



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 5 2002

Food and Drug Administration  
Rockville MD 20857

Martha M. Bennett  
Bennett and Company  
4140 Bison Boulevard  
Lake Havasu City, Arizona 86404

Re: Docket No. 01P-0350/CP1

Dear Ms. Bennett:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on August 13, 2001. Your petition requests that the Agency determine whether Sotradecol (sodium tetradecyl sulfate injection) was withdrawn from sale for safety and efficacy reasons.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-0350

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