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

Research (HFM–390), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3524.

SUPPLEMENTARY INFORMATION:

I. Background

The market for in vitro diagnostic devices is international. European Union (EU) member countries have attempted to harmonize their national legislation governing IVDs through the EU's Directive on In Vitro Diagnostic Medical Devices (Directive 98/79/EC) (IVD Directive). The EU's IVD Directive went into full effect on December 8, 2003. As of that date, IVD products marketed in the EU must comply with the IVD Directive and bear the CE mark (mark showing that the product is certified for sale in the European community) to indicate compliance.

The EU's IVD Directive and FDA regulations in § 809.10 (21 CFR 809.10) and parts 610 and 660 (21 CFR parts 610 and 660) all require substantial information to appear on the IVD itself and/or in its labeling. The IVD Directive specifically allows each EU member State to require that such information appear in its national language, so that a single IVD could be required to bear labeling in multiple languages in order to be sold in the EU. As an alternative, the IVD Directive encourages that, in place of text, IVDs use symbols from harmonized standards to convey the required information. Given that the use of national languages may be required by individual member States and that most IVDs and their packaging are quite small, the IVD Directive's symbols provision represents an avenue through which manufacturers can achieve compliance in an international marketplace.

Similarly, the use of symbols helps IVD manufacturers to create uniform labels and labeling for the United States and the EU (and any other countries that may permit use of symbols from these international standards), instead of needing designated labels for each marketplace. Because symbols take up less space than the text for which they may substitute, the use of symbols promotes less crowded and more legible IVD labels. An additional advantage is that there are likely to be fewer labeling errors when using a single label, rather than having one set of labels for use in the United States and another set for use in the EU. Of course, it is essential that the symbol convey the substance of the deleted text and be widely understood.

Therefore, in accordance with the consensus standards recognition process, established by section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), in the **Federal Register** of April 28, 2003 (68 FR 22391), corrected by 68 FR 61448 (October 28, 2003), FDA recognized for use on the labels and labeling of IVDs intended for professional use 25 symbols from the 2 international consensus standards:

- ISO 15223, Medical Devices; Symbols to be Used With Medical Device Labels, Labeling and Information to be Supplied, and
- EN 980, Graphical Symbols for Use in the Labeling of Medical Devices.

The guidance document entitled ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use'' provides guidance on the use of those recognized symbols.

FDA announced the availability of the level 1 draft guidance document in the **Federal Register** of October 28, 2003 (68 FR 61449). While comments on guidances may be submitted at any time, FDA invited interested persons to submit written or electronic comments on the draft guidance by November 28, 2003, to ensure adequate consideration of the comments. The comment period for the proposed information collection provisions closed on December 29, 2003. FDA received seven comments from manufacturers on the draft guidance. However, many of the comments addressed issues beyond the scope of the use of the 25 FDA recognized symbols on IVD for professional use. FDA will continue to study these comments to determine what other actions may be appropriate. One comment suggested that the glossary of symbols recommended by the guidance be permitted to be provided as a separate labeling piece, rather than being incorporated into the package insert. In the guidance document, FDA continues to express its preference for the inclusion of the glossary as part of the package insert, although it recognizes that while package inserts are being revised, manufacturers may prefer to provide the glossary as a separate labeling piece. As with all aspects of the guidance, this position represents FDA's recommendation, and manufacturers may select an alternative approach if that approach satisfies the requirements of the applicable statute and regulations.

In addition, in the guidance document, FDA has decided to remove the statement in section III where FDA had proposed to exercise enforcement discretion if a company used the symbol that represents ''Manufacturer'' to satisfy § 610.64. Upon reflection, that symbol does not appear applicable to § 610.64.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance, when finalized, will represent the agency's current thinking on the use of symbols on the labels and in labeling only of IVDs intended for professional use, and not for over-the-counter or prescription home-use IVDs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use'' by fax, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (4444) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (the PRA). The collections of information described in sections VII and VIII of the guidance regarding a glossary of terms and educational outreach were approved by OMB in accordance with the PRA under OMB control number 0910–0553 which

