

IN THIS SECTION**GUIDANCE DOCUMENT**

Guidance for Industry: Preparation of Food Contact Notifications for Food Contact Substances in Contact with Infant Formula and/or Human Milk

MAY 2019

Final

Docket Number:FDA-2016-D-1814 (<https://www.regulations.gov/docket?D=FDA-2016-D-1814>)**Issued by:**

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Office of Food Additive Safety

We are providing this guidance to represent our current thinking on recommendations for preparation of food contact notification (FCN) submissions for food contact substances (FCSs) used in contact with infant formula and/or human (breast) milk.

This document is intended to provide specific guidance to help manufacturers or suppliers submitting an FCN in the safety assessment of substances that are intended for use in contact with infant formula and/or human milk. FCSs that would be affected by this guidance document may include infant formula packaging for both liquid (concentrate and ready to feed) and powdered formula, baby bottles, bottle inserts, nipples, and any other materials that are in contact with infant food.

Download the Guidance (</media/124714/download>)More on Ingredients, Additives, GRAS & Packaging (</ingredients-additives-gras-packaging>)

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Division of Dockets Management (HFA- 305)
Food and Drug Administration
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