Activity (the CPG). The CPG provides guidance for FDA staff on its enforcement policies for pathogens and other indicators of inadequate pasteurization or post-pasteurization contamination of dairy products.

DATES: Submit either electronic or written comments on the CPG at any time.

ADDRESSES: Submit written requests for single copies of the 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 CPG.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the CPG to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Monica Metz, Center for Food Safety and Applied Nutrition (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2041.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 1, 2009 (74 FR 62795), FDA made available draft CPG Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity and gave interested parties an opportunity to submit comments by February 1, 2010. The agency reviewed and evaluated these comments and has modified the CPG where appropriate.

The CPG provides guidance for FDA staff regarding pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products. The CPG outlines regulatory enforcement policies for FDA staff to use to initiate legal action recommendations based on analytical determinations that a dairy product contains a pathogenic microorganism (*i.e., Salmonella* species, enterohemorrhagic *Escherichia coli* (EHEC) O157:H7 and other enterohemorrhagic *Escherichia coli, Campylobacter jejuni, Yersinia enterocolitica,* or *Clostridium botulinum*); toxins produced by *Clostridium botulinum,* enterotoxigenic *Staphylococcus,* or *Bacillus cereus; Staphylococcus aureus; Bacillus cereus;* nontoxigenic *Escherichia coli;* or alkaline phosphatase. The CPG also contains information that may be useful to the regulated industry and to the public.

FDA is issuing the CPG as level 1 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents FDA's current thinking on pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products. 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**) either electronic or written comments regarding the CPG. It is only necessary to submit one set of comments. It is no longer necessary to send two paper copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the CPG from FDA's Office of Regulatory Affairs history page. It may be accessed at *http://www.fda.gov/ora/compliance_ref/cpg/default.htm.*

Dated: December 16, 2010.

Dara Corrigan,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 2010–32232 Filed 12–22–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0298] (Formerly Docket No. 2004D–0499)

Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice To Extend Expiration Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of expiration date.

SUMMARY: The Food and Drug Administration (FDA) is extending the expiration date of compliance policy guide (CPG) Sec. 400.210 entitled "Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs" to December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Connie Jung, Office of the Commissioner, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4254, Silver Spring, MD 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 2004 (69 FR 67360), FDA announced the availability of CPG Sec. 400.210 entitled "Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs." Previous extensions of the expiration date of the CPG were published in 2007 and 2008 (72 FR 65750, November 23, 2007; 73 FR 78371, December 22, 2008). FDA has identified RFID as a promising technology to be used in the various efforts to combat counterfeit drugs. The CPG describes how the Agency intends to exercise its enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to studies involving RFID technology for drugs. The goal of the CPG is to facilitate performance of RFID studies and to allow industry to gain experience with the use of RFID technology and its effect on the long-term safety and integrity of the U.S. drug supply.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) was signed into law. Section 913 of FDAAA addressed pharmaceutical safety and created section 505D of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355e). Section 505D(b) of the FD&C Act requires the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) of the FD&C Act states that these new standards shall address promising technologies, which may include RFID technology.

In implementing section 505D of the FD&C Act, FDA is currently addressing issues, such as promising technologies, that are relevant also for the CPG. In addition, FDA is considering further the experience of stakeholders and the Agency under the CPG. As we consider all of these issues, the CPG will remain in effect until December 31, 2012.

Dated: December 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–32274 Filed 12–22–10; 8:45 am]

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