

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR - 4 1996 '02 JAN 26 12:52

Jeff Ivy
President
Au Pharmaceuticals, Inc.
4955 Profit Drive
Tyler, Texas 75707

Re: Docket No. 95P-0273
Comments No. CP1 and AMD1

Dear Mr. Ivy:

This is in response to your citizen petition dated August 11, 1995, filed with FDA's Dockets Management Branch on August 18, 1995, and the additional information dated August 23, 1995, filed on August 25, 1995, on behalf of Au Pharmaceuticals, Inc. The submissions are filed in Docket No. 95P-0273 as CP1 and AMD1, respectively.

The petition requested that the product, Feminine Gold, an external analgesic lotion containing menthol 2.5 percent and camphor 3.0 percent (as counterirritants) for the relief of pain associated with the menstrual period, be granted a waiver from the requirement for adequate well-controlled studies under 21 CFR Sections 314.90 and 300.50. The petition contended that the product meets the conditions of the proposed monograph for OTC external analgesic drug products. You claimed that there was no question regarding the safety and effectiveness of the active ingredients; therefore, compliance with the requirement of adequate well-controlled studies was unnecessary. You gave several reasons why the studies could not be achieved.

The agency is denying your petition for the reasons stated in the letter dated October 13, 1995, from Dr. William Gilbertson of our Office of Drug Evaluation V (copy enclosed). Your petition does not provide sufficient evidence to support the safety and effectiveness of the combination product containing camphor and menthol applied topically for the symptomatic relief of pain associated with the menstrual period. Further, it does not provide sufficient evidence to support a waiver from the requirement of adequate well-controlled studies for such a product.

95P-0273

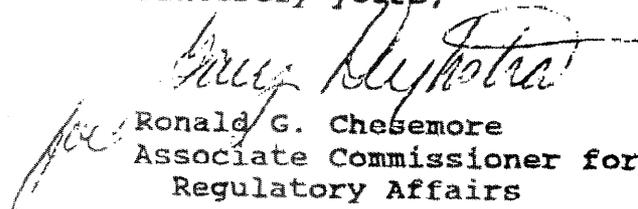
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If you have any questions regarding this matter, please refer to the docket and comment numbers shown at the beginning of this letter and submit three copies of all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

Sincerely yours,


Ronald G. Chesebrough
Associate Commissioner for
Regulatory Affairs

Enclosure