DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0058]

Draft Compliance Policy Guide Sec. 555.320—*Listeria monocytogenes*; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft Compliance Policy Guide (CPG) Sec. 555.320 *Listeria monocytogenes* (the draft CPG). The draft CPG provides guidance for FDA staff on the agency's enforcement policy for *Listeria monocytogenes* in ready-to-eat (RTE) foods that support growth of the organism and RTE foods that do not support growth of the organism.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 7, 2008.

ADDRESSES: Submit written comments on the draft CPG 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.regulations.gov*.

Submit written requests for single copies of the draft CPG to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Mary Losikoff, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1412.

SUPPLEMENTARY INFORMATION:

I. Background

L. monocytogenes is a pathogenic bacterium that is widespread in the environment and thus may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, disease (called invasive listeriosis). Foods that have been implicated in outbreaks or sporadic cases of invasive listeriosis have been foods that are RTE.

The draft CPG is intended to provide clear policy and regulatory guidance for FDA staff regarding *L. monocytogenes* in certain foods. In particular, the draft CPG sets forth an enforcement policy concerning *L. monocytogenes* in RTE foods that support the growth of *L. monocytogenes* and RTE foods that do not support the growth of *L. monocytogenes*. The draft CPG describes the characteristics of RTE foods that do and do not support the growth of *L. monocytogenes* and identifies examples of foods that fall into each category.

For RTE foods that support the growth of *L. monocytogenes*, FDA's current thinking is that it may regard the food to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1)) (the act) when *L. monocytogenes* is present in the food, based on an analytical method that can detect 1.0 colony forming units (CFUs) of *L. monocytogenes* per 25 grams (g) of food (i.e., 0.04 CFU/g). For RTE foods that do not support growth of *L. monocytogenes*, FDA's current thinking is that it may regard the food to be adulterated within the meaning of section 402(a)(1) of the act when *L. monocytogenes* is present at or above 100 CFUs/g of food.

Further discussion of FDA's current thinking on *L. monocytogenes* in RTE foods, including the scientific support informing FDA's current thinking, can be found in the Notice of Public Meeting regarding the draft CPG, published elsewhere in this issue of the **Federal Register**, and in the references cited therein.

The draft CPG is being issued as a Level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when final, will represent the agency's current thinking on *L. monocytogenes* in RTE foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft CPG. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through the FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the draft CPG from the Office of Regulatory Affairs home page. It may be accessed at *http://www.fda.gov/ora* under ''Compliance Reference.''

Dated: January 23, 2008.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 08–547 Filed 2–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0494]

Draft Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods'' (the draft *Listeria* guidance). This draft guidance, when finalized, will complement FDA's current good manufacturing practices (CGMP) regulations by providing specific guidance on the control of *L. monocytogenes* in the processing of refrigerated or frozen ready-to-eat foods (RF-RTE foods). The draft *Listeria* guidance and the CGMP regulations are intended to assist processors in controlling *L. monocytogenes* in the food processing environment during the manufacture of RF-RTE foods.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft

guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 7, 2008. Submit written or electronic comments concerning the collection of information provisions by April 7, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods'' to the Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–436–2601. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the draft guidance and the proposed collection of information provisions 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: *With regard to the information collection provisions*: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

With regard to the draft guidance document: Mary Losikoff, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1412.

SUPPLEMENTARY INFORMATION:

I. Background

L. monocytogenes is a pathogenic bacterium that is widespread in the environment and thus may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, disease (called invasive listeriosis). With rare exceptions, foods that have been implicated in outbreaks or sporadic cases of invasive listeriosis have been refrigerated foods that can support the growth of *L. monocytogenes* and that are RTE. RF-RTE foods can be contaminated if ingredients in the foods are contaminated with *L. monocytogenes* and not treated to destroy viable cells of this pathogen, or if *L. monocytogenes* is present on surfaces (e.g., in the food processing environment) that can contaminate food or food-contact surfaces.

With this notice, FDA is announcing the availability of the draft *Listeria* guidance. This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on the control of *L. monocytogenes* in the processing of RF-RTE foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C 3501–3520). Under the PRA, Federal agencies must obtain approval from the 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 proposed 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.

FDA invites comments on these topics: (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.

Title: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-To-Eat Foods.

