



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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FEB 29 2000

Lachman Consultant Services, Inc.
Attention: Robert W. Pollock
1600 Stewart Avenue
Westbury, NY 11590

Docket No. 99P-1416/CP1

Dear Mr. Pollock:

This is in response to your petition filed on May 18, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) and your amendment dated August 13, 1999, requesting to waive the pediatric study requirement for the following drug products : Methylphenidate Hydrochloride Oral Solution, 5 mg/5mL, and 10mg/5mL. The listed drug products to which you refer in your petition are Ritalin® (Methylphenidate Hydrochloride) Tablets, 5 mg and 10 mg, manufactured 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 Sections 505(j)(2)(C)(i) and (ii) of the Act such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug product, or the dosage form which differs from the listed drug product.

Your request involves a change in dosage form from that of the listed drug products (i.e., from tablets to oral solution). The change that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act.

This petition was 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 agency 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 of the proposed drug products in the pediatric population below the age of six. Please contact the Division of Neuropharmacological Drug Products at 301-594-2850 for further information.

99P-1416

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FDA may waive the study requirements for some or all pediatric age groups if the waiver request demonstrates both of the following conditions:

- (1) The product does not represent a meaningful therapeutic benefit for pediatric patients over existing treatments and,
 - (2) the product is not likely to be used in a substantial number of pediatric patients.
- (Pediatric Rule, 63 FR at 66635). Your waiver request has not demonstrated either of these two conditions. Therefore, your waiver request is denied.

Because the Agency has determined that your proposed change in dosage form and strength raises questions of safety and effectiveness in the pediatric population below the age of six, and has concluded that clinical trials are required for this specific drug product, 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, and your request that these investigations be waived is denied.

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 Agency 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 yours,



Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research