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

Research will limit the distribution of the HTLV–II Reference Panel 1 to conserve these reagents when necessary. The HTLV–II Reference Panel 1 is available for distribution from the contact person listed above.

Dated: October 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28219 Filed 10–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0814]

''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document (dated September 1998) entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.'' The guidance document provides recommendations for donor screening and supplemental testing for antibody to hepatitis C virus (HCV), notification of consignees and quarantine of prior collections from a donor who later tests repeatedly reactive for antibody to HCV, notification of recipients of blood and blood components at increased risk for transmitting HCV.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by calling the Fax Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

For technical/scientific questions, contact Robin M. Biswas, Center for Biologics Evaluation and Research (HFM–325), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3011 or by FAX 301–496–0338.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units From Prior Collections From Donors With Repeatedly Reactive Screening Test for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV.'' This guidance provides recommendations for the following: (1) Quarantine (and release) of prior collections form donors who later test repeatedly reactive for antibody to HCV; (2) supplemental testing and notification of consignees and transfusion recipients; (3) procedures and recordkeeping; (4) review of records of donor testing for ''historical'' repeatedly reactive donations; (5) quarantine (and release) of prior collections, notification of consignees and transfusion recipients based on the review of records; (6) additional testing following an indeterminate RIBA 2.0 test result; and (7) additional testing of donors with no record of supplemental testing on the ''historical'' repeatedly reactive screening test.

On March 20, 1998 (63 FR 13675), FDA announced the availability of ''Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV),'' (the March 1998 guidance). This guidance included a recommendation that consignee notification should commence no later than 6 months after date of issuance of the guidance, i.e., by September 20, 1998.

On June 18, 1998, FDA made known at a public meeting of its Blood Products Advisory Committee (BPAC) its intention to respond to public comments received to the docket for the guidance by reissuance of a comprehensive guidance on the same subject. At the BPAC meeting, FDA announced it was considering changes to the ''HCV lookback'' policy, including revision of recommendations for the additional testing of donor samples and revision of FDA recommendations for implementation timeframes. These changes were based on feasibility considerations which had been raised by the public comments and evaluated by FDA.

During June and July 1998, FDA continued to receive extensive public comments to the docket. These were reviewed and evaluated carefully by CBER. CBER continued to work on modification of the guidance. Although FDA intended to issue a revised guidance by the end of July, the revision was delayed in order to incorporate additional public comments that had been received.

Since FDA did not want to be in the position of having the guidance in place with a compliance date that was being revised, the best option, under the agency's Good Guidance Practices, was for FDA to issue a notice to withdraw the current guidance pending issuance of another comprehensive guidance. This withdrawal was posted on September 8, 1998. The guidance now being issued reflects the agency's current position on this matter. This guidance supersedes FDA's March 1998 guidance. Additionally, this guidance supersedes the recommendations related to HCV in FDA's July 19, 1996,