



OCT 15 2004

The Weinberg Group, Inc.
Attention: Nicholas M. Fleischer, Ph.D.
1220 Nineteenth Street NW, Suite 300
Washington, DC 20036-2400

Docket No. 2002P-0406/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on September 10, 2002, your comments dated May 16, 2003 and November 19, 2003, and your amendment dated March 10, 2004 requesting permission to file an Abbreviated New Drug Applications (ANDA) for the following drug products: Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension, 200 mg/28.5 mg, 400 mg/57 mg, and 600 mg/42.9 mg. The listed drug products to which you refer in your petition are Augmentin® (Amoxicillin and Clavulanate Potassium) Powder for Oral Suspension, 200 mg/28.5 mg per 5 mL, 400 mg/57 mg per 5 mL and Augmentin ES-600™ (Amoxicillin and Clavulanate Potassium) Powder for Oral Suspension, 600 mg/42.9 mg per 5 mL, manufactured by GlaxoSmithKline. Subsequently, on April 1, 2004, you withdrew the following two strengths from your petition: Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension, 200 mg/28.5 mg and 400 mg/57 mg.

Your request involves a change in dosage form (i.e., from a powder for oral suspension to a tablet for oral suspension) from that of the listed drug products. 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 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 products. We have also reviewed the comments submitted by Hogan & Hartson, L.L.P. on behalf of GlaxoSmithKline dated December 19, 2002, January 30, 2004, and June 28, 2004.

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 these specific drug products. Your proposed product does not allow for the same conditions of use as described in the dosage and administration section of the labeling of the listed drug Augmentin ES-600™ because the weight-based dosage regimen cannot be met with your proposed product. Accurate doses cannot be delivered for children of different weights using the tablets for oral suspension. The potential exists for an increase in adverse events from an overdose or ineffective treatment

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Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension, 600 mg/42.9 mg

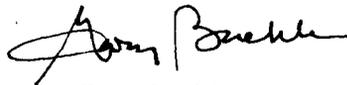
from an underdose. Clinical trials are needed to show that the children receiving the tablets for oral suspension at a fixed dose do not have a greater number of adverse events or decreased effectiveness, compared with the oral suspension. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product.

This petition is being denied because clinical trials are required for the approval of the requested change to the drug product. Therefore, the question of whether pediatric studies are necessary under the Pediatric Research Equity Act (PREA) has not been evaluated. Please contact the Division of Anti-infective Drug Products at 301-827-2133 if you wish to pursue approval of your product under Section 505(b) of the Act.

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
Director
Office of Generic Drugs
Center for Drug Evaluation and Research