



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC - 7 1990

Food and Drug Administration
Washington DC 20204

Anne B. Sayigh, Ph.D.
Parexel International Corporation
One Alewife Place
Cambridge, MA 02140

Dear Dr. Sayigh:

This is in response to your letter dated November 29, 1990 in which you inquired if your product, FIBERSOL #2, meets the requirements for GRAS status as set forth in 21 CFR 184.1444 Maltodextrin. Basically, this regulation requires that (1) the product be prepared from cornstarch with safe and suitable acids and enzymes and has a dextrose equivalent of less than 20 and (2) be of a purity suitable for its intended use.

FIBERSOL #2 is obtained from cornstarch using hydrochloric acid and acceptable enzymes. The specifications that you have listed for your product are typical of products of this type. Therefore, we would concur that your product is in compliance with 21 CFR 184.1444.

We trust that the above response satisfies your inquiry. If you need additional assistance, please contact us again.

Sincerely yours,

Robert Leo Martin, Ph.D.
Direct Additives Branch, HFF-334
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition