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OVERNIGHT DOCUMENT 11/19/03

Division of Documents Management
Food and Drug Administration
Department of Health and Human Services
(HFA-305)
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

CITIZEN PETITION

This petition is submitted in quadruplicate under Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355(j)(2)(C) and 21 CFR §10.20 and §10.30, and 21 CFR §314.93, to request the Commissioner of Food and Drug Administration to make a determination that an abbreviated new drug application (ANDA) may be submitted for Glyburide and Metformin Hydrochloride Oral Solution, 1.25 mg / 250 mg per **5** mL; 2.5 mg / 500 mg per **10** mL, and 5 mg / 500 mg per **10** mL.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that a Glyburide and Metformin Hydrochloride Oral Solution, at strengths of 1.25 mg / 250 mg per 5 mL, 2.5 mg / 500 mg per 10 mL, and 5 mg / 500 mg per 10 mL is suitable for submission as an ANDA. The reference listed drug (RLD) product upon which this petition is based is Glucovance® (Glyburide and Metformin HCl) Tablets, 5 mg / 500 mg. Glucovance® is also available in tablet strengths of 1.25 mg / 250 mg and 2.5 mg / 500 mg. Glucovance® Tablets are manufactured by Bristol-Myers Squibb Company. Since Glucovance® Tablets, 5 mg / 500 mg is the designated RLD upon which this petition is based, this petition requests a change in dosage form from tablets to oral solution from that of the listed drug.

B. Statement of Grounds

Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act provides for submission of an ANDA for a new drug that differs in dosage form from a listed drug, provided that the FDA has approved a petition seeking permission to file such an application. This petition seeks a change in dosage form from that of the reference listed drug product (i.e. from a tablet to an oral solution).

The oral solution dosage form can be a viable alternative for patients who have problems swallowing the tablet dosage form.

The proposed drug product will only differ in dosage form. The indications, dosage recommendations strengths and route of administration are the same as those included in

approved labeling of the listed drug. Therefore, the proposed change in dosage form (from tablets to oral solution) will not raise questions of the safety and efficacy of the proposed products. The indication remains unchanged and the proposed labeling will be the same as that of the approved labeling of the listed drug except for the change in dosage form, inactive ingredients and marketer of the product. Thus, the Agency should conclude that clinical investigations are not necessary to demonstrate the proposed product's safety or effectiveness.

The approved labeling for the listed drug, Bristol Myers Squibb's Glucovance® Tablets, is provided in Attachment 1. The proposed package insert for Glyburide and Metformin Hydrochloride Oral Solution is provided in Attachment 2. A copy of the appropriate page (3-178) from the *Approved Drug Products with Therapeutic Equivalence Evaluations* 23rd Edition (commonly referred to as the Orange Book) showing the listing of the reference listed drug product upon which this petition is based is included in Attachment 3.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR §25.31.

D. Economic Impact

According to 21 CFR §10.30(b), the petitioner will, upon request by the Commissioner, submit economic impact information.

E. Certification

The undersigned certifies that to the best of its 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,

Robert Pollock

Robert W. Pollock
Vice President
Lachman Consultant Services, Inc.
1600 Stewart Avenue
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RWP/pk

Attachments:
1. Labeling for the Innovator (Glucovance®)
2. Labeling for the Generic product
3. *Approved Drug Products with Therapeutic Equivalence Evaluations* 23rd Edition, page 3-178

cc: Martin Shimer (Office of Generic Drugs)

R03P3323