

HFA-305



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

2787 '02 JUL -8 A9:41

JUN 27 2002

Gordon R. Johnston
Associate
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Docket No. 01P-0549/CP1

Dear Mr. Johnston:

This letter responds to your citizen petition dated December 10, 2001, requesting that the Food and Drug Administration (FDA) determine whether Nitrolingual, Nitroglycerin Aerosol, Sublingual, 0.4 mg/spray, in chloroflourocarbon (CFC) propellant (nitroglycerin aerosol in CFC propellant) has been withdrawn from sale for safety or efficacy reasons.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible, given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0549

LET 1