Dated: November 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26331 Filed 11–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0063]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary Registration of Cosmetic Product Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Voluntary Registration of Cosmetic Product Establishments'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 19, 2004 (69 FR 43001), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 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 November 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: November 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26332 Filed 11–29–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004F–0455]

Sterigenics International, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sterigenics International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of ionizing radiation in the production of shelf stable foods, including multiple ingredient shelf stable foods.

FOR FURTHER INFORMATION CONTACT: Lane A. Highbarger, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1204.

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 3M4744) has been filed by Sterigenics International, Inc., P.O. Box 17349, Memphis, TN 31817–0349. The petition proposes that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR 179) be amended to provide for the safe use of ionizing radiation in the production of fully cooked shelf stable foods, including fully cooked multiple ingredient shelf stable foods, where the absorbed dose required to cause a 12-log reduction in *Clostridium botulinum* has been established.

The agency has determined under 21 CFR 25.32(j) 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: October 28, 2004.

Laura M. Tarantino,

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

[FR Doc. 04–26334 Filed 11–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0383]

Guidance for Industry and Food and Drug Administration Staff; Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.'' This document provides guidance on the use of selected symbols from international standards already recognized by FDA in place of text to convey some of the information required for in vitro diagnostic devices (IVDs) intended for professional use by FDA's labeling requirements for IVDs.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1217; or Sheryl A. Kochman, Center for Biologics Evaluation and