



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Via Federal Express

Craig D. Shimasaki, PhD, MBA
President, CEO
InterGenetics, Inc.
655 Research Parkway, Suite 300
Oklahoma City, OK 73104

JAN 27 2006

Dear Dr. Shimasaki:

The Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) has reviewed reports indicating that InterGenetics, Inc. is planning to market the OncoVue, a test intended for use in determining a woman's lifetime risk of developing breast cancer. Under section 201(h) the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 321(h)), any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is intended for use in the diagnosis of disease or other conditions is a device.

We have no record that such a test has been the subject of premarket review by FDA. We invite you to meet with us at your earliest convenience to discuss the nature and appropriate regulatory status of your technology, and the least burdensome ways that InterGenetics may fulfill any premarket review requirements that may apply.

Please contact me at (240) 276-0652 to set up a meeting. We are committed to working with you as we strive to protect the public health without unnecessarily imposing regulatory burdens on the marketing of products of potential clinical importance.

Sincerely yours,

A handwritten signature in blue ink that reads "Steven I. Gutman".

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