that a collection of information entitled ''Medical Devices; Current Good Manufacturing Practice (CGMP) Quality System (QS)'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 15, 1998 (63 FR 32667), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0073. The approval expires on July 31, 2001.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23403 Filed 8–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0385]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by October 1, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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

Supplements to Premarket Approval Applications for Medical Devices

The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) added section 515(d)(6) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(6)), modifying FDA's statutory authority regarding premarket approval of medical devices. This new section provides for an alternate form of notice to the agency for certain types of changes to a device for which the manufacturer has an approved premarket approval application (PMA). Under section 515(d)(6) of the act, PMA supplements are required for all changes that affect safety and effectiveness, unless such changes involve modifications to manufacturing procedures or the method of manufacture. For those types of manufacturing changes, the manufacturer may submit to the agency an alternate form of notice in the form of a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement. The 30-day notice must: (1) Describe the change the manufacturer intends to make, (2) summarize the data or information supporting the change, and (3) state that the change has been made in accordance with the requirements of 21 CFR part 820.

The manufacturer may distribute the device 30 days after FDA receives the notice, unless FDA notifies the applicant, within that 30-day period, that the notice is inadequate. If the notice is inadequate, FDA will inform the manufacturer that a 135-day supplement is required and will describe what additional information or action is necessary for FDA to approve the change. The rule would incorporate the provisions for a 30-day notice and 135-day supplements into FDA's regulations in § 814.39 (21 CFR 814.39) to reflect the changes made by FDAMA.

Description of Respondents: Businesses or other for profit organizations.

The information collection for § 814.39 has been approved by OMB until September 30, 1998, under Premarket Approval of Medical Devices (OMB control number 0910–0231) for a total of 36,063 hours. FDA believes that the submission of 30-day notices in lieu of PMA supplements will result in approximately a 10 percent reduction in the total number of hours needed to comply with § 814.39. As a result, FDA estimates that the new total number of hours needed to comply with the information collection requirements in § 814.39 is 32,612 for a reduction of 3,451 hours.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
814.39	493	1	493	66.15	32,612

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

Dated: July 31, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23404 Filed 8–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0717]

Mitsubishi Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Mitsubishi Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sucrose esters of fatty acids with an average degree of esterification ranging from four to seven, as an emulsifier or stabilizer at a level not to exceed 2 percent, in chocolate and in butter-substitute spreads. The petitioner is also proposing ''SOE'' as the common or usual name for this product.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3103.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8A4610) has been filed by Mitsubishi Chemical Corp., 5–2, Marunouchi 2-chome, Chiyoda-Ku, Tokyo 100, Japan. The petition proposes that the food additive regulations be amended to provide for the safe use of sucrose esters of fatty acids with an average degree of esterification ranging from four to seven, as an emulsifier or stabilizer at a level not to exceed 2 percent, in chocolate and in butter-substitute spreads. The petitioner is also proposing ''SOE'' as the common or usual name for this product.

The agency has determined under 21 CFR 25.32(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: August 12, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–23397 Filed 8–31–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of a meeting of the Center for Substance Abuse Treatment (CSAT) National Advisory Council to be held in September 1998.

A portion of the meeting will be open and include discussion of the Center's policy issues and current administrative, legislative, and program developments. Reports to the Council will include the Managed Care & Criminal Justice Conference, a CSAT/CMHS collaborative initiative on Dual Diagnosis, an ONDCP Update, SAMHSA HIV/AIDS Update and the Physicians Leadership Group. If anyone needs special accommodations for persons with disabilities, please notify the Contact listed below.

The meeting will also include the review, discussion, and evaluation of individual grant applications, contract proposals and discussion of information about the Center for Substance Abuse Treatment's procurement plans. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(3), (4), and (6) and 5 U.S.C. App. 2, § 10(d).

A summary of the meeting and roster of council members may be obtained from: Mrs. Marjorie Cashion, CSAT National Advisory Council, Rockwall II Building, Suite 619, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–8923.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Center for Substance Abuse Treatment, National Advisory Council.

Meeting Date: September 16, 1998—8:45 a.m.–5:00 p.m; September 17, 1998—9:00 a.m.–12:00 p.m.

Place: Holiday Inn/Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815.

Type: Closed: September 16, 1998—8:45 a.m.–10:00 a.m; *Open:* September 16, 1998—11:15 a.m.–5:00 p.m; September 17, 1998—9:00 a.m.–12:00 p.m.

Contact: Marjorie M. Cashion, Executive Secretary, Telephone: (301) 443–5050, and FAX: (301) 480–6077.

Dated: August 25, 1998.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 98–23396 Filed 8–31–98; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4369–N–08]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: November 2, 1998.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Shelia E. Jones, Department of Housing & Urban Development, 451 7th Street, SW, Room 7230, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Tony Johnston, Deputy Director, Financial Management Division, Office of Block Grant Assistance, Room 7180, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, telephone (202) 708–1871. Hearing- or speech-impaired individuals may access this number via TTY by calling the Federal Information Relay Service at 1–800–877–8399. Fax inquiries may be sent to Mr. Johnston at (202) 708–1789. (Other than the ''800'' number, these telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected