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FDA is issuing the draft CPG as level 1 draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115).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.