U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
October 1, 2001

Agency Response Letter
GRAS Notice No. GRN 000058

Mr. John Lemker
Bell, Boyd, and Lloyd LLC
Three First National Plaza
70 West Madison Street, Suite 3300
Chicago, IL 60602-4207

Re: GRAS Notice No. GRN 000058

Dear Mr. Lemker:

The Food and Drug Administration (FDA) is responding to letters, dated September 21, 2000 and September 6, 2001, that you submitted on behalf of Kerry Ingredients (Kerry). Your September 21, 2000 letter requests that FDA convert the filed GRAS affirmation petition GRP 3G0287 to a GRAS notice in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). FDA received this conversion request on September 25, 2000 and designated it as GRAS Notice No. GRN 000058. In a series of telephone conversations, representatives of the Office of Food Additive Safety (OFAS) discussed your conversion request with you. In your letter dated September 6, 2001, you requested that FDA convert GRP 3G0287 to a food additive petition rather than continue to evaluate it as a GRAS notice. Given your request, FDA ceased to evaluate GRN 000058 on September 10, 2001, the date that we received your letter dated September 6, 2001.

GRP 3G0287 was submitted to FDA by Beatrice Foods, the business predecessor of Kerry Ingredients. The subject of GRP 3G0287 is gum arabic (acacia), which is the dried gummy exudate obtained from stems and branches of trees belonging to the various species of the genus *Acacia*. Different investigators have attributed 500 to 900 such species to this genus. The gum consists of the calcium, magnesium and potassium salts of arabic acid, an acid polysaccharide. The polysaccharide is a polymer that ranges from 250,000 to 1,000,000 in molecular weight. Its composition is approximately 30 percent L-arabinose, 37 percent D-galactose, 11 percent L-rhamnose, and 14 percent D-glucuronic acid.

In GRP 3G0287, Kerry requests that FDA affirm that gum arabic is GRAS, through scientific procedures, for use as a thickener, emulsifier or stabilizer in the manufacture of creamers for use in manufacturing alcoholic beverages at a maximum level of use of 20 percent. Kerry relies on data and information discussed in a 1973 report of the Select Committee on GRAS substances (the Select Committee)[1] to support its view that the intended use of gum arabic in alcoholic beverages is GRAS (Ref. 1). In that 1973 report, the overall conclusion of the Select Committee was "[t]here is no evidence in the available information on gum arabic that demonstrates a hazard to the public when it is used at levels that are now current and in the manner now practiced. However, it is not possible to determine,

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without additional data, whether a significant increase in consumption would constitute a dietary hazard."

FDA has previously affirmed that gum arabic is GRAS for some uses at specified maximum levels of use (proposed rule, 39 FR 34204, September 23, 1974; final rule, 41 FR 53608, December 7, 1976; 21 CFR 184.1330). In large part, FDA based its affirmation of GRAS status on the 1973 report of the Select Committee in combination with the uses of gum arabic that manufacturers reported to the National Academy of Sciences/National Research Council in a comprehensive survey of the uses of various food ingredients.

In a rulemaking concurrent to the rulemaking that affirmed the GRAS status of some uses of gum arabic, FDA established 21 CFR 184.1(b)(2) (proposed rule, September 23, 1974, 39 FR 34194; final rule, December 7, 1976, 41 FR 53600). Under 21 CFR 184.1(b)(2), "[i]f the ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use. Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation." Subsequent to that rulemaking, FDA affirmed the GRAS status of a use of a food ingredient in accordance with 21 CFR 184.1(b)(2) when the Select Committee concluded "it is not possible to determine without additional data, whether a significant increase in consumption would constitute a dietary hazard." (See, e.g., 21 CFR 184.1097, 21 CFR 184.1115, 21 CFR 184.1115, and 21 CFR 184.1366). The Select Committee reached this conclusion in the case of gum arabic, and the rulemaking that affirmed the GRAS status of some uses of gum arabic makes clear that FDA viewed the regulation governing gum arabic within the same rubric as that of 21 CFR 184.1(b)(2) (see 39 FR 34194).

During the rulemaking that established 21 CFR 184.1(b)(2), FDA addressed a comment that contended that a subsequently instituted use that may in fact be GRAS would have to covered by a food additive regulation. In response to this comment, FDA advised that 21 CFR 184.1(b)(2) does not require that a subsequent use be covered by a food additive regulation even though it may be GRAS. FDA specifically pointed out that a regulation affirming a substance as GRAS with specific limitations on the conditions of use may be amended to cover additional uses that have become GRAS. Importantly, either mechanism requires rulemaking - i.e., rulemaking that results in a food additive regulation or rulemaking that amends the current GRAS affirmation regulation.

The rulemaking that affirmed the GRAS status of some uses of gum arabic, together with the rulemaking that established 21 CFR 184.1(b)(2), makes clear that the appropriate mechanism for Kerry to lawfully use gum arabic outside the limitations established in the existing regulation for gum arabic is to submit a petition to FDA. Kerry could petition FDA either to conduct rulemaking that results in a food additive regulation or to conduct rulemaking that amends the current GRAS affirmation regulation. Kerry did so when it submitted GRP 3G0287.

As discussed in the GRAS proposal, FDA is directing its resources to the food additive petition process, which is required by law, rather than to the GRAS affirmation petition process, which is voluntary. Given this fact, and given the regulatory framework that is associated with gum arabic, Kerry's letter dated September 6, 2001, requests that FDA convert GRP 3G0287 to a food additive petition. Because the agency already has devoted resources to the review of the data and information in GRP 3G0287, FDA expects to be able to process such a food additive petition promptly.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in Kerry's notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the homepage of the Office of Food Additive Safety (on the Internet at http://www.cfsan.fda.gov/~lrd/foodadd.html).

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition

References

1. Life Sciences Research Office, Federation of American Societies for Experimental Biology. 1973. Evaluation of the Health Aspects of Gum Arabic as a Food Ingredient.

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(1)During the 1970's, FDA initiated a comprehensive review of GRAS substances, including gum arabic. As part of the comprehensive review, FDA commissioned, through the Life Sciences Research Office of the Federation of American Societies for Experimental Biology, the "Select Committee on GRAS Substances." The charge to the Select Committee was to summarize the available scientific literature on certain substances and to provide a recommendation as to what restrictions, if any, on the use of each substance would be needed to ensure its safe use in food.

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