Description: The Federal Food, Drug, and Cosmetic Act prohibits the distribution of adulterated food in interstate commerce (21 U.S.C. 331 and 342). *L. monocytogenes* is a pathogenic bacterium that is widespread in the environment and thus may be introduced into a food processing facility. *L. monocytogenes* can contaminate foods and cause a mild illness (called listerial gastroenteritis) or a severe, sometimes life-threatening, disease (called invasive listeriosis). Foods that have been implicated in outbreaks of invasive listeriosis have been refrigerated foods that can support the growth of *L. monocytogenes* and that are RTE. RF-RTE foods can be contaminated if ingredients in the foods are contaminated with *L. monocytogenes* and not treated to destroy viable cells of this pathogen, or if *L. monocytogenes* is present on surfaces (e.g., in the food processing environment) that can contaminate food or food-contact surfaces. The draft *Listeria* guidance, when finalized, will complement FDA's CGMP regulations in 21 CFR part 110 by providing specific guidance on the control of *L. monocytogenes* in the processing of RF-RTE foods. The draft *Listeria* guidance and the CGMP regulations are intended to assist processors in controlling *L. monocytogenes* in the food processing environment during the manufacture of RF-RTE foods. FDA encourages processors of RF-RTE foods to adopt the general recommendations in the draft *Listeria* guidance and to tailor practices to their individual operations.

FDA's draft *Listeria* guidance represents the agency's recommendations to industry based on the current state of science. Following the recommendations set forth in the draft *Listeria* guidance is the choice of each individual operation, plant, or processor. FDA estimates the burden of this draft guidance on industry by assuming that those in the industry who process RF-RTE foods and who do not currently follow the recommendations put forth in the guidance will find it of value to do so. Therefore, the estimates of the burden associated with the issuance of this guidance represent the upper bound estimate of burden: the burden if every operation, plant, or processor that does not follow the recommendations of the guidance should choose to do so.

In order to minimize *L. monocytogenes* contamination in RF-RTE foods, FDA is recommending that the following records be maintained, as appropriate, to identify trends, document procedures, and facilitate corrective actions:

Ingredient and Process Control

- List of ingredients reasonably likely to be contaminated with *L. monocytogenes*
- Listeristatic or listericidal control measures
- Ingredient control records, i.e. certificate of conformance (COC), certificate of analysis (COA)
- Ingredient testing records

General Sanitation

- Written sanitation standard operating procedures (SSOP)
- Sanitation monitoring records

Monitoring of Critical Surfaces and Sampling of Finished Product

- Written plan for monitoring *L. monocytogenes* on food-contact and non-food-contact surfaces
- Procedures to detect and enumerate *L. monocytogenes*, unless the procedure used is the procedure that FDA identifies in the guidance
- Results of tests to detect or enumerate *L. monocytogenes* on food-contact and non-food contact surfaces
- Results of tests to detect or enumerate *L. monocytogenes* in finished product
- Corrective actions taken

Description of Respondents: The likely respondents to this request to keep the records described previously are U.S. processors of RF-RTE foods.

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

The estimated recurring annual burden for this information collection is 863,974 hours. Thus, the first year estimated burden for this information collection is 939,242 hours (863,974 hours + 75,268 first-year-only hours). A detailed breakdown of the estimated burden is shown in table 1 of this document.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Type of Record	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Capital Costs[2]	Total Hours
Ingredient and Process Control						
List of ingredients reasonably likely to be contaminated with *L. monocytogenes*[3]	3,755	1	3,755	1		3,755
Record of verification of technique used for listeristatic control measures[3]	188	3	564	1		564
Record of verification of technique used for listericidal control measures[3]	2,629	1	2,629	1		*COM041*2,629
Listeristatic control	376	900	338,400	0.1		33,840
Listericidal control	2,629	900	2,366,100	0.1		236,610
Ingredient control records (includes COC, COA, and ingredient testing)	1,126	72	81,072	0.1		8,107
General Sanitation						
Written SSOP[3]	4,270	1	4,270	8		34,160
Sanitation monitoring records	4,270	300	1,281,000	0.1		128,100
Environmental Monitoring and Product Sampling						
Written critical surface and finished product monitoring program[3]	4,270	1	4,270	8		34,160
Food-contact surface monitoring results	4,270	52	222,040	0.5		111,020
Record of corrective action taken for food-contact surface positive	4,270	10	42,700	0.5		21,350
Non-food-contact surface monitoring results	4,270	26	111,020	0.5		55,510

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

Type of Record	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Capital Costs[2]	Total Hours
Record of corrective action taken for non-food-contact surface positive	4,270	10	42,700	0.5		21,350
Finished product results	4,270	12	51,240	0.5		25,620
Record of corrective action taken for finished product positive	4,270	0.2	854	0.5		427
Written analytical method to detect or enumerate *L. monocytogenes* (besides the bacteriological analytical manual (BAM) or the international organization for standardization (ISO))[3]	0	1	0	0.1		0
Record Maintenance						
Record Maintenance	4,270	52	222,040	1		222,040
					$640,500	
Total hours for first year						939,242
Total recurring hours						863,974

[1]There are no operating and maintenance costs associated with this collection of information.
[2]Estimated capital costs for all record keeping items are combined.
[3]First year burden.

