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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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

September 19, 1996

Martin A. Baker
Vice President
Metabolic Solutions, Inc.
7 Henry Clay Drive
Merrimack, NH 03054

Re: Request for Designation
^{13}C-Urea Blood Test
Our File: RFD-96-16

Dear Mr. Baker:

We have completed our evaluation of the above-referenced request for a product jurisdiction determination, accepted for filing on July 22, 1996.

According to Metabolic Solutions, Inc. (MSI), ^{13}C-Urea Blood Test is a combination product used for the in vitro measurement of $^{13}CO_2$ in blood samples of subjects who have ingested ^{13}C-urea. The test is intended for use in the detection of Helicobacter pylori (H. pylori) in the human stomach, [ ]. The ^{13}C-Urea Blood Test consists of: (1) ^{13}C-urea; (2) blood collection supplies comprised of Vacutainer™ standard green top, [ ] coated tubes for collecting the blood, and a Vacutainer™ needle and needle holder; (3) sample storage tubes comprised of Exetainer™ tubes; and (4) [ ] liquid meal supplement. An isotope ratio mass spectrometer is also used in conjunction with the blood test for analysis of the blood samples, but is not intended to be included as a component of the test marketed by MSI.

MSI's request for designation recommended that the Center for Devices and Radiological Health (CDRH) be the Center with primary jurisdiction for the ^{13}C-Urea Blood Test.

After considering the information provided in the above-referenced request, and consulting with the 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. MSI's ^{13}C-Urea Blood Test will be regulated by CDRH using the device and drug authorities of the Act as follows:

(1) 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

(2) the combination product, ^{13}C-Urea Blood Test, including both the ^{13}C-urea covered by an NDA and the device components, will be regulated under the 510(k) premarket notification medical device provisions of the Act.

To apply for these marketing clearances, MSI should make one submission to CDRH. Any clinical investigations of the product should be conducted in accordance with the investigational device exemption requirements (IDE) in 21 C.F.R. Part 812. The IDE should contain sufficient information about ^{13}C-urea to ensure that appropriate regulatory requirements are met. A separate investigational new drug application (IND) is not required.

The Division of Clinical Laboratory Devices, Office of Device Evaluation, CDRH, will be the primary review division. The division will consult with reviewing staff in CDER regarding the review of the chemistry, manufacturing and controls section of the ^{13}C-urea drug application, and may consult with CDER staff on other aspects of the drug application as needed. MSI is strongly encouraged to discuss the content and format of each of its submissions (IDE, 510(k), NDA) with the review division at the appropriate time in product development. For further information contact Sharon L. Hansen, Ph.D., Chief, Microbiology Branch, Division of Clinical Laboratory Devices, (HFZ-440), 2098 Gaither Rd, Rockville, MD 20850, or by telephone at 301-594-2096. Please include a copy of this letter in your next 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 within 15 days of receipt of this letter. See 21 C.F.R. § 3.8(c). If you have any questions about this letter, please telephone Megan Foster, of this office, at 301-827-3390.

Sincerely yours,

Amanda Bryce Norton
Chief Mediator and Ombudsman

cc: Sharon L. Hansen, Ph.D.