omega

LABORATORIES LIMITED

7605 '01 DEC -6 P2:47

December 05, 2001

Dockets Management Branch
Food and Drug Administration
Dockets Management Staff, HFA-305
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Citizen Petition
Docket Number: 0 1 P-0350

The undersigned submits this Petition according to 21 CFR 3 14.122 of the Food and Drug Administration, to request the Commissioner of Food and Drugs to determine whether a listed drug that has been voluntarily withdrawn from sale in the United States, was withdrawn for safety or effectiveness reasons. This petition is submitted on behalf of Omega Laboratories, Ltd, and is identical to one submitted on August 8, 2001 by Bennett & Company, Docket Number: 0 1 P-0350-CP 1.

A. Action Requested
The undersigned is seeking a determination whether the listed drug, "Sotradecol", (Sodium Tetradecyl Sulfate Injection, 1% and 3%), has been withdrawn from sale for safety or effectiveness reasons. The listed drug was approved for Elkins Sinn under NDA # 05-970.

B. Statement of Grounds
The FDA shortage group contacted Omega Laboratories, Ltd. to determine if our product could quell a diminishing supply of Sotradecol. Omega Laboratories meet with the FDA and submitted an abbreviated new drug application for sodium tetradecyl sulfate, Tromboject. This Citizen petition was requested by agency to amend the deficiencies in the ANDA (application number 40-450), since the Reference Listed Drug is no longer available on the market. The undersigned believes that this action is voluntary and is not based upon safety or effectiveness reasons.

Physician who use the drug in their medical practices have reported that supplies are unavailable and last lots expired on September 2001 and November 2001 for Sotradecol 3% and 1% respectively. These same physicians are looking for alternate supplies but none are approved in the United States. Sodium tetradecyl sulfate injection was approved for use in the United States August 13, 1946 and its safety and effectiveness has long been established.

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01P-0350

CP 2

C. Environmental Impact

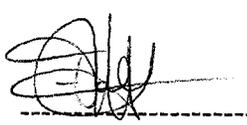
The undersigned claims a categorical exclusion for submission of an environmental assessment in accordance with 2 1 CFR 25.3 1 (a). This claim is based upon the fact that the proposed drug product has a chemical structure and composition with known pharmacological properties and indications for use that are identical to a drug product which is already on the market.

D. Economic Impact

A statement of the economic impact of the requested, action will be supplied at the request of the Commissioner.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petitioner relies, and that it includes representative data and information known to the Petitioner, which are unfavourable to the Petition.



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