

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 7, 2008.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

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**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