DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

3748 '01 MAY 10 P2:28

MAY - 7 2001

King and Spalding
Attention: Jess Stribling
1730 Pennsylvania Ave, N.W.
Washington, D.C. 20006-4706

Docket No. 98P-1219/CP1

Dear Mr. Stribling:

This letter is to reverse the prior Agency decision on September 16, 1999, to approve your petition filed on December 21, 1998, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Oxycodone Hydrochloride 4.5 mg; Oxycodone Terephthalate 0.38 mg; Acetaminophen 325 mg Tablets, and Oxycodone Hydrochloride 2.25 mg; Oxycodone Terephthalate 0.19 mg; Acetaminophen 325 mg Tablets. The listed drug products to which you refer are Percodan® (Oxycodone Hydrochloride 4.5 mg; Oxycodone Terephthalate 0.38 mg; Aspirin 325 mg) Tablets, and Percodan® Demi (Oxycodone Hydrochloride 2.25 mg; Oxycodone Terephthalate 0.19 mg; Aspirin 325 mg) Tablets, manufactured by Endo Pharmaceuticals.

Your request involves a change in one active ingredient for another active ingredient of the same pharmacologic class in a fixed combination listed drug product [i.e., substituting an equipotent dose of acetaminophen (APAP) for aspirin (ASA) in the listed drug products]. The change you request is the type of change that is authorized under 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 product, or of any of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug product.

New information has become available to the Agency that caused the petition to be re-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 and the Agency concludes that the proposed product should be evaluated for safety and efficacy in the pediatric population.

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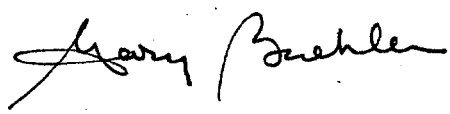
Therefore, the Agency is withdrawing the September 16, 1999, approval of your petition under 21 CFR 314.93(f) and is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product.

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 withdrawing approval and 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