DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Commissioner
5600 Fishers Lane
Room 14-105, HF-7
301-443-1306

Food and Drug Administration
Rockville MD 20857

RECEIVED NOV 2 8 1994

November 22, 1994

Robert F. Martin, Ph.D.
Meretek Diagnostics, Inc.
Medical Towers Building
1709 Dryden Road, Suite 1513
Houston, TX 77030

Re: Request For Designation
Meretek ^{13}C-Urea Breath Test (^{13}C-UBT) Collection Kit
Our File: RFD-94-15

Dear Dr. Martin:

We have completed our review of the above-referenced request for a product jurisdiction determination, accepted for filing on August 23, 1994. Meretek met with FDA officials on November 2 and November 8, 1994, to discuss the pending request. To permit the agency to consider fully the information presented at these meetings, the designation deadline was extended to November 22, 1994.

The combination product under consideration, Meretek's ^{13}C-Urea Breath Test Collection Kit, includes ^{13}C-labeled urea, a test meal { } sterile water, a breath bag assembly, and vacutainer specimen collection tubes. The request for designation indicates that the product is intended for use with appropriate general purpose laboratory equipment to detect the presence of urease associated with *Helicobacter pylori* in the human stomach. Meretek recommended that the Center for Devices and Radiological Health (CDRH) be given primary jurisdiction for the regulation of this combination product and recommended that the product be regulated under the device authorities of the Federal Food, Drug and Cosmetic Act (the Act).

After considering the information provided in the above-referenced request, meeting with representatives of Meretek, and consulting with appropriate officials in CDRH and the Center for Drug Evaluation and Research (CDER), I am designating CDRH as the agency component with primary jurisdiction for the premarket review and regulation of this combination product. CDRH will regulate Meretek's ^{13}C-Urea Breath Test Collection Kit using the device and drug authorities of the Act as follows:

(1) the breath collection device components of the kit will be reviewed and regulated under the device provisions of Section 510(k) of the Act (21 U.S.C. § 360(k));

(2) the drug component, ^{13}C-urea, will be reviewed and regulated under the new drug provisions of the Act (21 U.S.C. § 355), which requires a new drug application (NDA); and

(3) the combination product, the ^{13}C-Urea Breath Test Collection Kit, labeled for detection of the presence of *Helicobacter pylori* in the human stomach, which includes both the ^{13}C-urea covered by an NDA and the device components, will be regulated under the device provisions of section 510(k) of the Act.

To apply for these marketing clearances, Meretek should make one submission to CDRH, as specified below. Meretek has the option to advise CDRH that it does not want to seek the marketing clearance for the general breath collection device specified in subparagraph (1) above. Any clinical investigations of the product should be conducted in accordance with the investigational device exemption requirements in 21 C.F.R. Part 812.

The Division of Clinical Laboratory Devices in CDRH will be the primary review division. The division will consult with CDER staff regarding the review of the chemistry, manufacturing and controls section of the NDA for ^{13}C-urea, and may consult with CDER staff on other aspects of the NDA as needed. For further information, contact Sharon L. Hansen, Ph.D., Division of Clinical Laboratory Devices, 2098 Gaither Road (HFZ-440), Rockville, MD 20850 (301-594-2096). FDA recommends that Meretek contact CDRH early in the application process for guidance on organizing and formatting its submission. Please include a copy of this letter in your initial submission to CDRH.

Please note that the Prescription Drug User Fee Act requires an application fee for certain new drug applications filed after September 1, 1992. For further information regarding user fees, contact Mr. Thomas Hassall, Consumer Safety Officer, Center for Drug Evaluation and Research, Food and Drug Administration, HFD-5, 5600 Fishers Lane, Rockville, MD 20857, (301) 594-6740.

You may request reconsideration of this designation decision within 15 days of this letter. See 21 C.F.R. § 3.8(c). If you have any questions regarding this matter, please contact Ms. Andrea Chamblee of this office at 301-443-1306.

Sincerely yours,

Amanda B. Pedersen

Amanda B. Pedersen
Product Jurisdiction Officer

cc: Dr. Sharon L. Hansen