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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850

FEB - 2 1995

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Frank Maganaro
President
Nova Biomedical
200 Prospect Street
Walthman, Massachusetts 02254-9141

Re: Nova Stat Profile 9 and 10,

Dear Mr. Maganaro:

The Food and Drug Administration (FDA) has reviewed promotional materials for the Nova Stat Profile 9 and 10. These are both devices as defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

FDA has received the following promotional flyers: "TEN TEST E.D. PROFILE with BUN 80 Second TAT on Whole Blood Samples" and "NOVA Stat Profile Plus 9 The New Standard of Care in Blood Gas/ Critical Care Analyzers." A promotional claim made in your flyers states;

> "Transportable for use at patient sites with mobile cart and power supply."

The Nova Stat Profile 9 and 10 have been cleared under section 510(k) of the Act for use in clinical laboratory settings and have not received clearance for the intended use at patient sites.

The Nova Stat Profile 9 and 10 are adulterated under section 501(f)(1)(B) of the Act. They are Class III devices under section 513(f) and do not have approved applications for premarket approvals (PMAs) in effect pursuant to section 515(a) or approved applications for investigational device exemptions (IDEs) under section 520(g).

The Nova Stat Profile 9 and 10 are misbranded under section 502(o) in that notices or other information respecting the new intended use(s) of the devices were not provided to FDA as required by section 21 CFR 807.81 (a)(3)(ii) and the devices were not found to be substantially equivalent to predicate devices.

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. The specific violations noted in this letter also may be reflected in other promotional or advertising materials used by your firm. You are responsible for investigating and reviewing all materials to assure compliance with applicable regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action by the Agency. These include, but are not limited to injunction, seizure, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should also include steps being taken to address any misleading information currently in the market place and 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.

Your response should be sent to Mr. Byron Tart, Director, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance at the letterhead office.

A copy of this letter is being sent to FDA's Boston District Office. Please send a copy of your response to the Boston District Director, Food And Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely yours,

Philip D. Fragapane

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