DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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MAY - 7 2001

King and Spalding
Attention: Ellen Armentrout
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-3737

Docket No. 99P-5105/CP1

Dear Ms. Armentrout:

This is in response to your petition filed on November 23, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Oxycodone Hydrochloride, Oxycodone Terephthalate and Acetaminophen Tablets, 7 mg/0.57mg/325 mg, and 9.25 mg/0.85 mg/325 mg. The listed drug products to which you refer in your petition are Percodan® (Oxycodone Hydrochloride/Oxycodone Terephthalate/Aspirin) Tablets, 4.5 mg/0.38 mg/325 mg manufactured by Endo Laboratories.

Your request involves a change in an active ingredient in a combination drug product (i.e., from aspirin to acetaminophen), a change in strength of the Oxycodone Hydrochloride component (i.e., from 4.5 mg to 7 mg and 9.5 mg) and a change in strength of the Oxycodone Terephthalate component (i.e., from 0.38 mg to 0.57 mg and 0.85 mg) from that of the listed drug products. The changes that you request are the type of changes that are authorized under Section 505(j)(2)(C) of the Act.

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 Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug products, or of any of the active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug product.

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 December 2, 1998, in the Federal Register (Pediatric Rule)(63 FR 66632). The Agency has determined that your proposed change in active ingredient is subject to the Pediatric Rule and has concluded that investigations are necessary to demonstrate the safety and effectiveness in the pediatric population. The absence of appropriate strengths and formulations of analgesics for pediatric patients, and a paucity of information on the safety, efficacy and pharmacokinetics of analgesics in children, have resulted in potentially unsafe treatment practices in the care of pediatric patients in pain. Therefore, the Agency concludes that the proposed drug products should be evaluated for safety and efficacy in the pediatric population.

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The Agency has determined that your proposed change in active ingredient raises questions of safety and effectiveness, and has concluded that clinical trials are required for these specific drug products. 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 products.

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,

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