

Bennett and Company

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01
AUG 13 P1:42

August 8, 2001

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

Citizen Petition

The undersigned submits this Petition according to 21 CFR 314.122, to request the Commissioner of Food and Drugs to determine whether a listed drug has been withdrawn from sale in the United States for safety or effectiveness reasons.

A. Action Requested

The undersigned is seeking a determination whether the listed drug, "Sotradecol", (sodium tetradecyl sulfate injection) has been withdrawn from sale for safety or effectiveness reasons. The listed drug was approved for Elkins Sinn under NDA # 005970.

B. Statement of Grounds

The undersigned has learned that the listed drug is no longer manufactured and that its sponsor does not intend to continue to manufacture and market it. The undersigned believes that this action is voluntary and is not based upon safety or effectiveness reasons.

Physicians who use the drug in their medical practices have reported that available supplies are limited and approaching their expiration dates. 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.

01P-03570

CPI

C. Environmental Impact

The undersigned claims a categorical exclusion for submission of an environmental assessment in accordance with 21 CFR 25.31(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 unfavorable to the Petition.

Sincerely,

Martha M. Bennett

Martha M. Bennett, R.A.C.

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Packages up to 150 lbs. Delivery commitment may be later in some areas.

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* Call for Confirmation.

* Declared value limit \$500

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