Data for the number of establishments potentially affected by this guidance were obtained from U.S. Census Bureau's 2003 ''County Business Patterns.'' Including grocery stores, delicatessens, and retail establishments that might perform some sort of RF-RTE food processing would bring the number of affected establishments to over 100,000. However, FDA anticipates this guidance would be used mainly by firms that are primarily RF-RTE food processors and manufacturers. Overall, there are 4,270 RF-RTE food processors and manufacturers that might be affected by this guidance. Liquid milk producers account for 515 of the establishments, and are already regulated by each state individually through the adoption of the Pasteurized Milk Ordinance (PMO). FDA assumes that milk producers would refer to the PMO for guidance in production and therefore would only be collecting or maintaining new information for general sanitation and on environmental monitoring and product sampling. There are currently 34 butter manufacturers, 408 ice cream manufacturers, 514 cheese manufacturers, and 501 ice manufacturers in the United States. There are 643 producers of perishable foods (including sandwiches, salads, and fresh-cut vegetables).[1] There are 782 canned fruit and vegetable processors (including orange juice).[2] There are 259 frozen pastry manufacturers.[3]

[1]North American Industry Classification System (NAICS) code 311991 also includes items such as fresh pasta and prepared meals. Producers of some of these items will not follow the guidance, either because their item is not an RF-RTE food or they are under the jurisdiction of the U.S. Department of Agriculture (USDA). In this regard, using the total from NAICS 311991 is an overestimate of the total burden. However, this is offset by the establishments in ''County Business Patterns'' that are counted only under their primary NAICS code. Establishments whose primary line of business is not in NAICS 311991 are not counted in this category.

[2]NAICS 311421 includes many items that are not refrigerated. Therefore, this number is an overestimate of the burden of the guidance. However, that may be offset to some extent by failure to count establishments whose primary line of business is in another NAICS code.

[3]NAICS code 311813 contains some items, such as some frozen pies, that are not considered RF-RTE foods. Therefore, using the total number of establishments within NAICS 311813 is an overestimate. This overestimate is offset to an unknown degree by the undercounting of establishments whose primary product is in another NAICS code.

Furthermore, there are 614 RF-RTE seafood establishments.[4] Some aspects of this record collection, such as sanitation monitoring records, are covered by FDA's regulations concerning hazard analysis and critical control point (HACCP) systems (21 CFR parts 120 and 123), though not specifically for *L. monocytogenes*. Therefore, some of the records may already be collected by some establishments. For the purposes of this analysis, FDA assumes that none of the affected establishments are currently collecting the information specific to *L. monocytogenes*. There are approximately 3,755 establishments (4,270 establishments - 515 milk producers) that would be collecting new information on ingredient and process control. All 4,270 establishments would be collecting new information for general sanitation and on environmental

[4]Not all seafood processors are covered by this guidance.

monitoring and product sampling. All establishments would need to maintain those records.

The draft guidance recommends that establishments keep a list of ingredients likely to be contaminated with *L. monocytogenes*. It is not likely that many establishments will have such a list, so this will be a one-time burden for 3,755 establishments. FDA estimates the list will take about 1 hour to compile, for a total one-time burden of about 3,755 hours.

Plants employing either a listericidal or listeristatic step would be recommended to maintain documentation of scientific studies that demonstrate that the control measure consistently destroys viable cells or is effective in preventing the growth of *L. monocytogenes*. FDA believes that about 80 percent of the establishments will either employ a listericidal or listeristatic step (approximately 70 percent will have a listericidal step and 10 percent will have listeristatic steps).

Based on these assumptions, there will be roughly 2,629 establishments (0.70 x 3,755) that would be recommended to keep a new record showing the efficacy of their listericidal step. Although the time taken to commit the verification to record will vary, FDA estimates that, on average, it will take about 1 hour for the documentation.[5] The total one-time burden is estimated to be about 2,629 hours.

Under the draft guidance, listeristatic control measures fall into two categories: Those that are generally recognized as effective in preventing the growth of *L. monocytogenes* (such as maintaining a pH of 4.4 or below, or maintaining a water activity of 0.92 or below) and those that a firm would develop on its own (such as formulating a food to contain one or more inhibitory substances that, alone or in combination, prevent the growth of *L. monocytogenes*). We estimate that about 50 percent of firms that establish and use listeristatic control measures (0.50 x 376, or 188 establishments) would develop their own listeristatic control measures, and would do so for three different food products on average. We also estimate that it would take approximately 1 hour to establish a record documenting the scientific studies that establish that the control measure consistently prevents the growth of *L. monocytogenes*, for a total one-time burden of about 564 hours.

