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
101.93	700	1	700	0.5 to 1	350 to 700

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

The agency believes that there will be minimal burden on the industry to generate information to meet the requirements of section 403 of the act in submitting information regarding section 403(r)(6) of the act statements on labels or labeling of dietary supplements. The agency is requesting only information that is immediately available to the manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. This estimate is based on the average number of notification submissions received by the agency in the last 3 years.

Dated: April 29, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–11453 Filed 5–6–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–0124]

Agency Information Collection Activities; Submission for OMB Review; Comment Request and Correction; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA). In addition, this document is correcting the information collection notice that appeared in the **Federal Register** of February 9, 1999 (64 FR 6364).

DATES: Submit written comments on the collection of information by June 7, 1999.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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

Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910–0330—Extension)

Description: Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides for the notification of the Secretary of Health and Human Services (the Secretary) (and by delegation FDA) at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient. The agency established 21 CFR 190.6 as the procedural regulation for this program. This regulation provides details of the administrative procedures associated with the submission and identifies the information that must be included in the submission in order to meet the requirements of section 413(a) of the act and to show the basis on which a manufacturer or distributor of a new dietary ingredient or a dietary supplement containing a new dietary ingredient has concluded that the dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

Description of Respondents: Businesses or other for-profit organizations.

In the **Federal Register** of February 9, 1999 (64 FR 6364), the agency requested comments on the proposed collections of information. No comments were received.

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
190.6	11	1	11	20	220

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

The agency believes that there will be a minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files, and presenting it in a format that will meet the requirements of section 413 of the act, will require a burden of approximately 20 hours of work per submission. This estimate is based on the average number of premarket notifications received by the agency in the last 3 years.

Additionally, in FR Doc. 99–3014, appearing on page 6364 in the **Federal Register** of Tuesday, February 9, 1999, the following correction is made:

1. On page 6365, in the first column, the title ''New Dietary Ingredient Premarket Notification—21 CFR 190.6 (OMB Control Number 0910–0330—

Extension)'' is corrected to read ''Premarket Notification for a New Dietary Ingredient—21 CFR 190.6 (OMB Control Number 0910–0330—Extension)''

Dated: April 29, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–11454 Filed 5–6–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1076]

Risk Assessment of the Public Health Impact of Foodborne Listeria Monocytogenes; 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), in consultation with the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS), is announcing plans to conduct a risk assessment (RA) to determine the prevalence and extent of exposure of consumers to foodborne *Listeria monocytogenes* and to assess the resulting public health impact of such exposure. The agencies request comments on certain aspects of their approach to the RA and request that scientific data and information relevant to the conduct of the RA be submitted.

DATES: Written comments and scientific data and information by July 6, 1999.

ADDRESSES: Submit written comments and scientific data and information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Richard C. Whiting, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, rm. 3822, 200 C St. SW., Washington, DC 20204, 202–260–0511, FAX 202–260–9653, or e-mail ''rwhiting@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

L. monocytogenes is a bacterium that occurs widely in both the agricultural (soil, plants, and water) and food processing environment. The bacterium is resistant to various environmental conditions such as high salt or acidity (Ref. 1). *L. monocytogenes* grows at low oxygen conditions and refrigeration temperatures, and survives for long periods of time in the environment, on foods, in processing plants, and in household refrigerators. Although frequently present in raw foods of both plant and animal origin, it also can be present in cooked foods due to post-processing contamination. *L. monocytogenes* has been isolated in such foods as: Raw and pasteurized fluid milk, cheeses (particularly soft-ripened varieties), ice cream, raw vegetables, fermented raw meat sausages, raw and cooked poultry, raw meats (all types), and raw and smoked fish (Refs. 1, 2, and 3). Even when L. monocytogenes is initially present at a low level in a contaminated food, the organism can multiply during storage, including storage at refrigeration temperatures. A survey of a wide variety of foods from the refrigerators of listeriosis patients in the United States found 11 percent of the samples contained L. monocytogenes (Ref. 4).

It is well established that ingestion of *L. monocytogenes* can cause serious human illness, listeriosis (Refs. 1, 2, 5, 6, and 7). In 1997, the Centers for Disease Control and Prevention (CDC) Foodborne Diseases Active Surveillance Network (FoodNet) showed that of all foodborne illnesses, the rate of hospitalization was highest for persons infected with *L. monocytogenes* (88 percent). Similarly, of all of the foodborne pathogens tracked by CDC, *L. monocytogenes* had the highest case fatality rate in that 20 percent of persons infected died. CDC also found that the incidence of listeriosis is 0.5 per 100,000 population, compared to a combined rate of 51.2 per 100,000 for all 9 of the foodborne illnesses surveyed (Ref. 8). Thus, although serious, listeriosis is a relatively rare foodborne illness. Most cases of listeriosis occur in pregnant women or individuals with a predisposing disease (such as alcoholism, diabetes, or cirrhosis of the liver) or an impaired immune system resulting from either a disease (such as AIDS) or immunosuppressive treatment for a malignancy or an organ transplant. (Refs. 1 and 6).

Listeriosis has a long incubation time (up to 5 weeks) and a range of symptoms. Infection of a pregnant woman may result in flu-like symptoms with fever, muscular pain, or headache, or the listeriosis infection may be asymptomatic. Importantly, however, when a pregnant woman contracts listeriosis, the fetus or newborn infant is likely to suffer severe consequences from the maternal infection, including: Spontaneous abortion, fetal death, stillbirth, neonatal septicemia, or meningitis. In nonpregnant adults, septicemia and meningitis are the most common result of a listeriosis infection, although organ infections and mild gastroenteritis can also occur.

Although the consequences of listeriosis may be severe, an estimated 2 to 6 percent of the healthy population harbors *L. monocytogenes* in their intestinal tract without signs of illness (Refs. 1 and 6). Because the documented prevalence of *L. monocytogenes* in people and in commonly eaten foods is much higher than the documented incidence of listeriosis, some experts believe that the ingestion of low levels of *L. monocytogenes* may not result in illness and thus, may not constitute a general public health hazard (Refs. 9 and 10).

Since 1990, CDC has documented a decrease in the incidence of listeriosis. Although not certain, this decrease may be attributed to government and industry programs directed at improved sanitation and process control. Listeriosis is typically characterized by sporadic cases. However, a recent multi-State listeriosis outbreak associated with the consumption of processed meats, with at least 73 illnesses and 16 deaths, has reaffirmed concerns that more preventative efforts are needed.

Historically, FDA has had a policy of ''zero tolerance'' for *L. monocytogenes* based on the absence of the microorganism in a 25-gram sample of a given production lot. In other words, FDA's position has been that the detection of any *L. monocytogene* in a 25-gram sample renders the food adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)). As recently as 1995, FDA affirmed this policy, as reflected in the decision in *United States* v. *Union Cheese Co*., 902 F. Supp. 778, 784, 786 (N.D. Ohio 1995). In that litigation, FDA's expert witness testified that the *L. monocytogenes* bacterium grows at refrigerator temperatures and that the level of *L. monocytogenes* required to cause illness is unknown (902 F. Supp at 784). FSIS (which regulates meat and poultry) likewise has historically had a zero tolerance policy for *L. monocytogenes*.

Other countries, including certain major trading partners of the United States, take a slightly different approach to *L. monocytogenes* contamination. Relying upon their interpretation of the existing scientific data, countries such as Canada and Denmark have a ''non-zero tolerance'' for *L. monocytogenes* for some classes of foods (Refs. 10 and 11).