NDA 20-900

Alimenterics, Inc.
Attention: C. Lawrence Christman, Ph.D.
Director of Regulatory Affairs and Quality Assurance
118 American Road
Morris Plains, NJ 07950

Dear Dr. Christman:

Please refer to your new drug application (NDA) dated August 8, 1997, received August 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PYLORI-CHEK Breath Test Kit (^{13}C urea) 100 mg.

We acknowledge receipt of your submissions dated August 28, September 21, December 14 and 22, 1998, and January 13, 1999.

This new drug application provides for the use of ^{13}C urea oral solution, 100 mg as a component of the PYLORI-CHEK™ Breath Test for the detection of urease associated with *Helicobacter pylori* infection in adult patients.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted February 9, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-900." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Robin Anderson, Project Manager, at (301) 827-2127.

Sincerely,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research