[5] Many firms may choose a well-established listericidal measure, identified in the draft guidance (such as irradiation or thermal processing). The efficacy of these measures will take less time to record than less well-known means of listericidal control.

As stated, the draft guidance recommends that processors of RF-RTE foods select one or more identified measures to control ingredients. The recommended measures to control ingredients that may be adopted by firms expected to collect new records include: Eliminating *L. monocytogenes* by using a listericidal control measure at some point between the arrival of the ingredient and the shipping of the final product, receiving ingredients under a COA or COC, or testing the ingredients for the presence of *L. monocytogenes*.

For firms that choose to eliminate *L. monocytogenes* by using a listericidal control measure at some point between the arrival of the ingredient and the shipping of the final product, the draft guidance recommends that records of listericidal control measures be kept on a daily basis, per product, per lot, either per ingredient lot or per final product lot. FDA estimates that most firms choosing to employ a listericidal control measure would do so on the final product and that although the number of lots may vary from firm to firm, the time taken to record the entire process for each product would not. Therefore, the records can be treated as a daily collection for each unique product. We estimate that records of each listericidal control measure could be produced in approximately 6 minutes for an average of three products per plant. FDA does not have information to predict how many establishments would employ a listericidal control step. For this analysis, FDA estimates that about 70 percent of the affected establishments (2,629 establishments) would do so. These records would produce a total annual burden of about 236,610 hours ((2,629 plants) x (3 products) x (300 days of production) x (0.1 hours)).

Under the recommendations in the draft guidance, firms may instead choose to test ingredients for *L. monocytogenes* on a per ingredient basis, or to receive ingredients under a COC or a COA. Firms that choose to test would test each lot after it arrives at the facility. Firms employing a listericidal step would not need to perform this type of ingredient control, so FDA estimates that this may be a new burden for 1,126 establishments. FDA assumes that processors of RF-RTE foods typically receive ingredients twice a month and the number of ingredients varies from firm to firm. Although some products could contain more than 20 ingredients, we assume that only an average of 3 ingredients would need to be tested for the presence of *L. monocytogenes* in a single product. Therefore, the frequency of the collection is 72 times per year. FDA estimates that the record of the test results could be produced in about 6 minutes. Firms that choose to receive ingredients under a COC or a COA would produce a record of the COC or COA on a per ingredient, per delivery basis, resulting in an average of 72 collections per year. FDA believes that these records would take less than 6 minutes each to produce. Ingredient testing records or collecting a COC or COA would produce a total annual paperwork burden of about 8,107 hours ((1,126 plants) x (72 collections per year) x (6 minutes per record)).

Firms may choose to add a listeristatic step in addition to the COC, COA, or ingredient testing. FDA recommends in the draft guidance that records of listeristatic control measures be kept on a daily basis per lot, either per ingredient lot or per final product lot. FDA assumes that, similar to listericidal control records, listeristatic control records can be treated as a daily collection for each product, taking approximately 6 minutes. FDA does not have information to predict how many establishments would employ a listeristatic step. For this analysis, FDA estimates that about 10 percent of the affected establishments (376 establishments) would collect the information for an average of 3 products. These records would produce a total annual burden of about 33,840 hours ((376 plants) x (3 products) x (300 days of production) x (0.1 hours)).

In the draft guidance, FDA is recommending that firms have written SSOPs. FDA assumes this is a new collection for 4,270 establishments. Developing written SSOPs would be a one-time cost and we assume that this would take approximately 8 hours. This results in a first year burden of 34,160 hours (4,270 plants x 8 hours). The guidance also recommends that firms have written sanitation monitoring records. As stated previously, establishments subject to FDA's HACCP regulations are already required to have sanitation monitoring records, in order in order to comply with those regulations. However, because these records may not be specific to *L. monocytogenes*, FDA assumes this is a new collection for 4,270 establishments. We assume that sanitation monitoring records would be kept every day and could be produced in about 6 minutes per day. Therefore about 128,100 hours would be spent annually on sanitation records ((4,270 plants) x (300 days of production) x (0.1 hours)).

