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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004D-0453; Draft Revised Compliance Policy Guide "Sec. 560-400—Imported Milk and Cream—Federal Import Milk Act (CPG 7119.05)"; Availability; 69 Fed. Reg. 63158 (Oct. 29, 2004)

Dear Sir or Madam:

On behalf of our client, Nestle U.S.A., Inc. ("Nestle"), we appreciate this opportunity to offer comments concerning the Draft Revised Compliance Policy Guide ("Draft Guidance" or CPG) addressing requirements for imported milk and cream under the Federal Import Milk Act (FIMA). This Draft Guidance seeks to provide guidance regarding which imported dairy products require a permit under the FIMA, Public Law No. 69-625 (codified as 21 U.S.C. §§ 141-149).

Nestle is concerned that the Draft Guidance could be interpreted to advise that a FIMA permit is required before canned sweetened condensed milk may be imported into the United States. Such a result would be inconsistent with current agency practice and the plain language and intent of the FIMA, which Nestle has long understood to not apply to sweetened condensed milk that complies with the applicable standard of identity, set forth at 21 C.F.R. § 131.120. As described more fully below, a product produced in accordance with the standard will necessarily contain high levels of sugar, approaching 50% of the product weight, and thus is not reasonably regarded as "milk" or "cream" for FIMA purposes. Moreover, the permit provisions of FIMA are unnecessary to ensure the safety of sweetened condensed milk, a shelf stable product with a water activity (a_w) below 0.85. Accordingly, we ask that FDA revise the Draft Guidance to make clear that an FMIA permit is not required for sweetened condensed milk products marketed in accordance with the federal standard of identity.

SWEETENED CONDENSED MILK IS NOT PROPERLY REGARDED AS "MILK OR CREAM" FOR FIMA PURPOSES

Under the FIMA, as codified in 21 U.S.C. §§ 141-149, "the importation into the United States of *milk and cream* is prohibited unless the person by whom such milk or cream is shipped or transported into the United States holds a valid permit from the Secretary of Health and Human Services." 21 U.S.C. § 141 (emphasis added). The statute does not define milk or cream. The statute also does not reference any other dairy products, with the exception of references in the waiver provisions of 21 U.S.C. § 143 to condensed and evaporated milk—products that compositionally differ from milk only in terms of water content. Because the statute expressly addresses such similar products as milk, cream, evaporated milk, and condensed milk, the law on its face is most reasonably interpreted to include only products that either are exclusively milk or cream, or are so closely related to such products as to be considered the practical equivalent of milk or cream.

In contrast, canned sweetened condensed milk is a distinct product that differs substantially from milk and cream. Significantly, sweetened condensed milk by its very nature has a high sugar content that approaches and may exceed 50% of the product weight. Nutritive carbohydrate sweeteners play a central role in the formulation and stability of sweetened condensed milk: under the standard of identity for sweetened condensed milk, nutritive carbohydrate sweetener must be added in a quantity that is "sufficient to prevent spoilage." 21 C.F.R. § 131.120. Sweetened condensed milk produced in accordance with the applicable standard, therefore, differs from milk, cream, evaporated milk, or condensed milk, and thus is not reasonably interpreted as "milk" or "condensed milk" for FIMA purposes. 1/

1/ Nestle acknowledges that FDA's regulations to implement the FIMA interpret sweetened condensed milk to be within the purview of the statute. *See* 21 C.F.R. § 1210.3(d). These regulations, however, were promulgated long ago and cannot lawfully expand the meaning of "milk" beyond the boundaries established by the statute itself.

FDA has expressly recognized the limited scope of the FIMA permit provisions. Specifically, in an advisory opinion addressing the status of ice cream under the FIMA, FDA advised that—

> The terms milk and cream in the FIM Act are not as broadly defined as the jurisdictional terms under the Federal Food, Drug, and Cosmetic Act (FDC Act). . . We recognize that the literal language of the FIM Act applies only to milk and cream and not to products predominantly comprised of milk and cream . . . Therefore . . . we advise that we will interpret the FIM Act as not requiring the issuance of a permit to import ice cream.

Letter from Joseph Hile, Associate Commissioner for Regulatory Affairs, to Edward J. Farrell, Esq. (Oct. 4, 1983). In terms of FIMA applicability, sweetened condensed milk is no different from ice cream, and the same approach should apply.

