

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0453]

Compliance Policy Guide Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act (Compliance Policy Guide 7119.05); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled “Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05).” The CPG provides guidance on the applicability of the Federal Import Milk Act (FIMA) to imported milk and cream. This document updates the existing CPG.

**DATES:** Submit written or electronic comments concerning the CPG or the supporting document at any time.

**ADDRESSES:** Submit written requests for single copies of the CPG entitled “Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05)” to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, 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 document.

Submit written comments on the revised CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane,  
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rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Esther Lazar, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1485, FAX: 301-436-2632.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of October 29, 2004 (69 FR 63158), FDA announced the availability of a draft CPG entitled “Sec. 560.400—Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05).” After considering comments received, FDA has finalized the CPG. The CPG updates and replaces “CPG Sec. 560.400—Imported Milk and Cream—Import Milk Act (CPG 7119.05).”

FDA received 10 comments on the draft CPG. The comments represented the views of individual consumers, industry, and industry trade representatives. One comment requested clarification on whether sweetened condensed milk was subject to a FIMA permit. Nine comments were outside the scope of the draft CPG. After considering carefully the relevant comment received, FDA revised its intended treatment of sweetened condensed milk and evaporated milk under the FIMA. Accordingly, under Section III.B. of the CPG, “Application of the FIMA:,” the following changes were made:

- In paragraph 1.i. of the CPG, we removed “Sweetened Condensed Milk” and “Evaporated Milk” from the list of products that FDA intends to consider as subject to the FIMA’s permit requirements for importation; and

- In paragraph 2.ii. of the CPG, we added “Sweetened Condensed Milk” and “Evaporated Milk” to the list of products that FDA intends to consider as not subject to the FIMA’s permit requirements for importation.

We also edited the CPG to clarify the following:

- In section II of the CPG, regulations under the FIMA are found in 21 CFR part 1210;
- In section II of the CPG, FDA intends to consider sweetened condensed milk and evaporated milk as not subject to the provisions of the FIMA. Sweetened condensed milk is required by § 131.120 (21 CFR 131.120) to contain a quantity of nutritive carbohydrate sweetener sufficient to prevent spoilage, and evaporated milk is required by § 131.130 to be sealed in a container and so processed by heat as to prevent spoilage;
- In section III of the CPG, FDA intends to consider “Nonfat Milk” as subject to the FIMA’s permit requirement for importation; and
- In section V of the CPG, the specimen charge should be worded, “The article of [milk] [cream] is not accompanied by a valid import milk permit, as required by the Federal Import Milk Act (21 U.S.C. 141–149).”

The CPG is being issued as level 1 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The CPG represents the agency’s current thinking on its enforcement process concerning the FIMA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

## 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

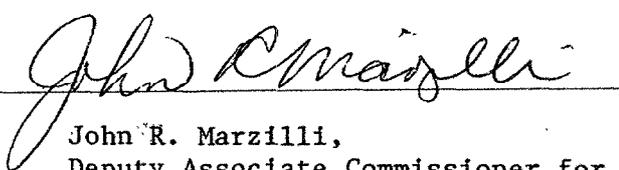
to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4.p.m., Monday through Friday.

**III. Electronic Access**

An electronic version of the revised CPG is available on the Internet at <http://www.fda.gov/ora> under "Compliance Reference<sup>S/</sup>"

*KMS*  
4/5/05

Dated: 3-30-05  
March 30, 2005.

  
John R. Marzilli,  
Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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