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VIA OVERNIGHT COURIER

December 11, 2003

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 2003P-0238/CP1, Comments

On June 2, 2003, THE WEINBERG GROUP INC. submitted a suitability petition requesting the Commissioner of FDA to declare that the drug product Clarithromycin Extended Release Tablets 1000 mg was suitable for submission as an Abbreviated New Drug Application (ANDA). The listed drug which was referred to in the petition was Biaxin® XL Filmtab® manufactured by Abbott. This petition seeks a change in strength from Clarithromycin Extended Release Tablets 500mg to Clarithromycin Extended Release Tablets 1000mg.

In a recent telephone communication, the FDA indicated that approval of this petition is subject to the Pediatric Rule. Under the pediatric rule, applications for new active ingredients, new indications, new dosage forms, new dosing regimens, and new routes of administration must contain a pediatric assessment unless the sponsor has obtained a waiver or deferral of pediatric studies (21 CFR 314.55(a) and 601.27(a)). The purpose of this letter is to submit to the Agency justification for a waiver from submitting the pediatric assessment.

As per CFR 314.55(c):

An applicant may request a full waiver of the requirements of paragraph (a) of this section if the applicant certifies that:

(i) The drug product does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients and is not likely to be used in a substantial number of pediatric patients;

(ii) Necessary studies are impossible or highly impractical because, e.g., the number of such patients is so small or geographically dispersed; or

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(iii) There is evidence strongly suggesting that the drug product would be ineffective or unsafe in all pediatric age groups

Per CFR 314.55(c)(4), *if a waiver is granted because there is evidence that the product would be ineffective or unsafe in pediatric populations, this information will be included in the product's labeling.*

According to the package insert of Biaxin® XL Filmtab®, this product is recommended for use in adult patients only. The current approved package insert of Biaxin® XL Filmtab® (Clarithromycin) Extended-Release Tablets indicates the use of this product in the management of acute maxillary sinusitis, acute exacerbation of chronic bronchitis and community-acquired pneumonia in adults. Please see the attached section of the Reference Listed Drug Package Insert for this information (Please Refer **Attachment 1**).

As stated in the Biaxin Package Insert, which is a combination package insert (for Biaxin tablets, Biaxin Extended Release Tablets and Biaxin Granules for Oral Suspension) "THE EFFICACY AND SAFETY OF BIAXIN XL IN TREATING OTHER INFECTIONS FOR WHICH OTHER FORMULATIONS OF CLARITHROMYCIN ARE APPROVED HAVE NOT BEEN ESTABLISHED," this clearly indicates that clarithromycin extended release tablets are not safe and effective for adult or pediatric use in instances where Clarithromycin Tablets or Granules for Suspension are indicated. This statement also satisfies the requirement of CFR 314.55(c)(4).

The package insert submitted by the petitioner has been made in line with the package insert of Abbott's Biaxin® XL Filmtab. The petitioner's Clarithromycin extended release tablets 1000 mg is also indicated for use only in adults. The petitioner's package insert also includes the same statement that the efficacy and safety of clarithromycin extended release tablets in treating other infections for which other formulations of clarithromycin are approved have not been established. Based on this information, the petitioner requests a waiver from submitting any additional pediatric assessment for the proposed Clarithromycin Extended Release Tablets 1000 mg. Please see enclosed the waiver request form in **Attachment 2.**

The June 2, 2003 petition was submitted only for a change in the dosage strength of the tablets (from 500 mg to 1000 mg strength tablet). The recommended dose of Clarithromycin Extended-Release Tablets (Biaxin® XL Filmtab®) is 1000 mg (2 x 500 mg) once daily. The proposed petition seeks only 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; however, only 1 tablet (1 x 1000 mg) will be administered.

The intended patient population, indications and recommendations for use for the proposed product remain the same as approved for Abbott Laboratories marketed product Biaxin® XL Filmtab®. As discussed above, according to the package insert of Abbot Laboratories Biaxin XL Filmtab, this product is not recommended for use in pediatric patients. The package insert submitted by the petitioner has been made in line with the package insert of Biaxin XL and therefore no additional pediatric studies are required for the proposed Clarithromycin

Extended Release Tablets 1000 mg, and we request waiver from submitting the pediatric studies.

Moreover, FDA has recently approved at least two suitability petitions, 2003P-0283/CP1 and 2003P-0307/CP1, which were filed after we submitted the petition for Clarithromycin Extended Release Tablets 1000 mg, and the approval letters do not indicate any need to address the pediatric rule. Therefore, an expeditious reply to our petition would constitute the fairest, most appropriate course of action by the FDA.

Based on the above considerations, THE WEINBERG GROUP respectfully requests the Agency to grant approval of the suitability petition for Clarithromycin Extended Release Tablets 1000 mg.

Very truly yours,

Joel Falk (kh)

Joel I. Falk
Executive Vice President – Life Sciences

THE WEINBERG GROUP INC.

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Attachments

cc Gary J. Buehler, Director, Office of Generic Drugs
Cecilia Parise, Pharmacist
Martin Shimer, Senior Regulatory Manager