

FDA Issues Draft Guidance on FCN Submissions for Substances Intended to Contact Infant Food

PRODUCTS OF INTEREST, US FDA

By LANA BECKETT, January 30, 2017

Keller and Heckman attorneys **Cynthia Lieberman**¹⁾ and **George Misko**²⁾ have **reported**³⁾ on the U.S. Food and Drug Administration's (FDA) long-awaited draft guidance titled "**Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and or Human Milk**⁴⁾," released on December 8, 2016, regarding the preparation of Food Contact Notifications (FCNs) for food-contact substances (FCS's) that are intended to come into contact with infant formula and/or human (breast) milk (collectively "infant food"). FDA noted the types of FCS's that are covered by the draft guidance include materials used in packaging infant formula and in manufacturing baby bottles, including bottle inserts and nipples.

Although FDA has been restricting the use of FCS's with infant food for several years now, the draft guidance formally sets out the data and other scientific information that FDA "recommends" notifiers to provide to support a determination that a substance intended for use in contact with infant food is safe for the intended use in accordance with Section 409(h) of the Federal Food Drug and Cosmetic Act.

The draft guidance contains detailed chemistry, toxicology, and administrative recommendations for preparing and submitting FCNs for substances intended to contact infant food. Electronic or written comments on this draft guidance should reference Docket No. FDA-2016-D-1814 and may be submitted through February 7, 2017.

Resources for this article

1. Cynthia Lieberman

http://www.lexology.com/1115/author/Cynthia_B_Lieberman/

2. George Misko

http://www.lexology.com/1115/author/George_G_Misko/

3. reported

http://www.lexology.com/library/detail.aspx?g=4777f746-1201-44b5-91d6-f6efbfff5127&utm_source=Lexology+Daily+Newsfeed&utm_medium=HTML+email+-+Body+-+General+section&utm_campaign=Lexology+subscriber+daily+feed&utm_content=Lexology+Daily+Newsfeed+2016-12-15&utm_term

4. Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and or Human Milk

<https://prop65clearinghouse.com/documents/19182>