



October 25, 1999

RECEIVED
11-1-99
LES

Ms. Marsha C. Wertzberger
Arent Fox Attorneys At Law
1050 Connecticut Avenue, NW
Washington, D.C. 20036-5339

Dear Ms. Wertzberger:

This letter responds to your letters dated July 1, 1998 and April 26, 1999 to the Office of Food Labeling requesting on behalf of your client MD Foods Ingredients amba that the Food and Drug Administration (FDA) recognize the caloric value of 1.5 kcal/g for D-tagatose for the purposes of nutrition labeling.

In support of your July 1, 1998 request, you submitted a report in which a 1.5 kcal/g net metabolizable energy value for D-tagatose was estimated using a factorial calculation model. The report was documented with copies of studies cited in the report, including in vitro, experimental animal, and human studies of the digestion, absorption, and fermentation of D-tagatose. Subsequently on April 26, 1999, you submitted two additional assessments of D-tagatose caloric value which were prepared by Geoffrey Livesey, Ph.D. and by Dennis Gordon, Ph.D. The opinion of both of the independent reviewers was that a net metabolizable energy value of 1.5 kcal/g is justified.

The agency finds that your submissions contain the type of scientific evidence upon which a self-determination of a caloric value for D-tagatose could be based. At this time the agency is neither confirming nor contesting your self-determined caloric value. Until such time as FDA approves a specific food factor for D-tagatose as provided for in 21 CFR 101.9(c)(1)(i)(D), the agency does not object to the use of the factor of 1.5 kilocalorie per gram in calculating the caloric value of D-tagatose.

The agency intends to propose energy values to be used in nutrition labeling for sugar alcohols and soluble dietary fiber in the future as our resources and priorities permit. It is likely that the agency would include energy values for other poorly digested and absorbed carbohydrates such as D-tagatose in the same rulemaking. As you are aware, it is possible that an energy value different from the above value may be established in the final rule resulting from such rulemaking. Once a final rule is published, adjustments on the food label may be necessary for compliance with the final rule.

It is the responsibility of MD Foods Ingredients to ensure that food ingredients that the firm markets are safe and in compliance with all applicable legal and regulatory requirements. Under § 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act, any ingredient

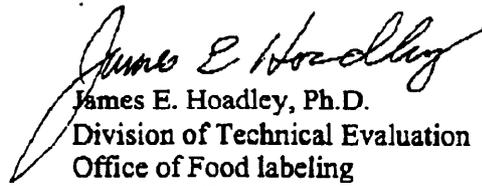
Page 2 - Ms. Marsha C. Wertzberger

intentionally added to food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) under the conditions of its intended use. D-tagatose is not listed in FDA's regulations as a food additive or as a GRAS ingredient. Although MD Foods Ingredients may market a GRAS ingredient without premarket approval, it would be the firm's responsibility to ensure that the ingredient satisfies GRAS criteria. For your information, FDA recently proposed rules that would clarify the criteria for GRAS status and establish a procedure whereby a manufacturer may notify FDA of a GRAS determination (62 FR 18938; April 17, 1997; copy enclosed). Although that proposed rule has not yet become final, a GRAS notification program is currently operating under the provisions of the proposed rule.

Our response to you addresses only your request that FDA recognize a caloric value of D-tagatose for purposes of nutrition labeling. If you have any questions about the regulatory status of D-tagatose, the procedures for obtaining approval for a food additive, or the proposed GRAS notification program, we recommend that you discuss those questions with the Office of Premarket Approval. An initial contact for such questions is Dr. Linda Kahl, who can be reached by telephone at (202)418-3101 or by electronic mail at LKAHL@BANGATE.FDA.GOV.

We trust that the foregoing will be helpful.

Sincerely yours,


James E. Hoadley, Ph.D.
Division of Technical Evaluation
Office of Food Labeling
Center for Food Safety
and Applied Nutrition

Enclosure