expires on October 31, 2007. The guidance document also refers to labeling requirements, annual reporting requirements, and other information collections established under existing regulations. The collections of information described in section III of the guidance that result from § 809.10 were approved under OMB control number 0910–0485. The collections of information described in section III of the guidance that result from §§ 610.60, 610.61, and 610.62 were approved under OMB control number 0910–0338. The collections of information described in section III of the guidance that result from part 660 (§§ 660.2, 660.28, 660.35, 660.45, and 660.55) were approved under OMB control number 0910–0527. The collections of information described in section X of the guidance, regarding annual reports, were approved under OMB control numbers 0910–0231 and 0910–0338. The collections of information described in section X of this guidance, regarding adverse event reporting, were approved under OMB control numbers 0910–0437 and 0910–0291.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 9, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04–26333 Filed 11–29–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health Extramural Clinical Research Loan Repayment Program for Individuals From Disadvantaged Backgrounds

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) and the National Center on Minority Health and Health Disparities (NCMHD) announce the 2005 Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR–LRP or Program). The ECR–LRP provides for the repayment of educational loan debt of up to $35,000 annually for qualified health professionals from disadvantaged backgrounds conducting clinical research for domestic non-profit or government entities. In addition, the program will cover up to 39 percent of the Federal tax liability resulting from loan repayments, and may provide reimbursement for State and local tax liabilities.

The purpose of the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds is the recruitment and retention of highly qualified health professionals from disadvantaged backgrounds in careers in clinical research. Through this notice, the NIH and NCMHD invite qualified health professionals who are from disadvantaged backgrounds and interested in engaging in clinical research for at least two years, and who agree to engage in this area of research for at least 50 percent of their time, *i.e.*, no less than 20 hours per week, to apply for participation in the NIH Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds (ECR–LRP).

DATES: Interested persons may request information about the Program beginning on November 30, 2004.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, NIH, 6011 Executive Blvd., Room 601, MSC 7669, Rockville, MD 20892, by e-mail: Moorej@mail.nih.gov, by fax: 301–402–0169, or by telephone: 301–496–4607 (not a toll-free number). For information regarding the requirements, application deadline dates, and on-line application for the ECR–LRP program, please visit the NIH Loan Repayment Program Web site at *http://www.lrp.nih.gov*, send an e-mail to *lrp@nih.gov*, call the LRP helpline at 866–849–4047 (toll-free number) or contact the NCMHD Loan Repayment Coordinator, Kenya McRae, at 301–402–1366 (not a toll-free number) or via e-mail: *mcraek@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: The Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds, which was originally authorized by section 487E of the Public Health Service (PHS) Act (42 U.S.C. 288–5), as amended by the National Institutes of Health Revitalization Act of 1993 (Pub. L. 103–43), provides for the repayment of the educational loan debt of health professionals who are from disadvantaged backgrounds, who have substantial debt relative to income, and who agree to conduct clinical research as employees of the NIH. The Consolidated Appropriations Act of 2001 (Pub. L. 106–554) amended section 487E of the PHS Act to allow expansion of the existing program to include health professionals who are not employees of the National Institutes of Health. Under the expanded authority, the Secretary of Health and Human Services (HHS) in consultation with the Director of NIH will enter into contracts with qualified health professionals from disadvantaged backgrounds under which such health professionals agree to conduct clinical research; in return, the Federal Government agrees to repay for each year of such research, up to $35,000 of their student loan debt.

The objective of the ECR–LRP is the recruitment and retention of highly qualified health professionals from disadvantaged backgrounds to clinical research careers. The emphasis on clinical research and individuals from disadvantaged backgrounds highlights the need for the involvement of a cadre of competent health professionals in clinical research.

''Clinical research'' as defined in section 206 of Pub. L. 106–505, the Public Health Improvement Act, enacted on November 13, 2000, means patient-oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiological or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

''An individual from a disadvantaged background'' is defined as one who comes from a family with an annual income below a level based on low-income thresholds according to family size published by the U.S. Bureau of the Census, adjusted annually for the changes in the Consumer Price Index, and adjusted by the Secretary of the U.S. Department of Health and Human Services (Secretary) for use in all health professions programs. The Secretary