEMENTARY INFORMATION: On October 3, 1991, Kaneka America Corp., New York, NY 10022, submitted to CDRH an application for premarket approval of the Liposorber LA–15 System. The device is a low density lipoprotein (LDL) apheresis system, indicated for use in performing low density lipoprotein cholesterol (LDL–C) apheresis to acutely remove LDL–C from the plasma of the following high risk patient populations for whom diet has been ineffective and maximum drug therapy has either been ineffective or not tolerated: Group A—functional hypercholesterolemic homozygotes with LDL–C > 500 milligrams/deciliter (mg/dL); Group B—functional hypercholesterolemic heterozygotes with LDL–C ≥ 300 mg/dL; and Group C—functional hypercholesterolemic heterozygotes with LDL–C ≥ 200 mg/dL and documented coronary heart disease (CHD).

The LDL–C levels for the indicated patient populations are baseline LDL–C levels obtained after the patient has had, at a minimum, a 6-month trial of an American Heart Association Step II diet (or equivalent) and maximum tolerated combination drug therapy designed to reduce LDL–C. Maximum tolerated combination drug therapy is an adequate trial of drugs from at least two separate classes of hypolipidemic agents such as, bile acid sequesterants, HMG–CoA reductase inhibitors, fibric acid derivatives, niacin/nicotinic acid, etc. Documented CHD includes documentation of coronary artery disease by coronary angiography or a history of myocardial infarction, coronary artery bypass surgery, percutaneous transluminal coronary angioplasty (PTCA) or alternative revascularization procedure (e.g., atherectomy or stent), or progressive angina documented by exercise or nonexercise stress test. Baseline lipid levels are to be determined after stabilization on diet and drug therapy by making two measurements during a 2- to 4-week period. (Note: the two values should be within 10 percent of each other, indicating a stable condition.)

Although clinical benefit of LDL–C lowering has been documented in several diet, drug and/or surgical intervention trials, clinical studies using the Liposorber LA–15 System were not designed to address and did not establish the long-term clinical benefit of acutely lowering LDL–C.

On April 21, 1995, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory panel, reviewed and recommended approval of the application. On February 21, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory

committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before July 31, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 9, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–16663 Filed 6–28–96; 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:

Advisory Committee for Reproductive Health Drugs

Date, time, and place. July 19, 1996, 9 a.m., FDA Technical Center, 16071 Industrial Dr., Gaithersburg, MD. Attendees should allow time to proceed through security procedures. Admission to the facility by public participants will be available on a first come, first serve basis, and will be limited to approximately 200, the number of seats available to the public in the conference room. There will be an overflow room with both audio and video link to the meeting. The overflow room is located at the Hilton Hotel, 620 Perry Pkwy., Gaithersburg, MD.

Type of meeting and contact person. Open committee discussion, 9 a.m. to 1:30 p.m.; open public hearing, 1:30 p.m. to 3:30 p.m., unless public participation does not last that long; open committee discussion, 3:30 p.m. to 5 p.m.; Philip A. Corfman, Center for Drug Evaluation and Research (HFD–580), Food and Drug Administration, 5600 Fishers Lane, rm. 14B–04, Rockville, MD 20857, 301–443–3510, FAX 301–443–9282, or e-mail july19@cder.fda.gov. Information concerning the meeting is available from FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Advisory Committee for Reproductive Health Drugs, code 12537. 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 the practice of obstetrics, gynecology, and related specialties.

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 in writing by mail, e-mail, or fax no later than 5 p.m., EDT on July 12, 1996, with a brief statement of the general nature of the evidence or arguments they wish to present, the names, telephone numbers, and addresses of proposed participants, and an indication of the approximate time required to make their comments. The time for presentations will be allotted equitably, and will depend on how many individuals give advance notice within the time indicated of their intention to speak. In the interest of time, the agency may require persons with common interests to make joint presentations.

Open committee discussion. The committee will discuss the new drug application for mifepristone for the interruption of early pregnancy.

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