A PERMIT IS UNNECESSARY TO ENSURE THE SAFE IMPORTATION OF SWEETENED CONDENSED MILK

The overriding purpose of the FIMA is to protect public health by ensuring that imported milk and cream products do not contain harmful microorganisms. Because compliance with the FDA standard for sweetened condensed milk is sufficient to ensure the microbial safety of the product, a FIMA permit is unnecessary to protect public health. Indeed, a permit requirement for sweetened condensed milk that complies with FDA's standard of identity would be inconsistent with FDA's determination to not require a permit for commercially sterile products in hermetically sealed containers.

The exemption for hermetically sealed containers may be traced to a March 1968 *Federal Register* notice, in which FDA determined that "imported milk products in hermetically sealed cans so processed by heat as to prevent spoilage" are not subject to the provisions of the Federal Import Milk Act. 33 Fed. Reg. 4881 (Mar. 22, 1968). On the basis of this determination, CPG 7119.05 currently advises that a permit is required for sweetened condensed milk "unless it can be conclusively demonstrated that the condensed milk has been hermetically sealed and sterilized." In Section III(B)(1)(i), the Draft Guidance provides that sweetened condensed milk is subject to the FIMA permit requirement for importation. In Section III(B)(2)(iii), however, an exemption is provided for "[a]ny of the dairy

products for which a permit is otherwise required (see III.B.1) if they have been processed and packaged in hermetically sealed containers so as to be commercially sterile in accordance with the requirements of 21 C.F.R. 108.35 and 113." The cited sections provide requirements for thermally processed low-acid foods packaged in hermetically sealed containers.

Sweetened condensed milk is not eligible for regulation under the requirements for thermally processed low-acid foods because it has a water activity below 0.85, and therefore does not meet the definition of "low-acid food" within the meaning of 21 C.F.R. § 113.3(n). Although the product cannot be regulated as a thermally processed low-acid food, it has a similar safety profile from a microbiological perspective, and, as a pasteurized canned product, may reasonably be classified as a hermetically sealed product that is so processed by heat as to prevent spoilage. Sweetened condensed milk may, therefore, be considered to be exempt from the FMIA permitting provisions pursuant to the long-standing exemption for products in appropriate hermetically sealed containers. 2/

Notably, FDA has defined "hermetically sealed container" to mean "a container that is designed and intended to be secure against the entry of microorganisms and thereby to maintain the commercial sterility of its contents after processing." 21 C.F.R. § 113.3(j). A product is deemed to have achieved "commercial sterility" if "the control of water activity and the application of heat" renders the food "free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution." 21 C.F.R. § 113.3(e)(1)(ii). These definitions may reasonably be used to describe canned sweetened condensed milk, which is pasteurized, hermetically sealed, and reliant upon water activity to control microorganisms.

Even if FDA does not agree that sweetened condensed milk is reasonably viewed as a hermetically sealed and sterilized product, the FIMA permit requirements should nonetheless not apply. Products having a low water activity

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2/ We recognize that the existing CPG advises that the exemption for hermetically sealed products, which is based on a legal opinion provided by the Attorney General, does not apply to sweetened condensed milk which has not been hermetically sealed and sterilized by heat. The CPG provides no factual, legal, or other justification for this determination.

are exempt from regulation under the low-acid canned food provisions because agency oversight under those provisions is considered unnecessary to ensure their safe distribution. Nestle is unaware of any reasonable basis for concluding that the FIMA permit requirement should not apply to products such as low-acid canned foods (presumably on the basis of microbiological safety) but should apply to products that are exempt (due to an inherently suitable safety profile), from those same requirements. In short, products for which similar assurances of safety may be obtained should be treated similarly under the FIMA.

ACTION REQUESTED

Sweetened condensed milk is a microbiologically sound food product that may be safely imported without a FIMA permit. Accordingly, for the reasons explained in these comments, Nestle asks that FDA clarify that sweetened condensed milk products marketed in compliance with the applicable FDA standard of identity are not subject to the FIMA permit provisions.

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Nestle appreciates FDA's consideration of these comments. If useful, we would be pleased to discuss with CFSAN any of the points made in these comments.

Sincerely,

Richard S. Silverman
Counsel to Nestle USA, Inc.

cc: Ann Mileur Boeckman