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JUL 30 2004

Lachman Consultant Services, Inc.
Attention: Robert W. Pollock
1600 Stewart Avenue
Westbury, NY 11590

Docket No. 2003P-0534/CP1

Dear Mr. Pollock:

This is in response to your petition filed on November 21, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: 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. The listed drug products to which you refer in your petition are Glucovance® (Glyburide and Metformin Hydrochloride) Tablets, 1.25 mg/250 mg, 2.5 mg/500 mg and 5 mg/500 mg, approved under NDA 21-178 held by Bristol-Myers Squibb Company. We also reference your amendment dated January 29, 2004.

Your request involves a change in dosage form from that of the listed drug product (i.e., from tablets to oral solution). The change you request is the type of change that is authorized under the Act.

We have reviewed your petition under Section 505(j) (2) (C) of the Federal Food, Drug, and Cosmetic Act (Act) and have determined that it is approved. This letter represents the Agency's determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the Agency must approve a petition seeking a dosage form which differs from the dosage form of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing dosage form.

The Agency finds that the change in dosage form for the specific proposed drug products does not pose questions of safety or effectiveness because the uses, dose, and route of administration of the proposed drug products are the same as that of the listed drug products. The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug products.

In addition, this petition and your waiver request were evaluated with respect to the "Pediatric Research Equity Act of 2003" (PREA). PREA requires that all applications for new active

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Glyburide and Metformin Hydrochloride Oral Solution

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ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations unless the requirement is waived or deferred. Your pending ANDA suitability petition is affected by this Act because it is a petition for a change in dosage form. The FDA has determined that your proposed change in dosage form is subject to PREA, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed products in the pediatric population.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the Agency has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA is submitted and reviewed by the Agency.

For your information, the listed drug products to which you refer are covered by a periods of patent protection and exclusivity which appear in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) published by the FDA. The existence of such patents exclusivities will require certifications and statements upon submission of an ANDA for your proposed drug products and may also affect the approval date of any ANDA.

To permit review of your ANDA submission, you must submit all information required under Sections 505(j) (2) (A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j) (2) (A) (iv) of the Act. We suggest that you submit your protocol for these drug products to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the products upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

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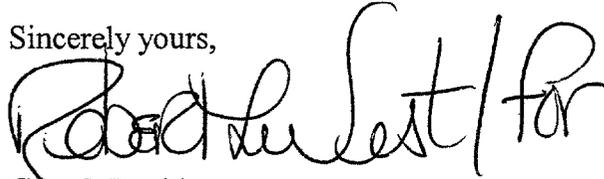
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A copy of this letter approving your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Gary J. Buehler". The signature is written in a cursive style with a large, stylized initial "G".

Gary J. Buehler

Director

Office of Generic Drugs

Center for Drug Evaluation and Research