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Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

CITIZEN PETITION

This petition is submitted pursuant to 21 CFR parts 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 (FDA) to declare that the drug product Carbidopa-Levodopa Dispersible Tablets, 10 mg + 100 mg; 25 mg + 100 mg and 25 mg + 250 mg, are suitable for submission as an abbreviated new drug application (ANDA).

A. Action Requested

The petition is submitted for a change in dosage form of the drug product from "Tablets" to " Dispersible Tablets". The "listed" drug product is Sinemet® Tablets 10 mg + 100 mg; 25 mg + 100 mg and 25 mg + 250 mg; manufactured by Dupont Pharmaceuticals. Carbidopa-Levodopa will be marketed as dispersible tablets in dosage strengths of 10 mg + 100 mg, 25 mg + 100 mg and 25 mg + 250 mg. The drug, the route of administration and the recommendations for use are same as the listed drug product. The proposed product would differ only in dosage form from Dupont's marketed product.

The proposed drug product is expected to demonstrate bioequivalence to 25 mg + 250 mg tablets of the listed product which will be submitted at a later date.

B. Statement of Grounds

Dispersible tablet is presented for administration by dispersing a single tablet in a specified amount of water.

01P-0358

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The dispersible tablets would be a better alternative to the currently marketed tablet dosage form for the patients who have problems swallowing the solid oral dosage forms.

As the proposed product will differ only in dosage form, the indications, strength, route of administration, intended patient population and recommendations for use remain the same as Dupont's marketed product. Therefore, there will be no difference in the safety and efficacy of the proposed dispersible tablets.

A package insert of Dupont's Sinemet® Tablets is attached along with the draft package insert of the proposed Carbidopa-Levodopa Dispersible Tablets.

C. Pediatric Use Information

Pursuant to 21 CFR 314.55, the petitioner hereby requests a waiver of the pediatric study requirement for Carbidopa-Levodopa Dispersible Tablets. The petitioner requests this waiver on the basis of the Federal Register notice published by the FDA on December 2, 1998 (63 FR 66632).

Carbidopa-Levodopa Tablets are indicated in the treatment of the symptoms of idiopathic Parkinson's disease (paralysis agitans), post-encephalitic Parkinsonism, and symptomatic Parkinsonism, which may follow injury to the nervous system, by carbon monoxide intoxication and/or manganese intoxication. The aforementioned indications for the use of Carbidopa-Levodopa Tablets are very rare conditions in children. The basis of the waiver request is that the drug product "is not likely to be used in a substantial number of pediatric patients" [21 CFR 314.66(c)(2)(i)]. As discussed in the 63 FR 66632 notice, the FDA has defined a "substantial number of pediatric patients" as " 50,000 pediatric patients with the disease or condition for which the drug ... product is indicated." The number of pediatric patients with Parkinson's disease or Parkinsonism symptoms is significantly below the designated 50,000.

Carbidopa-Levodopa is not listed in Docket No. 98N-0056, Update of List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population (May 20, 2001). In addition, Carbidopa-Levodopa is not included in the FDA's list of Approved Active Moieties to which FDA has issued a Written Request for Pediatric Studies under Section 505A of the Federal Food, Drug, and Cosmetic Act (updated April 27, 2001).

Based on the above information, the petitioner considers Carbidopa-Levodopa Dispersible Tablets eligible for a full waiver of the requirement of 21 CFR 314.55(a).

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 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,

Nicholas M. Fleischer, R.Ph., Ph.D.
Director of Biopharmaceutics
THE WEINBERG GROUP INC.

NMF/alh

Attachments: Sinemet® Insert Labeling
Draft Insert Labeling for Carbidopa-Levodopa Dispersible Tablets

cc: Gary Buehler, Director, Office of Generic Drugs (w/encls.)