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Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

COURIER 9/10/02

SUITABILITY PETITION

This petition is submitted pursuant to 21 CFR §10.20 and §10.30, as provided for in 21 CFR §314.93, and Section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, to request the Commissioner of the Food and Drug Administration to declare that the drug product Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension 200 mg/28.5 mg, 400 mg/57 mg and 600 mg/42.9 mg are suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petition is submitted for a change in dosage form of the drug product from "powder for oral suspension" to "Tablets for Oral Suspension". The reference listed drug product is Augmentin®/Augmentin ES-600™ powder for oral suspension 200 mg/5 mL, 400 mg/5 mL and 600 mg/5 mL manufactured by GlaxoSmithKline (GSK). Amoxicillin and Clavulanate Potassium will be marketed as Tablets for Oral Suspension in dosage strengths of 200 mg, 400 mg and 600 mg. The drug, the route of administration and the recommendations for use are the same as the listed drug product. The proposed product would differ only in dosage form from GSK's marketed product.

The proposed drug product is expected to demonstrate bioequivalence to the 600 mg/5 mL suspension dosage form of the listed product; data will be submitted at a later date.

02P-0406

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B. Statement of Grounds

Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension are presented for administration by dispersing a single tablet in a specified amount of water.

The new dosage form is expected to offer a better alternative to the powder for oral suspension due to the following advantages:

- Unit dose dispensing
- Convenience to the patient with respect to the ease of administration, even during travel
- Storage of the product will not require special conditions (e.g., refrigeration)
- Better precision of dosage over the traditional teaspoonful
- Ease of carrying

The proposed product will differ only in dosage form. The indications, strength, route of administration, intended patient population and recommendations for use will remain the same as the GSK-marketed products; therefore, there will be no difference in the safety and efficacy of the Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension.

The package inserts for GSK's Augmentin® (Attachment 1) and Augmentin ES-600™ (Attachment 2) are provided, as well as the draft package inserts of the proposed Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension (Attachments 3 and 4).

C. Pediatric Use Information

As the package insert of GSK's Augmentin® powder for oral suspension contains adequate dosing and administration information for the pediatric population, no additional studies are required.

D. Environmental Impact

An environmental assessment report on the action requested in this petition is not required under 21 CFR §25.31.

E. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.



F. **Certification**

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,



Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
THE WEINBERG GROUP INC.

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Enclosure

cc Gary Buehler, Director, Office of Generic Drugs

