



APR 19 2002

Diane B. McColl, Esquire
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, D.C. 20005-3960

RE: Health Claim Petition - Petition to Amend 21 CFR 101.80 to Authorize a Noncariogenicity
Dental Health Claim for D-Tagatose

Dear Ms. McColl:

This letter is in reference to the subject health claim petition that you submitted and was received by FDA on January 9, 2002. We informed you on January 22, 2002, that the date by which FDA would either file or deny your petition is April 19, 2002. We have completed our initial review of this petition and are filing it as specified in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act). We will either publish a proposal in response to the petition or deny the petition within 90 days of the filing date, i.e., within 90 days of April 19, 2002. Consistent with our strategy for implementation of the 1999 *Pearson* court decision (see 65 Fed. Reg. 59855, October 6, 2000) we will consider using our interim final rule authority under section 403(r)(7)(A)(iii) of the act to allow use of the health claim immediately upon publication of the proposal.

Sincerely yours,

Lynn A. Larsen, Ph.D.

Director

Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

02P-0177

LET /