DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Food and Drug Administration
Rockville MD 20857

October 2, 1995

Mr. Matt Klamrzynski
Director, Regulatory Affairs
Abbott Diagnostics Division
One Abbott Park Road
Abbott Park, Illinois 60064-3500
DEPT: 49C, BLDG. AP6C/2

Re: Request For Designation
AxSYM™ *in vitro* diagnostic hepatitis test kits
Our File: RFD-95-23

Dear Mr. Klamrzynski:

We have completed our review of the above-referenced request for product jurisdiction determination, accepted for filing on August 1, 1995.

The AxSYM™ hepatitis test kits are microparticle enzyme immunoassays. The request for designation covers [ ] hepatitis test kits:

[ ] The AxSYM™ CORE test kit is an immunoassay for the qualitative determination of antibody to hepatitis B core antigen in human serum or plasma, and is intended for use as an aid in the diagnosis of [ ] [ ] hepatitis B viral infection.

[ ] The AxSYM™ HBsAg is an immunoassay for the qualitative determination of antibody to hepatitis B surface antigen in human serum or plasma, and is intended for use as an aid in the diagnosis of acute or chronic hepatitis B viral infection.

[ ] The AxSYM™ HCV is an immunoassay for the qualitative determination of antibody to hepatitis C virus in human serum or plasma.

[ ] [ ] [ ]

[ ] The AxSYM™ CORE-M is an immunoassay for the qualitative determination of specific antibody (IgM anti-HBc) in human serum or plasma,

and is intended for use as an aid in the diagnosis of acute or recent [ ] [ ] hepatitis B viral infection.

The request for designation noted that the test kits are for in vitro diagnostic use only, and are not for use in blood or plasma donor screening.

Abbott recommended that the Center for Devices and Radiological Health (CDRH) be assigned primary jurisdiction for the premarket review of the test kits. Although Abbott did not recommend that the kits be regulated as medical devices, Abbott compared the products to other test kits that have been reviewed and regulated under the medical device premarket application (PMA) authorities of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360e et seq.).

After considering the information you have submitted, and after conferring with CDRH and the Center for Biologics Evaluation and Research (CBER), I am in substantial agreement with Abbott's recommended disposition. Therefore, I am designating CDRH as the agency component with primary jurisdiction for this product.

The test kits will be reviewed and regulated under the PMA requirements of the Act. Any clinical investigations of a test kit must be conducted in accordance with the investigational device exemption (IDE) requirements in 21 C.F.R. Part 812.

Please submit a copy of this designation letter with each of your initial submissions to CDRH. The Division of Clinical Laboratory Devices in CDRH will be the primary reviewing division. CDRH will consult with review team members in CBER, as necessary. Questions about submission requirements should be directed to Sharon Hansen, Ph.D., Division of Clinical Laboratory Devices (HFZ-440), CDRH, 2098 Gaither Road, Rockville, MD 20850, 301-594-2096.

Please note that this designation applies only to the designated products when intended for use as aids in the diagnosis and management of patients with hepatitis infection, and not for blood screening. If Abbott is interested in expanding the intended use of the products to include blood screening or other indications, Abbott must seek an agency determination of the regulatory requirements applicable to the new indications.

If you have any questions concerning this matter, please telephone Ms. Andrea Chamblee, of this office, at 301-827-3390.

Sincerely yours,

Amanda B. Pedersen
Chief Mediator and Ombudsman