DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 13 1997

TRANSMITTED VIA FACSIMILE

Andrew Lane, President
Lane Labs-USA, Inc.
110 Commerce Drive
Allendale, New Jersey 07401

RE: , BeneFin
MACMIS #5465

Dear Mr. Lane:

As part of its routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has obtained information that Lane Labs-USA, Inc. (Lane Labs) is promoting an unapproved drug, in violation of the Federal Food, Drug, and Cosmetic Act (the Act), and regulations promulgated thereunder.

At a recent medical conference, Lane Labs distributed promotional materials, including reprinted articles and a promotional brochure, at its booth in the commercial exhibit hall. These materials make numerous claims of safety and effectiveness, and thereby promote an unapproved drug. Promotion of an unapproved drug is in violation of the Act. Accordingly, Lane Labs should immediately cease all activities that promote its investigational drug, BeneFin.

Lane Labs' written response, describing its plan to address these violations, should be received by DDMAC no later than June 23, 1997. Please address your response to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, 5600 Fishers Lane, HFD-40, Rockville, Maryland 20857. DDMAC reminds Lane Labs that only written communication is considered official.

In all correspondence regarding this particular issue, please refer to MACMIS ID# 5465 in addition to the IND number.

Sincerely,

Tracy L. Acker, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications