



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFA-305

Food and Drug Administration
Rockville MD 20857

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Madeleine Fall, M.Sc.
Regulatory Affairs and R&D Associate
Omega Laboratories, Ltd.
11 177 Hamon
Montreal, Quebec H3M 3E4

Docket No. 01P-0350/CP2

Dear Ms. Fall:

This letter responds to your citizen petition dated December 5, 2001, requesting that the Food and Drug Administration (FDA) determine whether Sotradecol (Sodium Tetradecyl Sulfate Injection, 1% and 3%) has been withdrawn from sale for safety or efficacy reasons.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

OIP-0350

LET 2