



JAN 22 2002

Food and Drug Administration
Washington DC 20204

Diane B. McColl, Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

RE: Health claim petition to amend 21 CFR 101.80 to authorize a noncariogenicity dental health claim for d-tagatose

Dear Ms. McColl:

This letter acknowledges receipt on January 9, 2002, by the Food and Drug Administration (FDA) of the petition submitted by you on behalf of Arla Foods Ingredients amba pursuant to section 403(r)(4) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 343(r)(4)).

Your petition is undergoing initial FDA review. In accordance with 21 U.S.C. 343(r)(4)(A)(i) and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition (i.e., April 19, 2002), FDA will notify you by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in "B. Summary of Scientific Data" if the information in "A. Preliminary Requirements" is inadequate in explaining how the substance conforms to the requirements of 21 CFR 101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. A petition that has been denied, or has been deemed to be denied, without filing will not be made available to the public. A filed petition will be available to the public to the extent provided in 21 CFR 101.70(e).

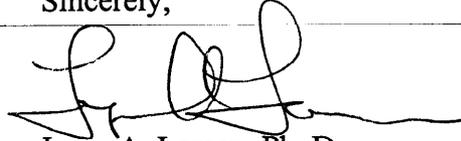
02P-0177

ACK 1

Page 2 - Ms. McColl

Dr. Susan Thompson on my staff has been assigned your petition. Please feel free to contact her at (301) 436-1784 if you have questions concerning this petition.

Sincerely,

A handwritten signature in black ink, appearing to read 'Lynn A. Larsen', with a long horizontal flourish extending to the right.

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