The total annual burden is 78.00. Send comments to Desk officer, CDC; Human Resources and Housing Branch, New Executive Office Building, Room 10235; Washington, DC 20503.

Dated: June 25, 1996.

Wilma G. Johnson,
Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–16648 Filed 6–28–96; 8:45 am]
BILLING CODE 4163–18–P

National Center for Environmental Health; Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) will convene the following meeting cosponsored by the American Association for Clinical Chemistry and the American Heart Association.


Times and Dates: 8 a.m.–5 p.m., October 4, 1996; 8 a.m.–5 p.m., October 5, 1996; 8 a.m.–12 noon, October 6, 1996.

Place: Renaissance Hotel—Dallas, 2222 Stemmons Freeway, Dallas, Texas 75207, telephone 214/631–2222.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 500 people.

Purpose: The purpose of this meeting is to provide a forum for presentation of recent advances in lipid and lipoprotein research by recognized experts in the areas of clinical practice, biochemistry, analytical measurement, and public health.

Matters To Be Discussed: Agenda includes: significant advances in lipid and lipoprotein research and new observations that are of critical importance to clinical practice and public health; an integrated review of relevant advances in basic science, measurement technology, epidemiological and clinical research, and public health practice to clearly define the state of the art for understanding and preventing morbidity and mortality due to heart disease.

Contact Persons For More Information: Mary M. Kimberly, Ph.D., Research Chemist, Special Activities Branch, Division of Environmental Health Laboratory Sciences, M/S F 25, NCEH, CDC, 4770 Buford Highway, NE., Chamblee, Georgia 30341–3724, telephone 770/488–4683, or Paula M. Steiner, Medical Research Laboratories, 2 Tesseneer Drive, Highland Heights, Kentucky 41076, telephone 606/781–8877 extension 252, fax 606/781–9310.

Dated: June 24, 1996.

Carolyn J. Russell,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–16649 Filed 6–28–96; 8:45 am]
BILLING CODE 4163–18–M

ANNUAL BURDEN ESTIMATES

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Estimated Total Annual Hours: 43,200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and any comments may be forwarded 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. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 25, 1996.

Larry Guerrero,
Director, Office of Information Services.
[FR Doc. 96–16694 Filed 6–28–96; 8:45 am]
BILLING CODE 4164–01–M

Submission for OMB Review; Comment Request

Title: State Plan for Foster Care and Adoption Assistance—Title IV–E.

OMB No.: 0980–0141.

Description: A State Plan for foster care and adoption assistance is required by section 471 of the Social Security Act from any State wishing to claim Federal Financial Participation for foster care and adoption assistance. States may use a preprint format or may develop their own format which meets the requirements of the law. The Plan is...
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

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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 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 the 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 cholesterol (LDL–C) 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 homozygotes 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 sequestrants, HMG-CoA reductase inhibitors, fibrac 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