

Dated: November 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-28593 Filed 11-30-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0466]

Draft Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity (Compliance Policy Guide 7106.08); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft Compliance Policy Guide Sec. 527.300 Dairy Products—Microbial Contaminants and Alkaline Phosphatase Activity (CPG 7106.08) (the draft CPG). The draft CPG, when finalized, will provide guidance for FDA staff on its enforcement policies for pathogens and other indicators of inadequate pasteurization or post-pasteurization contamination of dairy products.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on the draft CPG before it begins work on the final version of the CPG, submit written or electronic comments on the draft CPG by February 1, 2010.

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 on the draft CPG 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

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

The draft CPG is intended to provide guidance for FDA staff regarding pathogens and indicators of inadequate pasteurization or post-pasteurization contamination of dairy products. The draft 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 micro-organism (i.e., *Salmonella* species, enterohemorrhagic *Escherichia coli* (EHEC) O157:H7, *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 draft CPG also contains information that may be useful to the regulated industry and to the public.

FDA is issuing the draft CPG as level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent the agency'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**) written or electronic comments regarding this document. 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. 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 draft CPG at http://www.fda.gov/ora/compliance_ref/cpg/default.htm or <http://www.regulations.gov>.

Dated: November 24, 2009.

Michael A. Chappell,

Acting Associate Commissioner for Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0524]

Guidance for Industry on Listing of Ingredients in Tobacco Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled "Listing of Ingredients in Tobacco Products." The guidance document is intended to assist persons making tobacco product ingredient submissions to FDA under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Listing of Ingredients in Tobacco Products" to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

Submit written comments on the 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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michele Mital, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 301-796-4800, Michele.Mital@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: