20900

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-900

Trade Name: Pylori-Chek Breath Test Kit

Generic Name: 13 c Urea 100 mg.

Sponsor: Alimenterics, Inc.

Approval Date: February 4, 1999

Indications: For detection of urease associated with Helicobacter Pylori infection in adult patients

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APPLICATION NUMBER:

20-900

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				
Approvable Letter				
Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)				
Administrative Document(s)	X			
Correspondence	X			

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APPLICATION NUMBER:

20-900

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-900

FEB 4 1999

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,

/S/

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

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 26 1998

Janet G. Murnick, Ph.D.
Alimenterics Inc.
301 American Road
Morris Plains, NJ, 07950

Re: K973000
Device: Alimenterics LARA™ Breath Test System
Regulatory Class: I
Product Code: MSQ (LYR)
Dated: August 6, 1997
Received: August 12, 1997

Dear Dr. Murnick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent for the indications for use stated in the enclosure to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your product contains the following component subject to regulation as drugs: ^{13}C-Urea (powder-100 mg).

Our substantially equivalent determination does not apply to the drug component (NDA 20-900) of your product. For information on applicable Agency requirements regarding the drug component, we suggest you contact:

Mark Goldberger, M.D., M.P.H.
Division Director
Division of Special Pathogens
and Immunologic Drug Products (HFD-590)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 827-2335

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality Systems Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification only after the Center for Drug Evaluation and Research has approved the drug component of your product. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

/S/

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure