of notifications FDA received during fiscal years 2002 to 2004 increased by 24. Because the premarket notification program for new dietary ingredients is relatively new, the agency anticipates that this upward trend in receiving more notifications will continue over the next 3 fiscal years, from October 1, 2005, through September 30, 2007. Therefore, FDA estimates that the agency will receive an annual average of 71 notifications with an annual average of 1 notification per submitter during fiscal years 2005 to 2007.

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8767 Filed 5–2–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0153]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring

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 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 regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring.

DATES: Submit written or electronic comments on the collection of information by July 5, 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: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 collection of information, including each 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: (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.

Regulations For In Vivo Radiopharmaceuticals Used For Diagnosis and Monitoring (OMB Control Number 0910–0409)—Extension

FDA is requesting OMB approval of the information collection requirements contained in § § 315.4, 315.5, and 315.6 (21 CFR 315.4, 315.5, and 315.6). These regulations require manufacturers of diagnostic radiopharmaceuticals to submit information that demonstrates the safety and effectiveness of a new diagnostic radiopharmaceutical or of a new indication for use of an approved diagnostic radiopharmaceutical.

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), FDA published a final rule (64 FR 26657, May 17, 1999) amending its regulations by adding provisions that clarify FDA's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products[1] already in place under the authorities of the act and the PHS act. The information, which is usually submitted as part of a new drug application (NDA), biologics license application, or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under 21 CFR part 315, information required under the act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the agency estimates the time needed to prepare a complete

[1] The information collection requirements for biological products are no longer submitted to OMB for approval in this package, but are included under OMB control number 0910–0338.

application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (OMB control number 0910–0001 approved by OMB until March 31, 2005). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well established, low risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. The burden totals do not include an increase in burden. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

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
315.4, 315.5, and 315.6	2	1	2	2,000	4,000
Total					4,000

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

Dated: April 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8818 Filed 5–2–05; 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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 5, 2005, the comment period for the notice that appeared in the **Federal Register** of March 4, 2005 (70 FR 10650). In the notice, FDA requested comments and scientific data and information to assist the agency in its plans to conduct a risk assessment for *Listeria monocytogenes* in smoked finfish and to evaluate the provisions of the 2001 Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments and scientific data and information.

DATES: Submit written and electronic comments and scientific data and information by July 5, 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.gov/dockets/ecomments*.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 2005 (70 FR 10650), FDA published a notice with a 60-day comment period to request comments and scientific data and information to assist the agency in its plans to conduct a risk assessment for *L. monocytogenes* in smoked finfish (smoked finfish risk assessment) and to evaluate the provisions of the 2001 Food Code that address preventive controls for *L. monocytogenes* in retail and foodservice establishments.

For the smoked finfish risk assessment, the agency specifically requested information on the following topics:

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.

For evaluating the Food Code provisions for preventive controls for *L. monocytogenes* in retail and foodservice establishments, the agency specifically requested 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.),