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U.S. Food and Drug Administration



Department of
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Department of Health and Human Services

Public Health Service
Food and Drug Administration

2098 Gaither Road
Rockville MD 20850

SEP 29 2008

Warning Letter

Via Federal Express

David P. King
President and Chief Executive Officer
Laboratory Corporation of America
358 South Main Street
Burlington, North Carolina 27215

Dear Mr. King:

The Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) has reviewed information about the OvaSure™ on the Laboratory Corporation of America (LabCorp) website including a press release <http://www.shareholder.com/lh/ReleaseDetail.cfm?ReleaseID=317876>(copy attached) and a technical bulletin

(<https://www.newlabcorp.com/wps/wcm/connect/7e0575004abea8aa8d9cbdce2e728548/L6367.pdf?MOD=AJPERES>)(copy attached) as well as information you provided during a meeting with FDA on September 5, 2008. This review has revealed serious regulatory problems involving these devices manufactured by your firm.

Based on the information collected, FDA has determined that the OvaSure™ is a test that was designed, developed, and validated by investigators at Yale University and not LabCorp. Instructions for use and performance characteristics appear to have been developed by Yale investigators. In addition, the materials being used to produce this test including **[(b)(4)]** and **[(b)(4)]** are manufactured by **[(b)(4)]** based on specifications by the workers at Yale. This device is not within the scope of laboratory developed tests over which the agency has traditionally exercised enforcement discretion.

Our review indicates that this product is a device under section 201(h) of the Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 321(h), because it is intended for use in the diagnosis of disease or other conditions, or in the cure, treatment, prevention, or mitigation of disease. The Act requires that manufacturers of devices that are not exempt obtain marketing approval or clearance for their products from the FDA before they may offer them for sale. This helps protect the public health by ensuring that new devices are shown to be both safe and effective or substantially equivalent to other devices already legally marketed in this country for which approval is not required.

According to our records, no such determination has been made for OvaSure™. Because you do not have marketing clearance or approval from the FDA, marketing OvaSure™ is in violation of the law. The device is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. 351(f)(1)(B), because you do not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. 360e(a), or an approved application for an investigational device exemption (IDE) under section 520(g) of the Act, 21 U.S.C. 360j(g). The device is also misbranded under section 502(o) the Act,

21 U.S.C. 352(o), because you did not notify the agency of your intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. 360(k). For a product requiring premarket approval before marketing, the notification required by section 510(k) of the act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR §807.81(b).

This letter is not intended to be an all-inclusive list of deficiencies associated with your devices. It is your responsibility to ensure adherence to each requirement of the Act and regulations for every FDA-regulated product that you market. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.


Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Please direct your response to James Woods, Deputy Director of Patient Safety and Product Quality, Office of In Vitro Diagnostic Device Evaluation and Safety, 2098 Gaither Road, HFZ-440, Rockville, Maryland 20850.

Sincerely yours,

/S/

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

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