In 2001, when preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under part 7 (21 CFR part 7) (the agency's recall provisions). FDA has determined that estimates of the reporting burden in §§ 806.10 and 806.20 should be revised to reflect a reduction of 29 percent for reports and records submitted under part 7 due to a decrease in recall actions. The time needed to collect information has been reduced by 4 hours per record due to the implementation of a computerized program for information collection requirements in part 806.

Dated: February 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4159 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0401]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Customer/Partner Service Surveys

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 4, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Customer/Partner Service Surveys—(OMB Control Number 0910–0360)—Extension

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the agency. Executive Order 12862, entitled ''Setting Customer Service Standard,'' directs Federal agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as the following: Food processors; cosmetic drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers ''partner'' (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, courtesy, and problem resolution in the context of individual programs.

FDA projects that approximately 15 customer/partner service surveys will be conducted per year, with a sample of between 50 and 6,000 customers, requiring an average of 18 minutes for review and completion for each survey. Some of these surveys will be repeats of earlier surveys, for purposes of monitoring customer/partner service and developing long-term data.

In the **Federal Register** of September 16, 2004 (69 FR 55823), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
Mail/telephone/fax/web-based	15,000	1	15,000	.30	4,500

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

Dated: February 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4160 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0498]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Medical Devices; Device Tracking

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 4, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on

the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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 compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

Section 211 of the Food and Drug Administration Modernization Act of 1997 (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.

In the **Federal Register** of November 30, 2004 (69 FR 69604), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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) and (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 FDA's 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 Co., provided statistics on hospitals.

Dated: February 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4161 Filed 3–3–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0065]

Risk Assessment of the Public Health Impact from Foodborne Listeria Monocytogenes in Smoked Finfish; and Evaluation of Food Code Provisions That Address Preventive Controls for Listeria Monocytogenes in Retail and Foodservice Establishments; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and scientific data and information that would assist the agency in its plans to conduct a risk assessment for *Listeria monocytogenes* in smoked finfish (smoked finfish risk assessment), and evaluate the provisions of the 2001 Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments. The purpose of the smoked finfish risk assessment is to ascertain the impact on public health from the reduction and/or prevention of *L. monocytogenes* growth and recontamination during the manufacturing and/or processing of hot- and cold-smoked finfish. The smoked finfish risk assessment and the evaluation of the Food Code provisions for preventive controls for *L. monocytogenes* in retail and foodservice establishments support the agency's commitment to the *Listeria* Action Plan (revised 2003) that FDA and the Centers for Disease Control and Prevention (CDC) developed to reduce *L. monocytogenes* illnesses associated with the consumption of ready-to-eat (RTE) foods.

DATES: Submit comments and scientific data and information by May 3, 2005.

ADDRESSES: Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Sherri B. Dennis, Center for Food Safety and Applied Nutrition (HFS–06), Food and Drug Administration, rm. 2B–023, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1903.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Health and Human Services *Healthy People 2010* is a comprehensive set of disease prevention and health promotion objectives for the Nation to achieve over the first decade of the new century. Created by scientists both inside and outside of Government, it identifies a wide range of public health priorities and specific, measurable objectives. One of these objectives calls on Federal food safety agencies to reduce foodborne listeriosis (Ref. 1). In support of this goal, in 2003, FDA issued an assessment of the relative risk to the public health from foodborne *L. monocytogenes* among selected categories of RTE foods (*Listeria* risk assessment) (Ref. 2). The *Listeria* risk assessment formed the basis of the 2003 FDA/CDC *Listeria* Action Plan (Ref. 3), which identifies prevention and control activities that FDA and CDC will take to reduce the incidence of foodborne listeriosis in the United States. The smoked finfish risk assessment and the evaluation of the Food Code (Ref. 4) provisions for preventive controls for *L. monocytogenes* in retail and foodservice establishments are two of these prevention and control activities that support the agency's commitment to fulfilling the *Listeria* Action Plan.

Smoked Finfish Risk Assessment: The 2003 *Listeria* risk assessment used data on food contamination at retail, the ability of the food to support growth, and the impact of home storage time and temperature to estimate the likelihood of a type of food to cause listeriosis. The *Listeria* risk assessment determined that smoked seafood has a relatively high rate of contamination and a high predicted per serving relative risk, yet a lower per annum risk because it is generally consumed only occasionally in small quantities and/or eaten by a relatively small portion of the population.

As a followup to the *Listeria* risk assessment, the smoked finfish risk assessment model will evaluate the sources of contamination, how individual steps in manufacturing and/or processing contribute to contamination, and the effectiveness of various preventative strategies. The objectives of the smoked finfish risk assessment are to evaluate the impact on public health from the reduction/prevention of the following: (1) *L. monocytogenes* growth during the manufacturing and/or processing of smoked finfish, (2) *L. monocytogenes*