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THE WEINBERG GROUP INC.

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VIA FEDERAL EXPRESS

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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

Re: Docket Number 02P-0406, Comments

On September 10, 2002, THE WEINBERG GROUP INC. submitted a suitability petition requesting the Commissioner of the Food and Drug Administration to declare that the 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 were suitable for submission as an Abbreviated New Drug Application (ANDA). The listed drug product that was referred to in the petition was GlaxoSmithKline's Augmentin® Suspension 200 mg/28.5 mg per 5ml and 400 mg/57 mg per 5ml.

In a recent telephone communication, FDA indicated that the 200 mg/28.5 mg and 400 mg/57 mg strengths of the proposed product may be declared suitable for submission as an ANDA if the Reference Listed Drug (RLD) were changed from Augmentin Suspension to Augmentin Chewable tablets. The purpose of this letter is to examine further the appropriate RLD for the 200 mg/28.5 mg and 400 mg/57 mg proposed products.

It should be noted that, as the proposed 200 mg/28.5 mg and 400 mg/57 mg Tablets for Oral Suspension products are a distinct dosage form, these products are not intended to be therapeutically equivalent ("AB rated") substitutes for the GSK Augmentin products. Rather, the proposed products are intended to be pharmaceutical alternatives where a Tablet for Oral Suspension may be a preferred therapeutic modality.

THE WEINBERG GROUP submits the comments herein in response to the Agency's request that the RLD for Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension, 200 mg/28.5 mg and 400 mg/57 mg, be changed from Augmentin Suspension

to Augmentin Chewable tablets. THE WEINBERG GROUP would like to request that the Agency reconsider this position on the following grounds.

First, this dosage form of Amoxicillin and Clavulanate Potassium, a "tablet for oral suspension," is a value-added generic product. In other words, the tablet for suspension offers a conveniently portable form of the drug relative to the suspension dosage form.

Second, the tablet for oral suspension is a dispersible tablet that forms a suspension when dispersed in water. Thus, the tablets for oral suspension are ultimately consumed by the patient as a suspension. It is therefore most appropriate to compare the proposed product to Augmentin Suspension rather than Augmentin Chewable Tablets.

Third, the proposed products are most suitable as comparable alternatives of the Augmentin Suspension product. A number of features make the proposed products unique from Augmentin Suspension, and these features result in benefits to the consumer that are not available with a conventional suspension dosage. These features include:

-Unit dose dispensing;
-Convenience to the patient with respect to ease of administration even during travel;
-Storage of product will not require special conditions like refrigeration;
-Better precision of dosage;
-Convenience of carrying; and
-Easy administration to patients who have difficulty swallowing.

Fourth, the FDA has approved other suitability petitions for tablets for oral suspension that have designated Suspension dosage forms as the RLD, including the following:

Docket No.02P-0358/CP1:	Permission to file ANDA for Amoxicillin Tablets for Oral Suspension 300 mg and 600 mg against listed drug Amoxil® for Oral Suspension 200 mg/5 ml and 400 mg/5 ml
Docket No.99P-5450/CP1:	Permission to file ANDA for Amoxicillin Tablets for Oral Suspension, 125 mg, 200 mg, 250 mg and 400 mg against listed drug Amoxil® for Oral Suspension 125 mg/5 ml, 200 mg/5 ml, 250 mg/5 ml and 400 mg/5 ml
Docket No.99P-5448/CP1:	Permission to file ANDA for Cefaclor Dispersible Tablets, 125 mg, 187 mg, 250 mg and 375 mg against listed drug Ceclor® for Oral Suspension 125 mg/5 ml, 187 mg/5 ml, 250 mg/5 ml and 375 mg/5 ml
Docket No.99P-5449/CP1:	Permission to file ANDA for Cefadroxil Dispersible Tablets, 125 mg, 250 mg and 500 mg against listed drug Duricef® for Oral Suspension 125 mg/5 ml, 250 mg/5 ml and 500 mg/5 ml
Docket No.99P-5451/CP1:	Permission to file ANDA for Cephalexin Dispersible Tablets, 125 mg, 250 mg and 500 mg against listed drug Keflex® for Oral Suspension 125 mg/5 ml, 250 mg/5 ml and 500 mg/5 ml

Docket No.99P-5452/CP1: Permission to file ANDA for Acyclovir Dispersible Tablets, 200 mg against listed drug Zovirax® Suspension.

Based on the above considerations, THE WEINBERG GROUP respectfully requests the Agency to grant the use of Augmentin Suspension as the Reference Listed Drug for Amoxicillin and Clavulanate Potassium Tablets for Oral Suspension 200 mg/28.5 mg and 400 mg/57 mg.

Very truly yours,

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THE WEINBERG GROUP INC.

NMF/kh

Enclosure

cc Gary Buehler, Director, Office of Generic Drugs
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