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]

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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*

growth between the smoking process and distribution at retail, and (3) recontamination with *L. monocytogenes* during the manufacturing and/or processing of smoked finfish.

Listeria monocytogenes contamination is a problem in cold-smoked finfish because the heat applied during processing is not sufficient to inactivate the organism, and the fish are consumed without further cooking. Cold-smoked finfish may become contaminated during processing due to inadequate sanitation, particularly because of insufficient cleaning and sterilizing of the slicer. For hot-smoked finfish, although *L. monocytogenes* is killed by adequate hot-smoking, recontamination after hot-smoking can result in high numbers of the organism in the finished products. Additionally, the ability of the organism to grow under both refrigerated aerobic and anaerobic conditions makes it a concern in products packed in permeable wrappers and under modified atmosphere or vacuum. This sealing of the product extends shelf-life and, therefore, provides additional time for the organism to grow.

Preventive Controls for L. monocytogenes in Retail and Foodservice Establishments: FDA is evaluating the Food Code to determine whether it should consider recommending revisions to the provisions addressing preventive controls for *L. monocytogenes* in retail and foodservice establishments. Specifically, FDA will take the following steps: (1) Review the Food Code to determine whether it should consider recommending revisions to the provisions that address preventive controls, such as approved source, date marking, and cold holding times and temperatures; and (2) in conjunction with the Conference for Food Protection, issue guidance to the retail and food service industries and State and local regulatory professionals on the use of Hazard Analysis Critical Control Point (HACCP) principles to identify and control risk factors contributing to foodborne illness. FDA intends for such guidance to discuss intervention strategies that industry can use to control *L. monocytogenes* and other pathogens.

II. Request for Comments and for Scientific Data and Information

Smoked Finfish Risk Assessment: FDA requests comments on the risk assessment approach outlined previously in this document and the submission of data and any information relevant to this risk assessment. The agency specifically requests information for the following: (1) *L. monocytogenes* levels in raw fish, smoked fish, and finished product; (2) effect of mitigation measures (e.g., ozonation, acidified sodium chlorite) to reduce *L. monocytogenes* levels in raw and finished product; (3) potential for transfer of *L. monocytogenes* to food from contaminated food contact and noncontact surfaces during manufacturing and/or processing (e.g., equipment, workers, floor drains, etc.); (4) potential for transfer of *L. monocytogenes* from the slicer to cold-smoked fish; (5) impact of adding inhibitors (e.g., bacteriocins and bacteriocins-producing bacterial strains or sodium lactate) to smoked finfish to reduce or prevent *L. monocytogenes* growth; (6) impact of frozen versus refrigerated storage conditions on levels of *L. monocytogenes*; (7) impact of time and temperature on levels of *L. monocytogenes* for commercial and home storage conditions of finished product; and (8) effect of training regarding sanitation and hygienic practices on reducing the levels of *L. monocytogenes* in smoked finfish.

Preventive Controls for L. monocytogenes in Retail and Foodservice Establishments: Under the FDA/CDC *Listeria* Action Plan, FDA is continuing its commitment to review the Food Code to determine whether it should consider recommending revisions to the provisions that address preventive controls for *Listeria* in retail and foodservice establishments. The agency specifically requests the following data and information: (1) *L. monocytogenes* levels in products stored in retail and foodservice establishments; (2) levels of environmental contamination and harborage of *L. monocytogenes* on food contact and nonfood contact surfaces in retail and foodservice establishments (e.g., equipment, workers, floor drains, etc.); (3) effects of short- and long-term refrigerated storage on levels of *L. monocytogenes* in retail and foodservice establishments; (4) impact of time and temperature on levels of *L. monocytogenes* in products stored in retail and foodservice establishments; (5) efficacy of cleaning procedures and sanitizing agents on environmental surfaces and utensils; (6) frequency of use and impact of adding inhibitors to food products in retail and foodservice establishments to reduce or prevent *L. monocytogenes* growth; and (7) effect of training regarding hygienic practices and sanitation on levels of *L. monocytogenes* in products in retail and foodservice establishments.

Interested persons should submit comments, scientific data, and information to the Division of Dockets Management (see **ADDRESSES**). Three copies of all comments, scientific data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

III. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Health and Human Services, *Healthy People 2010*, v. 1. Washington, DC, 2000, *http://www.healthypeople.gov*.

2. U.S. Department of Health and Human Services and U.S. Department of Agriculture/Food Safety and Inspection Service, ''Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods,'' September 2003, *http://www.foodsafety.gov/~dms/lmr2–toc.html*.

3. U.S. Department of Health and Human Services, Food and Drug Administration/Centers for Disease Control and Prevention, ''Reducing the Risk of *Listeria monocytogenes* FDA/CDC 2003 Update of the *Listeria* Action Plan,'' November 2003, *http://www.cfsan.fda.gov/~dms/lmr2plan.html*.

4. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Food Code*, 2001, *http://www.cfsan.fda.gov/~dms/fc01–toc.html*.

Dated: February 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–4217 Filed 3–3–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0058]

Hospira, Inc. et al.; Withdrawal of Approval of 76 New Drug Applications and 60 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.