



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Public Health Service

Food and Drug Administration
Rockville MD 20857

3206 '02 JUL 12 19:24

Lachman Consultant Services, Inc.
Attention: Gordon R. Johnston
1600 Stewart Ave.
Westbury, NY 11590

JUL - 9 2002

Docket No. 00P-1568/CP1

Dear Mr. Johnston:

This is in response to your petition filed on October 16, 2000, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Ursodiol Oral Suspension, 20 mg/mL. The listed drug product to which you refer in your petition is Actigall® (Ursodiol) Capsules USP, 300 mg, NDA 19-594 held by Novartis Pharmaceuticals, Corp.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) of the Act such a petition will be approved unless the Food and Drug Administration (FDA) finds that investigations must be conducted to show the safety and effectiveness of the proposed drug product's dosage form and strength that differ from that of the listed drug product's dosage form and strength.

Your request involves changes in dosage form and strength from that of the listed drug product (i.e., from capsules containing 300 mg to an oral suspension containing 20 mg/mL). The changes that you request are the type of changes that are authorized under Section 505(j)(2)(C) of the Act.

This petition and your waiver request were evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published Wednesday, December 2, 1998, in the Federal Register (Pediatric Rule)(63 FR 66632). The FDA has determined that your proposed change in dosage form is subject to the Pediatric Rule and has concluded that investigations are necessary to demonstrate the safety and effectiveness in the pediatric population because the use of this product in the pediatric population is likely to be substantial and because use of this product for medical management is an important therapeutic alternative for non-surgical patients.

Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product. Please contact the Division of Gastrointestinal and Coagulation Drug Products at (301) 827-7310 if you wish to pursue approval of your proposed drug product under Section 505(b) of the Act.

OOP-1568

PDN 1

00P-1568/CP1

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the FDA to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

A handwritten signature in black ink, appearing to read "Gary Buehler". The signature is fluid and cursive, with a long horizontal stroke at the end.

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research