



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

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King & Spalding  
Attention: Ellen Armentrout  
1730 Pennsylvania Avenue, N.W.  
Washington, D.C. 20006-4706

Docket No. 99P-2776/CP1

Dear Ms.Armentrout:

This is in response to your petition filed on August 12, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Oxycodone Hydrochloride and Acetaminophen Oral Solution, 7.5mg/500mg per 15 mL. The listed drug product to which you refer in your petition is Oxycodone and Acetaminophen Tablets 7.5mg/500 mg manufactured by Endo Pharmaceuticals, Inc.

Your request involves a change in dosage form from that of the listed drug product (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 Federal Food, Drug, and Cosmetic Act (Act). Under Sections 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.

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 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. 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 product should be evaluated for safety and efficacy in the pediatric population.

The Agency has determined that your proposed change in dosage form raises questions of safety and effectiveness, and has concluded that clinical trials are required for this specific drug product. 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.

99P-2776

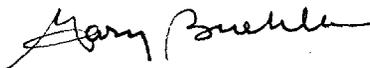
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If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based 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 J. Buehler  
Acting Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research