



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Phadia U.S., Inc.
c/o Mr. Martin R. Mann
Senior Regulatory Affairs Manager
4169 Commercial Ave.
Portage, MI 49002

FEB 15 2012

Re: k103039
ImmunoCAP Tryptase
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR §866.5760
Regulation Name: Tryptase Test System
Regulatory Classification: Class II
Product Code: OYL
Dated: January 11, 2012
Received: January 12, 2012

Dear Mr. Mann:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Evaluation of Automatic Class III Designation Petition (de novo) for classification of the ImmunoCAP Tryptase Assay that is indicated for use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the ImmunoCAP Tryptase assay system and substantially equivalent devices of this generic type, into class II under the generic name, tryptase test system.

FDA identifies this generic type of device as: A tryptase test system is a device that aids in the diagnosis of systemic mastocytosis. It is intended for in vitro diagnostic use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the FD&C 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 FD&C 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 FD&C Act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the FD&C 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. 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.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on January 3, 2012 automatically classifying the ImmunoCAP Tryptase 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, nor which was subsequently reclassified into class I or class II. On January 12, 2012, FDA filed your petition requesting classification of the ImmunoCAP Tryptase Assay into class II. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the ImmunoCAP Tryptase 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 ImmunoCAP Tryptase Assay indicated for use as an aid in the clinical diagnosis of patients with a suspicion of systemic mastocytosis in conjunction with other clinical and laboratory findings can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.

FDA has identified the following risks to health associated with the use of a tryptase test system. A false negative result may result in a patient not being appropriately diagnosed with systemic mastocytosis, and therefore not receiving appropriate therapy. A false positive result may result in patients with other disorders being inappropriately diagnosed with systemic mastocytosis, and thereby receiving inappropriate or delayed treatment. Finally, it has been reported in the literature that tryptase can be used to evaluate a potential anaphylactic reaction, but this use of a tryptase assay system has not been reviewed by FDA and therefore the clinical validity of a tryptase assay system for this indication is unknown.

In addition to the general controls of the FD&C Act, the tryptase test system is subject to the following special controls: the guidance document entitled “Class II Special Controls Guidance Document: Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis”. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket

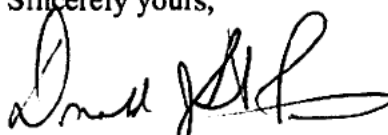
notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the tryptase test system they intend to market prior to marketing the device and receive clearance to market from FDA.

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 your device as described in the de novo, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact [REDACTED]

Sincerely yours,


for Alberto Gutierrez, Ph.D.
Director

Office of *In Vitro* Diagnostic Device Evaluation
and Safety
Center for Devices and Radiological Health