



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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WARNING LETTER

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

VIA FEDERAL EXPRESS

Alfred J. Roach  
Chairman and Chief Executive Officer  
American Biogenetic Sciences, Inc.  
1385 Akron St.  
Copiague, New York 11726

Dear Mr. Roach:

The Food and Drug Administration (FDA) has reviewed several press releases issued by American Biogenetic Sciences, Inc. (ABS), some press releases that appear on the Internet and material on the ABS home page discussing the Thrombus precursor protein (TpP) in vitro diagnostic test marketed by ABS. The TpP diagnostic test is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). Statements issued by the company make numerous claims for the device other than those for which the device was cleared. We have discussed the inappropriate claims below. Some of them have misbranded and adulterated your device and others could be corrected by the submission of substantiating data to the agency.

A January 27, 1997 press release available on the Nexis database starts with the title, "Heart Attack-Detection Breakthrough Reported by American Biogenetic Sciences" and continues with the subtitles, "Human Clinical Trial Shows New FDA-Cleared Blood Clot Test, TpP™, May Facilitate Early, Cost-Effective Detection of Thrombosis and Thereby Reduce Mortality and Morbidity in Patients with Acute Cardiac Symptoms" and "An Accurate, Rapid and Reliable Clinical Test for Detecting a Blood Clot Will Assist in the Early Diagnosis of Acute Myocardial Infarction (Heart Attack)." The press release says that the ABS test was "at least three times more sensitive in a clinical study than commercially available biochemical markers currently used for diagnosing heart attacks."

The titles of the press release and the comparison of your device with heart attack markers (i.e., creatine kinase-MB and troponin I and T) imply that your test can be used to diagnose heart attacks. The device has not been cleared for that use. The intended use of the TpP device was cleared as follows: "TpP EIA is an enzyme linked immunoassay for the quantitative determination of soluble fibrin polymers in human plasma as an aid in risk assessment of thrombosis and monitoring anticoagulant

(heparin) therapy." ABS should therefore refrain from making these comparisons that result in a change in the intended use.

The press release quotes Dr. Joseph Laurino as saying that the specificity for the detection of a blood clot in patients with conditions associated with the formation of blood clots was nearly 95 percent. The Office of Device Evaluation has indicated that the specificity of the device should be reported as relative specificity because it is determined in comparison with other diagnostic tools. Your press release does not provide such a comparative statement.

In a January 27 Reuters press release appearing on the Internet, the company is quoted as saying that one of its drugs appeared to be at least three times more sensitive than other commercial drugs in helping doctors diagnose heart attacks, that the TpP helped detect blood clots faster than did other biochemical markers in clinical tests conducted at Brown University's School of Medicine, and that the peak plasma concentration of the drug preceded those of other heart attack markers by two to four hours in patients with acute myocardial infarction. The release also says that the company had stated that "the drug has already been cleared by the U.S. Food and Drug Administration."

The TpP test is a device, not a drug, and it has been inappropriately represented in the Reuters release. Further, as noted above, the claims made in these statements are not supported by data submitted to FDA.

In documents on the company's home page at [www.mabxa.com/tpp.htm](http://www.mabxa.com/tpp.htm) and at [www.mabxa.com/hadvp.htm](http://www.mabxa.com/hadvp.htm), ABS claims that the test has potential use for screening potential heart attack patients who present to emergency rooms with acute chest pain, monitoring patients admitted to the hospital with unstable angina to determine their risk of progression to a heart attack, and for ruling out heart attack in patients with chest pain.

Promoting the TpP device for screening for heart attacks, for diagnosing heart attacks, for ruling out heart attacks, as being more sensitive than other markers and as possibly reducing mortality and morbidity has misbranded your device under section 502(o) of the act in that appropriate premarket notification required by section 510(k) of the act was not submitted. FDA's regulations at 21 CFR 801.4 provide that the term "intended uses" refers to the objective intent of the persons legally responsible for the labeling of the device. That intent may be shown by

labeling claims or advertising matter or oral or written statements by such persons or their representatives. Making claims related to the diagnosis or elimination as a risk of heart attacks impermissibly changes the intended use of the device. Pursuant to section 510(k) of the act and as explained in 21 CFR 807.81(a)(3)(ii), claims that state or imply that the device can be used to diagnose or prevent heart attacks and their sequelae require the submission to FDA of premarket notification.

In addition,, the TpP device marketed with claims related to heart attack diagnosis, for better sensitivity, and for reducing morbidity and mortality is adulterated within the meaning of section 501(f)(1)(B) of the act in that it is a class III device under section 513(f) of the act and does not have an approved application for premarket approval in effect pursuant to section 515(a) of the act, or an approved application for an investigational device exemption under section 520(g).

The repeated references to clearance by FDA also misbrand your device. The agency's regulations at 21 CFR 807.97 provide that submission of a premarket notification in accordance with agency regulations and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976 or to a device introduced into commercial distribution after that date that has been subsequently reclassified into class I or II does not in any way denote official approval of a device. Any representation that creates an impression of official approval of a device because of complying with premarket notification regulations is misleading and constitutes misbranding.

Finally, the January 27 press release subtitle that claims that the device may facilitate early, cost-effective detection of thrombosis is a claim that requires substantiation. ABS has not submitted data to support the cost effectiveness claim.

This letter is not intended to be an all-inclusive list of deficiencies associated with the ABS TpP test. It is your responsibility to ensure adherence to each requirement of the act and the Federal regulations. The specific violations in this letter may represent practices used in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing these materials to ensure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in FDA's initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction,

and/or civil penalties.

Please notify this office within 15 working days of the receipt of this letter of the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address false and misleading information currently in the marketplace and actions to prevent similar violations in the future. 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.

Send your response to Deborah Wolf, Regulatory Counsel, Promotion and Advertising Policy Staff, Office of Compliance (HFZ-302), 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New York District Office. Please send a copy of your response to Director, New York District Office (HFR-NE100), 850 3<sup>rd</sup> Avenue, Brooklyn, New York 11232-1593.

Sincerely yours,

*Byron Tart for*

Lillian Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health