DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Associates of Cape Cod Inc.
c/o Stacy Suberg, Ph.D.
President
RBR Limited
1738 Tamberwood Echo
Woodbury, MN 55125

MAY 21 2004

Re: K032373
Evaluation of Automatic Class III Designation
Glucatell™
Regulation Number: 21 CFR 866.3050
Classification: Class II
Product Code: NQZ

Dear Dr. Suberg:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the Glucatell™, a Beta-glucan serological assay that is intended for the qualitative detection of Beta-glucan in the serum of patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection and as an aid in the diagnosis of deep seated mycoses and fungemias. The assay should be used in conjunction with other diagnostic procedures, such as microbiological culture, histological examination of biopsy samples and radiological examination. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Beta-glucan serological assay, and substantially equivalent devices of this generic type into class II under the generic name, Beta-glucan serological assays. This order also identifies the special controls applicable to this device, entitled, "Class II Special Controls Guidance Document: Serological reagents for the detection of Beta-glucan".

FDA identifies this generic type of device as:

21 CFR 866.3050 Beta-glucan serological reagents

Beta-glucan serological reagents are devices that consist of antigens or proteases used in serological assays. The device is intended for use for the presumptive diagnosis of fungal infection. The assay is indicated for use in patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection. The device can be used as an aid in the diagnosis of deep seated mycoses and fungemias.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On March 22, 2004, FDA filed your petition requesting classification of the Glucatell™ serological assay into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA issued an order on March 18, 2004, automatically classifying the Glucatell™ serological assay in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. In order to classify the Glucatell™ serological assay into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, FDA has determined that the Glucatell™ serological assay, intended for use for the presumptive diagnosis of fungal infection in patients with symptoms of, or medical conditions predisposing the patient to invasive fungal infection and as an aid in the diagnosis of deep seated mycoses and fungemias, can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

There are no known *direct* risks to patient health. However, failure of the test to perform as indicated or error in interpretation of results may lead to improper patient management. A falsely low glucan assay measurement could result in a determination that the patient does not have an invasive fungal infection and could delay appropriate treatment. A falsely high measurement could contribute to unnecessary monitoring or potentially toxic therapy. Therefore use of assay results to adjust a treatment regimen without consideration of other clinical factors could pose a risk. The special controls document aids in mitigating risk by establishing performance characteristics and appropriate labeling.

In addition to the general controls of the act, the Glucatell™ assay is subject to the following special controls: Class II Special Controls Guidance Document: Serological Reagents for the Detection of Beta-glucan". Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification submission containing information on the glucan assay they intend to market prior to marketing the device.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Ms. Freddie Poole at (301) 594-2096.

Sincerely yours,

for Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health