TABLE 1.—ESTIMATED ANNUAL RECORDING BURDEN[1]—Continued

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
900.6(c)(1)	1	0.1	0.1	1	0.1		
900.11(b)(1)	9,200	0.33	3,067	2	6,134		
900.11(b)(2)	250	1	250	2	500		
900.11(b)(3)	5	1	5	.5	2.5		
900.11(c)	9,200	0.04	368	5	1,840		$1,000
900.12(c)(2)	9,200	3,478	36,000,000	5 Minutes	3,000,000		
900.12(j)(1)	25	1	25	1	25		
900.12(j)(2)	25	0.08	2	50	100		
900.15(c)	9,200	0.05	46	2	92		
900.15(d)(3)(ii)	9,200	0.0001	0.92	2	1.8		$10
900.18(c)	9,300	0.00032	3	2	6		$30
900.18(e)	10	0.0100	0.1	1	0.1		$10
FDA Form 3422	800	1	800	.25	200		
TOTAL					3,095,716	$50	$1,040

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating and Maintenance Costs
900.3(f)(1)	5	0.02	0.1	200	20	
900.4(g)	1	0.33	0.33	1	0.33	
900.12(c)(4)	9,200	1	9,200	1	9,200	$18,400
900.12(e)(13)	9,200	52	478,400	0.125	59,800	
900.12(f)	9,200	1	9,200	5	46,000	
900.12(h)	9,200	2	18,400	0.5	9,200	
TOTAL					124,220	$18,400

The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

The total capital cost associated with these regulations is $50 (§ 900.3(b)(3)). This is a one-time start up cost associated with the application for approval as an accreditation body.

The total operating and maintenance cost associated with these requirements is: $19,440. This is the cost that facilities bear to maintain records under the initial and final mammography regulations.

Dated: November 3, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28006 Filed 11–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N–1168]

Relative Risk to Public Health From Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods; Quantitative Risk Assessment and Risk Management Action Plan; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) is announcing a public meeting to present the ''Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods'' and to present information relative to the risk management action plan that has been updated in light of the results of the risk assessment. The risk assessment was conducted by FDA in cooperation with the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture and in consultation with the Centers for Disease Control and Prevention (CDC) of HHS. The notice of availability of the risk assessment was published in the **Federal Register** on October 24, 2003 (68 FR 61006). This public meeting is intended to provide clarification about the results of the risk assessment and information as to how the risk assessment may be utilized. Stakeholders will have an opportunity to ask questions about the risk assessment and the risk management action plan. Questions may also be submitted in advance of the public meeting (see the *Contact* section of this document).

Date and Time: The meeting will be held on December 4, 2003, from at 8:30 a.m. to 5 p.m. Registration and requests for formal oral presentations by December 2, 2003.

Location: The meeting will be held at the FDA/CFSAN Harvey W. Wiley Building, 1500 Paint Branch Pkwy., College Park, MD 20740–3835.

Contact: Lori Pisciotta, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 301–436–2279, FAX: 301–436–2630, e-mail: *lpisciot@cfsan.fda.gov*.

Registration and Requests for Oral Presentation: Send registration information (including name, title, firm name, address, telephone and fax number), to the contact person by December 2, 2003. Interested persons may present data, information, or views orally or in writing, on the issue. If you desire to make a formal oral presentation, you should notify the contact person before December 2, 2003, and be prepared to give a brief description of the general nature of the information you wish to present. Time allotted for each presentation may be limited. Written submissions must also be made to the contact person by December 2, 2003.

If you need special accommodations due to a disability, please contact Ms. Pisciotta (see the *Contact* section) at least 7 days in advance of the meeting.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: FDA is announcing a public meeting on December 4, 2003, to present the ''Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods'' and the risk management action plan that has been updated in light of the risk assessment. In the **Federal Register** of January 19, 2001 (66 FR 5515), FDA and FSIS announced the availability of a draft *Listeria monocytogenes* risk assessment and a draft risk management plan based on the risk assessment. FDA, FSIS, and CDC held a public meeting on March 19, 2001, to receive comments on the technical aspects of the draft risk assessment on the relationship between foodborne *L. monocytogenes* and human health. Interested persons were given until March 20, 2001, with extensions to May 21, 2001, and to July 18, 2001, to comment on these documents. The risk assessment has been revised in response to public comments, newly available data, and updated modeling techniques, and was made available to the public in the **Federal Register** of October 24, 2003 (68 FR 61006). Comparable revisions also have been made to the draft risk management action plan.

Dated: October 31, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28005 Filed 11–6–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0493]

Draft Guidance for Industry on Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment.'' The draft guidance is intended to provide recommendations to manufacturers of human drug products on how to develop a single control procedure to demonstrate the adequacy of mix to ensure uniformity and homogeneity of in-process powder blends and finished dosage units.

DATES: Submit written or electronic comments on the draft guidance by March 8, 2004. General comments on agency draft guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jon Clark, Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5103.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Powder Blends and Finished Dosage Units—Stratified In-Process Dosage Unit Sampling and Assessment.'' The draft guidance is intended to respond to industry concerns regarding FDA policies on demonstrating the adequacy of in-process powder mixing and uniform content in finished products under 21 CFR 211.110(a)(3).

In the **Federal Register** of August 27, 1999 (64 FR 46917), FDA published notice of the availability of a draft guidance for industry on blend uniformity analysis. Although FDA subsequently withdrew the draft guidance on May 17, 2002 (67 FR 35120), comments submitted on the draft guidance led to the formation of the Blend Uniformity Working Group (BUWG). The BUWG, which includes representatives from the agency, industry, and academia, conducted a public meeting on September 7 and 8,