information collection: E-mail address: *rsargis@acf.hhs.gov.*

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, Attn: Desk Officer for ACF, E-mail address: *lauren_wittenberg@omb.eop.gov.*

Dated: September 4, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–23335 Filed 9–12–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Low Income Home Energy Assistance Program (LIHEAP) Leveraging Report.

OMB.: 0970–0121.

Description: The LIHEAP leveraging incentive program rewards LIHEAP grantees that have leveraged nonfederal home energy resources for low income households. The LIHEAP leveraging report is the application for leveraging incentive funds that these LIHEAP grantees submit to the Department of Health and Human Services (HHS) for each fiscal year in which they leverage countable resources. Participation in the leveraging incentive program is voluntary and is described at 45 CFR 96.87.

The LIHEAP leveraging report obtains information on the resources leveraged by LIHEAP grantees each fiscal year (as cash, discounts, waivers, and in-kind); the benefits provided to low income households by these resources (for example, as fuel and payments for fuel, as home heating and cooling equipment, and as weatherization materials and installation); and the fair market value of these resources/benefits. HHS needs this information in order to carry out statutory requirements for administering the LIHEAP leveraging incentive program, to determine countability and valuation of grantees' leveraged nonfederal home energy resources, and to determine grantees' shares of leveraging incentive funds. HHS proposes to request a 3-year extension of OMB approval for the currently approved LIHEAP leveraging report information collection.

Respondents: State, Local or Tribal Governments.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Detailed Model Plan	70	1	38	2,660
Estimated Total Annual Burden Hours				2,660

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.*

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, Attn: Desk Officer for ACF. E-mail address *lauren_wittenberg@omb.eop.gov.*

Dated: September 9, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–23336 Filed 9–12–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0222]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 15, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Product Jurisdiction Assignment of Agency Component for Review of Premarket Applications

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)), as added by the Safe Medical Devices Act of 1990 (Public Law 101–629), and amended by the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA assigned to have primary jurisdiction for

the premarket review and regulation of products that are comprised of any combination of these components: (1) A drug and a device, (2) a device and a biological, (3) a biological and a drug, or (4) a drug, a device, and a biological. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for classifying and determining which agency component is designed to have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute.

The regulation establishes a procedure by which an applicant may obtain an assignment or designation determination. The regulation requires that the request include the identity of the applicant, a comprehensive description of the product and its proposed use, and the applicant's recommendation as to which agency component should have primary jurisdiction, with an accompanying statement of reasons. The information submitted would be used by FDA as one of the bases for making the assignment or designation decision. Most information required by the proposed regulation is already required for premarket applications affecting drugs, devices, biological, and combination products. The respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3	28	1	28	24	672
Total					672

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the **Federal Register** of Monday, June 23, 2003 (68 FR 37160), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: September 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–23509 Filed 9–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1984F–0095]

Genencor International, Inc.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 4A3806) proposing that the food additive regulations be amended to provide for the safe use of a polyamine-epichlorohydrin resin and glutaraldehyde, together, as fixing agents in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3106.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 26, 1985 (50 FR 16558), FDA announced that a food additive petition (FAP 4B3806 (which was later redesignated as FAP 4A3806)) had been filed by Miles Laboratories, Inc., Elkhart, IN 46515. The petition proposed to amend the food additive regulations in §173.357 *Materials used as fixing agents in the immobilization of enzyme preparations* (21 CFR 173.357) to provide for the safe use of a polyamine-epichlorohydrin resin and glutaraldehyde, together, as fixing agents in the immobilization of glucose isomerase enzyme preparations for use in the manufacture of high fructose corn syrup. On May 24, 2000, Genencor International, Inc., 925 Page Mill Rd., Palo Alto, CA 94304, informed FDA in writing that they had acquired the rights to FAP 4A3806. Genencor International, Inc., has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: August 27, 2003.

Laura M. Tarantino,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 03–23332 Filed 9–12–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 7, 2003, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Dornette Spell-LeSane, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *spelllesaned@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the Women's Health Initiative study