



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 17 2003

Shotwell & Carr, Inc.
Attention: Paul W. Carr
3535 Firewheel Dr., Suite A
Flower Mound, TX 75028-2628

Docket No. 02P-0004/CP1

Dear Mr. Carr:

This is in response to your petition filed on January 4, 2002, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Hydrocodone Bitartrate and Acetaminophen Tablets, 5 mg/200 mg, 7.5 mg/200 mg and 10 mg/200 mg. The listed drug products to which you refer in your petition are Hydrocodone Bitartrate and Acetaminophen Tablets, 5 mg/400 mg, 7.5 mg/400 mg and 10 mg/400 mg, ANDA 40-288 held by Endo Pharmaceuticals, Inc.

Your request involves a change in strength of the acetaminophen component of the listed drug products, i.e., from acetaminophen 400 mg to acetaminophen 200 mg. 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 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 strength of the proposed drug product that differs from the strength of the listed drug product.

The FDA has determined that your proposed change in strength of the acetaminophen component raises questions of safety and effectiveness, and has concluded that clinical trials are required for this specific drug product. The adult oral dose for acetaminophen established by the Agency for its safe and effective range is 325 mg to 650 mg every 4 hours, or 325 mg to 500 mg every 3 hours, or 650 mg to 1,000 mg every 6 hours while symptoms persist, not to exceed 4,000 mg in 24 hours. The dose of acetaminophen that you propose is below the safe and effective range established by the FDA. Please refer to the Tentative Final Monograph for Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use (53 FR 46204, November 16, 1988). 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.

02P-0004

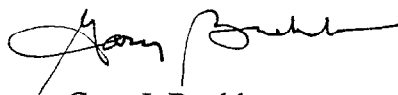
PDN 1

02P-0004/CP1
Shotwell & Carr, Inc.

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 yours,



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