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THE WEINBERG GROUP INC.

June 2, 2003

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

OVERNIGHT COURIER 6/2/03

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, Clarithromycin Extended-Release Tablets, 1000 mg, is suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that the drug product, Clarithromycin Extended-Release Tablets, 1000 mg, is suitable for submission as an abbreviated new drug application (ANDA). The petition is submitted for a change in dosage strength of the drug product from 500 mg to 1000 mg. The reference listed drug product upon which this petition is based is Biaxin® XL Filmtab® (clarithromycin extended-release tablets), manufactured by Abbott Laboratories. Clarithromycin Extended-Release Tablets will be marketed as extended-release tablets in a dosage strength of 1000 mg. The drug, the route of administration, and the recommendations for use are the same as those of the listed drug product. The proposed product would differ only in dosage strength from Abbott Laboratories' marketed product.

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The proposed drug product is expected to demonstrate bioequivalence to the listed product; data will be submitted at a later date.

B. **Statement of Grounds**

The Federal Food, Drug, and Cosmetic Act provides for the submission of an ANDA for a new drug that differs in dosage strength from that of a listed drug provided the FDA has approved a petition that proposed the filing of such an application. This petition requests a change in strength for the proposed drug from that of the reference listed drug.

The recommended dose of Biaxin® XL Filmtab® is 2 x 500 mg (1000 mg) once daily. The proposed petition seeks a change in strength from 500 mg to 1000 mg, where the administered dose will be same as the dose of the Reference Listed Drug (i.e., 1000 mg), but only 1 tablet (1 x 1000 mg) will be administered. Thus, the proposed product confers the advantage of 1-tablet vs. 2-tablet dosing.

The proposed product will differ from the listed drug only in dosage strength. The indications, route of administration, intended patient population, and recommendations for use will remain the same as the Abbott Laboratories-marketed product. Therefore, there will be no difference in the safety and efficacy of the proposed Extended-Release Tablets.

The package insert for Abbott Laboratories' Biaxin® XL Filmtab® is provided in Attachment 1 of this petition. The draft package insert for the proposed Clarithromycin Extended-Release Tablets, 1000 mg is provided in Attachment 2.

C. **Pediatric Use Information**

According to the package insert of Abbott Laboratories' Biaxin® XL Filmtab®, this product is not recommended for use in pediatric patients. Therefore, no additional studies are required for the proposed Clarithromycin Extended-Release Tablets, 1000 mg.

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 also includes representative data and information known to the petitioner that are unfavorable to the petition.

Sincerely,

Joel I. Falk
Executive Vice President – Life Sciences
THE WEINBERG GROUP INC.

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Enclosure

cc Gary Buehler, Director, Office of Generic Drugs