and agreement to provide for the physical, mental and financial well-being of an unaccompanied minor and the sponsor's assurance to appear before immigration courts. To ensure the safety of the children, sponsors must undergo a background check. Suitable sponsors may be parents, close relatives, friends or entities concerned with the child's welfare. In this Notice, ACF announces that it proposes to employ the use of several information collections for recording: (1) The Sponsor's Agreement to Conditions of Release, which collects the sponsor's affirmation to the terms of the release; (2) the Verification of Release, which collects the children's affirmation to the terms of their release; (3) the Family Reunification Packet, which collects information related to the sponsor's ability to provide for the physical, mental and financial well-being of the child(ren); and (4) the Authorization for Release of Information, which collects information to be utilized for a background check.

Respondents: Potential sponsors of unaccompanied alien children and unaccompanied alien children in Federal custody.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Sponsor's Agreement	3,000	1	.166666	500
Verification of Release	3,000	1	.166666	500
Family Reunification Packet	3,000	20	.05	3,000
Authorization for Release of Information	3,000	12	.05	1,800

Estimated Total Annual Burden Hours: 5,800.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *grjohnson@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 24, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–26379 Filed 11–29–04; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0498]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of information of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for tracking of medical devices.

DATES: Submit written or electronic comments on the collection of information by January 31, 2005.

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

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Medical Devices; Device Tracking—21 CFR Part 821 (OMB Control Number 0910–0442)—Extension

Section 211 of the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115) became effective on February 19, 1998. It amended the previous medical device tracking provisions in section 519(e)(1) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(e)(1) and (e)(2) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629). Unlike the tracking provisions under SMDA, which required tracking for any device meeting certain criteria, FDAMA allows FDA discretion in applying tracking requirements to devices that meet certain criteria and provides that tracking requirements can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule to conform existing tracking regulations to changes in tracking provisions effected by FDAMA (part 821 (21 CFR part 821)).

Current section 519(e)(1) of the act, as amended by FDAMA, provides that FDA may by order require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of three criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences; (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a ''tracked implant''); or (3) the device is life-sustaining or life-supporting (referred to as a ''tracked l/s-l/s device'') and is used outside a device user facility.

Tracking information is collected to facilitate identifying the current location of tracked devices and patients possessing the devices, to the extent that patients permit the collection of identifying information. Manufacturers and, as necessary, FDA use the data to expedite the recall of distributed devices that are dangerous or defective, and to facilitate the timely notification of patients or licensed practitioners of the risks associated with the devices.

Respondents to this collection of information are manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The regulations include requirements for exemptions and variances; system and content requirements of tracking; obligations of persons other than device manufacturers, e.g., distributors; records and inspection requirements; confidentiality; and record retention requirements.

FDA estimates the burden of 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
821.2 (also 821.30(e))	4	1	4	12	48
821.25(a)	1	1	1	76	76
821.25(d)	22	1	22	2	44
821.30(a), (b)	17,000	72	1,222,725	0.1666	203,706
821.30(c)(2)	1	1	1	28	28
821.30(d)	17,000	15	259,186	0.1666	43,180
Total					247,082

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
821.25(b)	229	46,260	10,593,433	0.2899	3,071,036
821.25(c)	229	1	229	63.0	14,430
821.25(c)(3)	229	1,124	257,454	0.2899	74,636
Total					3,160,102

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

The annual reporting burden hours to respondents for medical device tracking is estimated to be 247,082 hours, and recordkeeping burdens for respondents is estimated to be 3,160,102 hours. These numbers have been rounded up. The estimates cited in tables 1 and 2 of this document are based primarily upon the data and methods provided in FDAs 1999 assessment entitled ''A Cost Assessment of Medical Device Tracking.'' Using implantation procedures from the National Center for Health Statistics, FDA applied a 2 percent annual growth rate to estimate the number of procedures for tracked implant devices from 1997–2006. The assessment also used unit shipment data in combination with various growth rates to estimate annual/sales distribution for the tracked l/s-l/s devices over the same time period. Additionally, the assessment estimates the industry burden for developing and maintaining tracking systems for these devices from 1997–2006.

For the annual recordkeeping burden, the number of manufacturers subject to device tracking (229) is based on data from FDA's manufacturers database. FDA issued tracking orders to 20 additional manufacturers during the time period 2002–2004. Under § 821.25(c), the additional manufacturers collectively bear a one-time burden of 10,560 hours to develop a device tracking system. FDA's estimate of 17,000 distributor respondents contained in the assessment is derived from Dun & Bradstreet sources on medical equipment wholesalers, retailers, home care dealers, and rental companies. Health Forum, an American Hospital Association Company, provided statistics on hospitals.

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]

BILLING CODE 4160–01–S

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