TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

Collection Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Total					57,050

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

Maintenance costs were not estimated for the additional maintenance of records beyond the current 5 years to the recommended 10 years, because modern storage technology has markedly reduced the space needed to store records.

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. Because HCV frequently causes chronic infection of the liver, it can cause serious liver injury and can be life threatening, and because new therapies are recently available, it is essential to the agency's mission of protecting and promoting the public health that this guidance be made available to the public immediately. The information is needed immediately to replace the March 20, 1998, guidance that was withdrawn September 8, 1998. The use of normal clearance procedures could take 180 days or more, during which time guidance would not be in place, thus disrupting or preventing this collection of information.

Dated: October 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28218 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0811]

Agency Emergency Processing Request Under OMB Review

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns the submission by sponsors of investigational new drugs and applicants for new drug approvals or biological licenses under the Federal Food, Drug, and Cosmetic Act (the act) and the guidance for industry on fast track drug development programs.

DATES: Submit written comments on the collection of information by November 5, 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION:

I. Guidance for Industry

FDA is preparing a guidance entitled ''Guidance for Industry: Designation, Development, and Application Review for Products in Fast Track Drug Development Programs.'' The guidance will provide the agency's interpretation of terms central to FDA's fast track programs and the agency's views on information that should accompany fast track program submissions.

With respect to the following collection of information, FDA invites comment on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry: Designation, Development, and Application Review for Products in Fast Track Drug Development Programs

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amends the act by adding section 506 (21 U.S.C. 356) and authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to meet an unmet medical need. The issuance of the guidance will be under section 112(b) of FDAMA, which requires the agency to issue guidance regarding fast track policies and procedures within 1 year of the date of enactment of FDAMA, November 21, 1997. The guidance will discuss collections of information that are expressly specified under section 506 of the act, other sections of the Public Health Service Act (PHS Act), or implementing regulations. For example, under section 506 of the act, an applicant who seeks fast track designation must submit a request to FDA. Some of the support for such a request may be required under regulations, such as parts 312, 314, and 601 (21 CFR parts 312, 314, and 601), which specify the types and format of information and data that should be submitted to FDA for evaluation of the safety and effectiveness of investigational new drug applications (IND's) (part 312), new drug applications (part 314), or biological license applications (part 601). The guidance will describe three general areas involving collection of information: Designation requests, pre-meeting packages, and requests to submit portions of an application. Of these, designation requests, and pre-meeting packages in support of obtaining a fast track program benefit will provide for additional collections of information not provided elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the agency, may, in some cases, be incorporated by referring to them rather

than by resubmission. In some instances, a summary of data and information may be submitted in support of fast track designation or fast track program benefits. Therefore, FDA anticipates that the PRA reporting burden under the guidance will be minimal.

II. Fast Track Designation Request

Under section 506(a)(1) of the act, an applicant who seeks fast track designation is required to submit a request to the agency. In order to receive a fast track designation, the requester must establish that the product meets the statutory standard for designation, i.e., that: (1) The product is intended for a serious or life-threatening condition; and (2) the product has the potential to address an unmet medical need. In most cases, the agency expects that information to support a designation request will have been gathered under existing provisions of the act, the PHS Act, or the implementing regulation. Such information, if already submitted to the agency, may be summarized in a fast track designation request. The guidance will also recommend that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to meet an unmet medical need where approved therapy exists for the serious or life-threatening condition to be treated. Such information may include: Clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

A. Pre-Meeting Packages

After the agency makes a fast track designation, a sponsor or applicant may submit a pre-meeting package, which may include additional information to support a request to participate in certain fast track programs. As with the request for fast track designation, the agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the act, the PHS Act, or implementing regulations, such as descriptions of clinical safety and efficacy trials not conducted under an IND (i.e., foreign studies), and information to support a request for accelerated approval. If information has been previously submitted to FDA under an OMB approved collection of information, the discussion of such information in a fast track pre-meeting package may be summarized. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

B. Request to Submit Portions of an Application

Section 506(c) of the act requires a collection of information before an applicant may be permitted to submit to FDA portions of an application for review. Under this provision of the fast track statute, a sponsor must submit clinical data sufficient for the agency to determine, after preliminary evaluation, that a fast track product may be effective. Section 506(c) also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance will not provide for any new collection of information regarding the submission of portions of an application that is not required under section 506(c) or any other provision of the act.

