



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Chief Mediator and Ombudsman
5600 Fishers Lane (HF-7)
Room 14-105
Rockville, MD 20857

Food and Drug Administration
Rockville MD 20857

March 19, 1999

Associates of Cape Cod, Inc.
704 Main Street
Falmouth, MA 02540

Re: Request for Designation
Diagnostic for Glucan in blood
Our file: RFD 99.004

Dear Dr. []

The Food and Drug Administration (FDA) has completed its evaluation of the above-referenced request for designation, received January 19, 1999, and filed January 25, 1999.

Associates of Cape Cod, Inc.'s request covers [] a clinical diagnostic for the determination of the presence of fungal glucan. The test will be used on blood and blood components of human clinical specimens. According to your request, the detection of glucan is clinically useful in screening for invasive fungal infections (e.g. candida, aspergillus, []) especially in immunocompromised patients.

[] is based on a horseshoe-crab coagulation enzyme (Limulus Amebocyte Lysate (LAL)) that is []

According to your letter, the manufacturing process for the [] [] The currently licensed products are used for the detection of endotoxins in biologicals, drugs, and medical devices and are regulated by FDA's Center for Biologics Evaluation and Research (CBER). Because of CBER's experience regulating the manufacture and testing of LAL and LAL-related products, you recommended that FDA designate the [] as a biologic and assign it to CBER for review.

We have considered the information in the request and discussed the issues raised with staff in CBER and the Center for Devices and Radiological Health (CDRH). For the reasons enumerated below, we are assigning this product to CDRH to be regulated under the medical device provisions of the Food, Drug and Cosmetic Act.¹

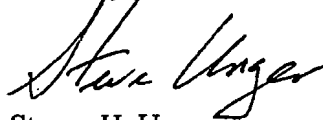
We recognize that section VI. B.1. of the Intercenter Agreement between CBER and CDRH currently assigns CBER review responsibility for LAL in vitro reagents for either manufacturing or clinical diagnostic use. However, in our view, this provision is intended solely to cover endotoxin-detecting products.² As you note, {

Assignment of this product to CDRH is consistent with section VI. C.1. of the Intercenter Agreement which assigns CDRH review responsibility for in vitro tests that are, like { } intended only for diagnostic use in the clinical management of individual patients.

The Division of Clinical Laboratory Devices, CDRH, will be the primary review group. The Division will conduct its review in consultation with CBER review staff, as appropriate. In particular, CBER may be consulted on manufacture and control issues. For further information, contact Dr. D. DuBois, Chief, Microbiology Branch, Office of Device Evaluation, CDRH, 2098 Gaither Road (HFZ-440), Rockville, MD 20850, or by telephone at 301-594-2090. Please include a copy of this letter in your initial submission to CDRH.

If you have any questions about this letter, please contact Tracey Forfa, of this office, at 301-827-3390.

Sincerely yours,



Steven H. Unger
Deputy, Office of the Chief Mediator and Ombudsman

¹ 21 U.S.C. § 360c et. seq

² 21 CFR § 660.100. LAL was originally defined in the biologics regulations as "an extract that is derived from the blood of *Limulus polyphemus* and is capable of detecting bacterial endotoxins." In the Federal Register of August 1, 1996 (61FR40153), FDA issued a final rule removing Part 660 because these product-specific regulations were deemed unnecessary.