

effectiveness of marketed and investigational human drug products for use in the treatment of dermatologic and ophthalmic disorders and makes appropriate recommendations to the Commissioner.

#### *E. Endocrinologic and Metabolic Drugs Advisory Committee*

The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of endocrine and metabolic disorders and makes appropriate recommendations to the Commissioner.

#### *F. Nonprescription Drugs Advisory Committee*

The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the issuance of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded, or on the approval of new drug applications for such drugs. The committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

#### *G. Pulmonary-Allergy Drugs Advisory Committee*

The committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner.

## **II. Criteria for Members**

Persons who are nominated for membership on the committees as consumer representatives must meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The

consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

## **III. Selection Procedures**

The selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

## **IV. Nomination Procedures**

All nominations must include a cover letter, a curriculum vitae or resume (that includes the nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Any interested person or organization may nominate one or more qualified persons for membership on one or more of the advisory committees to represent consumer interests. Self-nominations are also accepted. FDA will ask the potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of a conflict of interest. The nomination should specify the committee(s) of interest. The term of office is up to 4 years, depending on the appointment date.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: April 1, 2005.

**Sheila Dearybury Walcott,**

*Associate Commissioner for External Relations.*

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## **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.

**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, 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 References.”

Dated: March 30, 2005.

**John R. Marzilli,**

*Deputy Associate Commissioner for Regulatory Affairs.*

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**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Inspector General

### Program Exclusions: March 2005

**AGENCY:** Office of Inspector General, HHS.

**ACTION:** Notice of program exclusions.

During the month of March 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject name, address	Effective date
<b>PROGRAM-RELATED CONVICTIONS</b>	
ALLEN, SHARON ..... LIVINGSTON, TN	4/20/2005
ARTHUR C O'BRIEN MD, INC HAYWARD, CA	4/20/2005
AUGUSTINE, SCOTT ..... BLOMMINGTON, MN	4/20/2005
BAINBRIDGE MANAGEMENT CHICAGO, IL	4/20/2005
BEILHARZ, JOYCE ..... HILLIARD, OH	4/20/2005
BENHAM, JAMES ..... NORTH OAKS, MN	4/20/2005
BLUE, FELICIA ..... DUNN, NC	4/20/2005
BRADDOCK MANAGEMENT LP ..... CHICAGO, IL	4/20/2005
CHEATAM, MARION ..... REYNOLDSBURY, OH	4/20/2005
CORRAI, ANNIE ..... MARYSVILLE, OH	4/20/2005
CORRAL, EDMOND ..... LOS ANGELES, CA	4/20/2005
CUBRIA, ANDREW ..... LISBON, OH	4/20/2005
DIAZ, BLAS ..... LOS ANGELES, CA	4/20/2005
EDOHO-UKWA, ANIETIE ..... MCKINNEY, TX	4/20/2005
EDOHO-UKWA, UKWA ..... FRISCO, TX	4/20/2005
ELLIS, CRISTINA ..... FONTANA, CA	4/20/2005
FLEISCHER, MARK ..... OTISVILLE, NY	4/20/2005
FOREMAN, PAUL ..... COLUMBIA, MO	4/20/2005
GARADA, HAZEM ..... MORGANTOWN, WV	4/20/2005
GRAYSON, CYNTHIA ..... BATON ROUGE, LA	4/20/2005
GREENWALD, BRUCE ..... ST LOUIS, MO	4/20/2005
HEALTH CARE 2000, INC ..... CHAVIES, KY	4/20/2005
HOWARD, ANNIESA ..... REYNOLDSBURG, OH	4/20/2005
J & J SLEEP, INC ..... NEW PORT RICHEY, FL	4/20/2005
JAPSON, SUSANNE ..... BROOKHAVEN, NY	4/20/2005
JETTER, RODNEY ..... CINCINNATI, OH	4/20/2005
JORDAN, LAKESHA ..... SPENCER, NC	4/20/2005
JUN, DINA ..... LONG BEACH, CA	4/20/2005
KARKOTSYAN, KIRAKOS ..... LONG BEACH, CA	4/20/2005
KINGEN, JACK ..... NEW PORT RICHEY, FL	4/20/2005
KIRPICHYAN, HAKOP ..... VAN NUYS, CA	4/20/2005
KLEBER, PENNI ..... PORTLAND, OR	4/20/2005
KOPP, RUTH ..... EDELSTEIN, IL	4/20/2005
KRAJIAN, JOHN ..... BEVERLY HILLS, CA	4/20/2005
KUYKENDALL, PAMELA ..... COOS BAY, OR	4/20/2005
LATONN, EDWARD ..... LATONN, EDWARD	4/20/2005