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RESEARCH**

APPLICATION NUMBER:
20-900

PHARMACOLOGY REVIEW

PHARMACOLOGIST'S REVIEW

NDA #: 20 - 900 (Original)

DATE SUBMITTED: 8/11/97
 DATE ASSIGNED: 8/21/97
 DATE REVIEW COMPLETED: 11/26/97
 HFD - 590

SPONSOR: Alimenterics, Inc.
 301 American Road
 Morris Plains, NJ 07950

DEVICE: Alimenterics LARA™ Breath Test System (¹³C urea breath test for *Helicobacter pylori*)

PROPOSED USE: Non-invasive analytical procedure to test for the presence of *H. pylori* based upon the enzymatic breakdown of ¹³C urea to ammonia and ¹³CO₂ by urease enzyme endogenous to *H. pylori*. The ratio of expired ¹³CO₂ to ¹²CO₂ will be utilized to indicate the presence of *H. pylori*.

EVALUATION AND CONCLUSION:

There are no pharmacology / toxicology issues in this submission.

/S/

Stephen G. Hundley, PhD

concurrences:

HFD - 590 / R. Albrecht / DDDir
 HFD - 590 / K. Hastings / TL

S/1/8/98
 S/3/93

disk:

HFD - 590 / K. Hastings

cc:

HFD - 590 Original NDA

HFD - 590 / Stat / N. Silliman

HFD - 590 Division File

HFD - 345

HFD - 590 / CSO / R. Anderson

HFD - 590 / Pharm / S. Hundley

HFD - 590 / MO / R. Hopkins

HFD - 590 / Micro / L. Utrup

HFD - 590 / Biopharm / A. Funmilayo