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The Weinberg Group Inc.
Attention: Nicholas M. Fleischer, Ph.D.
1220 Nineteenth St. NW, Suite 300
Washington, DC 20036-2400

Docket No. 01P-0358/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on August 17, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Carbidopa and Levodopa Tablets for Oral Suspension [i.e., Dispersible Tablets]¹, 10mg/100mg; 25 mg/100 mg, and 25 mg/250 mg. The listed drug products to which you refer in your petition are, Sinemet® (Carbidopa and Levodopa) Tablets USP, 10 mg/100 mg; 25 mg/100 mg; 25 mg/250 mg, approved under NDA 17-555 held by Bristol Myers Squibb.

Your request involves a change in dosage form from that of the listed drug products (i.e., from tablets to tablets for oral suspension). The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act). We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug products.

In addition, this petition and your waiver request were evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published in the Federal Register (Pediatric Rule)(63 FR 66632). The FDA has determined that your proposed change in dosage form is subject to the Pediatric Rule, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed products in the pediatric population, because these specific drug products do not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and are not likely to be used in a substantial number of pediatric patients.

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¹ The Labeling and Nomenclature Committee (Committee) of the Center for Drug Evaluation and Research (Center) has reviewed the term for your proposed dosage form. It was concluded that the terminology "Dispersible Tablets" is not optimal for this dosage form. The Committee determined that the optimal nomenclature for this dosage form would be either "Tablets for Oral Solution", or "Tablets for Oral Suspension." The Center concurred with this recommendation. In addition, you have informed the FDA that this product forms a suspension when mixed with an appropriate liquid. Therefore, the FDA is recommending that appropriate term that should be applied to this dosage form is "Tablets for Oral Suspension".

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Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking a dosage form that 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 FDA 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 FDA 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.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA 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 itself is submitted and reviewed by the FDA.

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 product 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 FDA may require the submission of additional information.

The listed drug products to which you refer in your ANDA must be the drug 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.

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,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research