1.*FDA Forms Referred to in the Guidance*

All forms that will be referred to in the guidance have valid OMB control numbers. These forms include: FDA Form 1571 (OMB Control No. 0910–0104, expires December 31, 1999); FDA Form 356h (OMB Control No. 0910–0338, expires April 30, 2000); and FDA Form 3397 (OMB Control No. 0910–0297, expires April 30, 2001).

2. *Description of Respondents*

Sponsors and applicants that seek fast track designation under section 506 of the act.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Designation request	60	1	60	60	3,600
Pre-meeting packages	54	1	54	100	5,400
Total	114		114		9,000

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

The agency estimates that the aggregate annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) will be approximately 60. To obtain this estimate, FDA extrapolated from the number of requests for fast track designation actually received by CBER and CDER in a 6-month period since November 21, 1997, the date of enactment of FDAMA. Within this time period, CBER received 9 requests, and CDER received 20 requests. FDA estimates that the number of hours needed to prepare a request for fast track designation may generally range between 40 and 80 hours per request, depending on the complexity of each request, with an average of 60 hours per request, as indicated in Table 1 of this document.

Not all requests for fast track designation may meet the statutory standard. The agency estimates that approximately 90 percent of all annual requests, approximately 54 respondents, for fast track designation would be granted. Of those respondents who receive fast track designation for a product, FDA expects that all will submit a pre-meeting package and that a pre-meeting package would generally need more preparation time than needed for a designation request because the issues may be more complex and the data may need to be more developed. FDA estimates that the preparation hours may generally range between 80 and 120 hours, with an average of 100 hours per package, as indicated in Table 1 of this document.

The hour burden estimates contained in Table 1 of this document are for information collections requests in the guidance only and do not include burden estimates for statutory requirements specifically mandated by the act, the PHS Act, or implementing regulations.

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately to implement section 506 of the act, which requires the agency to facilitate development and expedite the review of new drug products, including biological products, intended to treat a life-threatening or serious condition and that demonstrate a potential to meet an unmet medical need. The use of normal information clearance procedures would be likely to result in the prevention or disruption of this collection of information because section 112(b) of FDAMA requires FDA to issue guidance on fast track policies and procedures no later than November 21, 1998, i.e., within 1 year of the date of enactment of FDAMA.

Dated: October 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28305 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0893]

Great Lakes 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 Great Lakes Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine as an ultraviolet (UV) stabilizer for high density polyethylene and polypropylene intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 8B4633) has been filed by Great Lakes Chemical Corp., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) to provide for the safe use of siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine as a UV stabilizer for high density polyethylene and polypropylene intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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: October 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–28149 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0194]

Agency Information Collection Activities; Announcement of OMB Approval; Registration of Cosmetic Product Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Registration of Cosmetic Product Establishment'' 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 July 30, 1998 (63 FR 40718), 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 0910–0027. The approval expires on October 31, 2001.

Dated: October 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28220 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Antibody to Human T–Cell Lymphotropic Virus Type II (HTLV–II) Reference Panel 1; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a new FDA reference panel for tests intended to detect antibody to human T–cell lymphotropic virus Type II (HTLV–II Reference Panel 1). The HTLV–II Reference Panel 1 is used for the qualitative and semiquantitative evaluation of in vitro tests to detect antibody to HTLV–II in human serum or plasma. The HTLV–II Reference Panel 1 is designed to provide a release criterion for lots of HTLV–II antibody detection kits produced by licensed manufacturers of such tests and should not be used for experimental or other reference purposes.

DATES: The HTLV–II Reference Panel 1 was made available to the licensed manufacturers on June 4, 1998.

FOR FURTHER INFORMATION CONTACT: Charles O. Roberts, Center for Biologics Evaluation and Research (HFM–323), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–6721.

SUPPLEMENTARY INFORMATION: The HTLV–II Reference Panel 1 is a regulatory test panel intended for lot release testing of enzyme-linked immunosorbent assay (ELISA) HTLV–II antibody test kits produced by licensed manufacturers. The HTLV–II Reference Panel 1 consists of eight samples, six of which are reactive for antibody to HTLV–II. These reactive sera have been prepared by diluting known positive sera into a pool of normal human sera negative for antibodies to HTLV–II. Three of the diluted samples are expected to be repeatedly reactive for antibodies to HTLV–II by ELISA and three have borderline ELISA reactivity. The Center for Biologics Evaluation and