FDA assumes that although some firms may have an environmental monitoring program for critical surfaces in place (including surfaces that contact

food as well as surfaces that do not contact food), very few would have a program in place as thorough as the one described in the draft guidance. Therefore, FDA estimates that 4,270 establishments may choose to adopt the recommendations to develop a written environmental monitoring program, keep environmental testing results, and record finished product testing results. Developing a written environmental monitoring program would be a one-time cost and we assume that it would take approximately 8 hours. This results in a first year burden of about 34,160 hours (4,270 plants x 8 hours). For critical food-contact surfaces, the draft guidance recommends that tests be conducted on a weekly basis. We assume that it would take up to half an hour to produce a record of the results of the test, depending on the number of sites tested and subject to variability between firms, resulting in an annual burden of about 111,020 hours ((4,270 plants) x (52 records per year) x (0.5 hours)). For critical non-food-contact surfaces, the draft guidance recommends that tests be conducted every 2 weeks. As with testing for food-contact surfaces, we assume that the records would take up to half an hour to produce, resulting in an annual burden of about 55,510 hours ((4,270 plants) x (26 records per year) x (0.5 hours)). The draft guidance recommends ''periodic'' testing of finished product, such as weekly, monthly, or quarterly. For purposes of this analysis, FDA assumes most firms would conduct monthly testing of finished product. As with testing of critical surfaces, we assume the records would take approximately one half hour to produce, for an annual burden of about 25,620 hours ((4,270 plants) x (12 records per year) x (0.5 hours)).

In the draft guidance, FDA is recommending that firms that detect *Listeria* species on critical surfaces or in the finished product take corrective action and keep a record of what was done. The time to record the corrective actions would vary, but on average FDA estimates the record would require one half hour to produce. FDA cannot accurately predict how often firms would detect *Listeria* species in the environment. For the purposes of this analysis, and assuming that firms follow the rest of the guidance, FDA conservatively assumes that firms would detect *Listeria* species on food-contact surfaces about 20 percent of the time that tests are run, producing a total of 10 new records per establishment annually. Because non-food-contact surfaces cover inherently more space than food-contact surfaces and may be cleaned less stringently, FDA estimates that firms would detect *Listeria* species twice as often per test as they do when running tests on food-contact surfaces. Because these tests are run only half as often as food-contact surface tests (every 2 weeks rather than every week), this record would also be produced an average of 10 times annually per establishment. We assume that *Listeria* species would not often be detected in the final product, based on the projections of the ''Quantitative Assessment of Relative Risk to Public Health From Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods,'' (the Risk Assessment), written jointly by USDA and FDA. The Risk Assessment projected that 2 percent of RF-RTE food is contaminated with *L. monocytogenes*. FDA uses this number to estimate that records for corrective action due to finished product testing would produce, on average, 0.2 new records per establishment annually. The total annual burden produced by corrective action records would be about 43,127 hours ([(4,270 plants) x (10 records per year for corrective actions taken after food-contact surface positive) x (0.5 hours per record)] + [(4,270 plants) x (10 records per year) x (0.5 hours per record for corrective actions taken after non-food-contact surface positive)] + ((4,270 plants) x (0.2 records per year for corrective actions after finished product positive) x (0.5 hours per record)]).

If a firm does not use one of the methods described in FDA's BAM or by ISO, FDA is recommending that the firm have a written record of its method to enumerate or detect *L. monocytogenes*. FDA assumes most firms would use one of the methods described in the BAM or by ISO. Therefore, there would be no new collection of information.

FDA estimates that record maintenance would require roughly 1 hour per week for each firm, for a total of about 222,040 annual hours ((4,270 plants) x (52 weeks maintenance) x (1 hour per week)).

FDA estimates that each of the 4,270 establishments expected to keep new records would purchase a storage unit for the records. A standard file cabinet large enough for such records as described in the guidance costs about $150. Therefore, there would be total first year capital costs of about $640,500 (4,270 plants x $150).

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance and the collection of information provisions. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through the FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance from the Center for Food Safety and Applied Nutrition home page at *http://www.cfsan.fda.gov/guidance.html*.

Dated: January 16, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 08–548 Filed 2–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0058]

Draft Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes*; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss a Draft Compliance Policy Guide Sec. 555.320 *Listeria monocytogenes* (the draft CPG) that provides guidance for FDA staff on the agency's enforcement policy for *L. monocytogenes* in ready-to-eat (RTE) foods that support growth of the organism and RTE foods that do not support growth of the organism.

DATES: The meeting will be held on March 28, 2008, from 9 a.m. to 4:30 p.m. The closing date for requests to make an oral presentation is March 7, 2008. The closing date for advance registration, for notifying the contact person about a need for special accommodations due to a disability, and for providing a brief description of an oral presentation and