



Memorandum

Date **April 8, 1996**

From **Acting Chief, Additives Evaluation Branch #1 (HFS-226)**

Ref 9

Subject **Gum Arabic in Alcoholic Beverages: Final Toxicology Evaluation**

To **R. Martin, Ph.D., Direct Additives Branch (HFS-217)**

GRP 3G0287

**Beatrice Foods, Inc.
Chicago, IL**

CHRONOLOGY OF TOXICOLOGY REVIEWS FOR GRP 3G0287

9/6/83, 2/15/85

SCOGS indicated a Type 2 conclusion for gum arabic based on potential allergenicity. Petitioned increase in use for this compound in cream type liqueurs represents no toxicologic hazard other than the potential allergenicity. [Based on allergenicity concerns,] we recommend that, when used in alcoholic beverages, the substance be identified on the label..

3/8/88

Dr. Griffiths pointed out that 21 CFR 101.4 requires labeling for gum arabic and other food additives under the general food labeling provisions, which would enable individuals to avoid exposure to additives to which they are allergic. [This regulation does not extend to additives used in alcoholic beverages, unless a documented safety concern for an additive can be addressed by labeling.] Because the evidence supporting a safety problem relating to allergenicity of gum arabic is extremely weak, Toxicology does not feel there is a significant body of data to support the [listing of gum arabic] on the labeling of alcoholic creme-style liquors.

8/12/92

An updated search of the scientific literature revealed no direct evidence that would indicate that gum arabic in food is allergenic.

Chemistry review of 3/7/94

Chemistry estimates that up to 0.75 g gum arabic/p/d could be consumed from the petitioned use in alcoholic beverage mixes. This EDI represents a 50% increase over Chemistry's previous estimate of 0.5 g/p/d for gum arabic (11/21/83). Available safety information (including an NTP carcinogenesis bioassay) supports this increase in exposure.

CONCLUSION

Because the evidence supporting a safety problem relating to allergenicity of gum arabic remains extremely weak, we see no need on grounds of safety to require the listing of gum arabic on the label of alcoholic creme-style liquors. We reaffirm our previous conclusion that the petitioned increase in use for gum arabic in cream type liqueurs represents no toxicologic hazard.

Carl B. Johnson
Carl B. Johnson, Ph.D.