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About the GRAS Notification Program

CFSAN/Office of Food Additive Safety

October 2016

Submission of a GRAS Notice to FDA

A substance that will be added to food is subject to premarket approval by FDA unless it is generally recognized, among qualified experts, to be safe under the conditions of its intended use (GRAS is the acronym for generally recognized as safe).[1] On August 17, 2016, FDA issued a final rule (The GRAS final rule; 81 FR 54960) that formalized a notification procedure and established our regulations in Subpart E of part 170. Our regulations state that any person may notify FDA of a conclusion that a substance is GRAS under the conditions of its intended use. Our regulations explain that any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the FD&C Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use. Subpart E of part 170 further describes how to notify FDA through the submission of a GRAS notice and explains what FDA will do with a GRAS notice.

FDA strongly encourages any person to make a submission to our GRAS notification program following the available procedures for FDA oversight of GRAS conclusions. FDA also encourages any person to contact us about the GRAS notification program or to request a pre-submission meeting with FDA to discuss issues that may be relevant to the submission of a GRAS notice.

FDA's Responses to GRAS Notices

In general, FDA's response has been in one of three categories:

1. The agency does not question the basis for the notifier's GRAS conclusion;
2. The agency concludes that the notice does not provide a sufficient basis for a GRAS conclusion (e.g., because the notice does not include appropriate data and information or because the available data and information raise questions about the safety of the notified substance); or
3. The response letter states that the agency has, at the notifier's request, ceased to evaluate the GRAS notice.

The Inventory of GRAS Notices

In the GRAS final rule, FDA noted the intention to maintain an Inventory of GRAS notices and the agency's response to those notices, which continues the practice that began under a proposed rule published in 1997 (the GRAS proposal; 62 FR 19838). The **GRAS Inventory (/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm)**page is the

entry point to this information. Importantly, the inventory includes all filed GRAS notices since 1998, regardless of whether the notice is pending at FDA or has come to closure, and regardless of the nature of FDA's response.

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[1] In addition, a substance that is used in accordance with a sanction granted prior to September 6, 1958 is not subject to premarket approval.

Contact FDA

(240)-402-1192
premarkt@fda.hhs.gov (mailto:premarkt@fda.hhs.gov)

GRAS Notification Program
Additional Contact Information
(http://www.fda.gov/Food/IngredientsPackagingLabeling/ucm081905.htm)
Office of Food Additive Safety
5001 Campus Drive
College Park, MD 20740

More in Generally Recognized as Safe (GRAS)
(/Food/IngredientsPackagingLabeling/GRAS/default.htm)

GRAS Notice Inventory
(/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm)

GRAS Substances (SCOGS) Database
(/Food/IngredientsPackagingLabeling/GRAS/SCOGS/default.htm)

Enzyme Preparations Used in Food
(/Food/IngredientsPackagingLabeling/GRAS/EnzymePreparations/default.htm)

Microorganisms & Microbial-Derived Ingredients Used in Food
(/Food/IngredientsPackagingLabeling/GRAS/MicroorganismsMicrobialDerivedIngredients/default.htm)