



NOV 26 2002

The Weinberg Group, Inc.  
Attention: Nicholas M. Fleischer, Ph.D.  
1220 Nineteenth, St. NW, Suite 300  
Washington, DC 20036-8077

Docket No. 02P-0358/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on August 9, 2002, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Amoxicillin Tablets for Oral Suspension, 300 mg and 600 mg. The listed drug products to which you refer in your petition are Amoxil® (amoxicillin) for Oral Suspension, 200 mg/5 mL and 400 mg/5 mL approved under NDA 50-760 held by GlaxoSmithKline.

Your request involves changes in both dosage form and strength from that of the listed drug products (i.e., from Powder for Oral Suspension, 200 mg/5 mL and 400 mg/5 mL to Tablets for Oral Suspension, 300 mg and 600 mg). The changes you request are the types of changes that are authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug products.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a dosage form and strength that differs from the dosage form and strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form and strength.

The FDA finds that the change in dosage form and strength for the specific proposed drug products do not pose questions of safety or effectiveness because the proposed products (Amoxicillin Tablets for Oral Suspension, 300 mg and 600 mg) are dosed on a mg/kg basis and the uses, dose, and route of administration of the proposed drug products are the same as that of the listed drug product. In addition, both proposed strengths are intermediate strengths that are within the dosage range of previously approved amoxicillin products. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.

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On October 17, 2002, the United States District Court for the District of Columbia ruled that the Food and Drug Administration (FDA) did not have the authority to issue the Pediatric Rule and enjoined FDA from enforcing it. (Civil Action 00-02898(HHK)).<sup>1</sup> The government has not yet decided whether to seek a stay of the court's order. In addition, the government has not yet decided whether to appeal the decision; an appeal must be filed within 60 days of the issuance of the decision. Because FDA is currently enjoined from enforcing the Pediatric Rule, you are under no obligation to conduct pediatric studies on your petitioned drug products at this time. Please be aware that if the decision to invalidate the Pediatric Rule is appealed and the Pediatric Rule is upheld on appeal, an abbreviated new drug application (ANDA), submitted under an ANDA suitability petition<sup>2</sup>, may be subject to the requirements of the Pediatric Rule in the future.<sup>3</sup> If the Pediatric Rule is reinstated and pediatric clinical studies are required for these products in the future, you will be notified as soon as possible. Under those circumstances, the petitioned products may not be eligible for approval under the ANDA approval authorities.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol for these drug products to the Office of Generic Drugs, Division of Bioequivalence prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the drug products upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

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1 ). The Pediatric Rule (rule) is codified at 21 CFR 314.55/21 CFR 601.27.

2 An ANDA suitability petition is a petition submitted pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act requesting permission to submit an ANDA for a new drug which has a different active ingredient, or whose route of administration, dosage form, or strength differ from that of the listed drug. Also see 21 C.F.R. § 314.93.

3 While it was in effect, the Pediatric Rule required that all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

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A copy of this letter approving 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,

A handwritten signature in black ink, appearing to read "Gary Buehler". The signature is fluid and cursive, with a long horizontal stroke at the end.

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