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January 17, 2002

**OVERNIGHT COURIER 1/17/02**

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
HFA-305, Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

**CITIZEN PETITION**

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.93, on behalf of a client, to request that the Commissioner of Food and Drugs permit the filing of an Abbreviated New Drug Application (ANDA) for a drug that has the same strengths as a drug listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations", but differs in dosage form.

**A. Action Requested**

By this petition, the Commissioner of the Food and Drug Administration (FDA) is hereby requested to declare that Carbidopa and Levodopa Orally Disintegrating Tablets in the strengths cited below are suitable for submission as an ANDA:

Carbidopa and Levodopa Orally Disintegrating Tablets 25-100, containing  
25 mg of Carbidopa and 100 mg of Levodopa

Carbidopa and Levodopa Orally Disintegrating Tablets 10-100, containing  
10 mg of Carbidopa and 100 mg of Levodopa

Carbidopa and Levodopa Orally Disintegrating Tablets 25-250, containing  
25 mg of Carbidopa and 250 mg of Levodopa

The reference listed drug (RLD) product on which this petition is based is Sinemet® (Carbidopa-Levodopa) Tablets of Dupont Pharma in the three strengths listed above. Therefore, the petitioner requests a change from the RLD, Dupont Pharma's Sinemet® (Carbidopa-Levodopa) Tablets 25-100, 10-100, and 25-250, only in its dosage form (from a conventional tablet to orally disintegrating tablet).

02P-0033

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## **B. Statement of Grounds**

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a drug product that differs in dosage form from that of the listed drug provided the FDA has approved a petition that proposed filing such an application. A copy of the most recent Internet listing of the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), included in Attachment 1, lists the RLD, Sinemet® Tablets manufactured for DuPont Pharma.

The proposed drug product is an orally disintegrating form of the tablets, in the same dosage strengths as the RLD. The proposed product contains the same active ingredients as the RLD and is intended for the same route of administration. Thus, the proposed product will be labeled with the same dosage recommendations as the listed drug and is expected to have the same therapeutic effect when used as indicated in the approved labeling. The labeling for Sinemet® is included in Attachment 2. The labeling of the proposed product is expected to be substantially the same as that for the RLD with the exception changes necessitated by the fact that the product is manufactured by a different party and those changes associated with the mode of administration, which will instruct the user to place the orally disintegrating tablet on the tongue, allowing it to rapidly disintegrate and be swallowed. A copy of the draft proposed package insert is provided in Attachment 3.

In support of the change in dosage form requested in this petition, the petitioner would like to point out that the Agency has previously approved ANDA suitability petitions allowing for a change in dosage form in many instances. A suitability petition was recently approved for the drug product Famotidine (Docket 00P-1422) to allow a change from a tablet to an orally disintegrating tablet. The petitioner is seeking the change in dosage form in an effort to make an alternate dosage form (rapidly disintegrating tablet) available to those individuals that may have difficulty in swallowing an intact tablet (as may be the case with Parkinson disease patients) or prefer the proposed dosage form.

The petitioner is also requesting a waiver of the requirement to conduct pediatric studies in accordance with the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drug and Biological Products in Pediatric Patients; Final Rule (Pediatric Final Rule) 63 FR 66632, published December 2, 1998, and the requirements set forth in 21 CFR § 314.55. In support of the request to waive the requirement to conduct pediatric studies, the petitioner notes that the RLD is indicated in the treatment of the symptoms of Parkinson's disease. In the Pediatric Final Rule, Parkinson's disease has been identified by the FDA as a disease, which is not likely to occur in the pediatric population, and thus a waiver will likely be granted (63 FR 66648). In fact, the draft guidance Recommendations for Complying With the Pediatric Final Rule (21 CFR § 314.55(a) and 601.27(a)), published November 2000, states:

The FDA has developed a list of diseases that have extremely limited applicability to pediatric patients in that the signs and symptoms of these diseases occur for the most part in the adult population. Thus, products being developed for the treatment of these conditions in adults are likely to be granted a waiver. These include the following:

- Parkinson's disease...

The change in dosage form is not likely to promote the use of the drug product in pediatric patients. As stated in the above references, use of the proposed drug product has extremely limited applicability to the pediatric population. The absence of specific pediatric labeling would not pose any risks to pediatric patients and the lack of use of the drug in the pediatric population would not be expected to change. Therefore, in accordance with the concepts in the Pediatric Final Rule, the petitioner requests a waiver under 21 CFR § 201.23 for the need to conduct pediatric studies.

#### **C. Environmental Impact**

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

#### **D. Economic Impact**

The information will be provided upon request by the Agency.

#### **E. Certification**

The undersigned certifies, that to the best knowledge and belief of the undersigned, 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.

Respectfully submitted,



Gordon R. Johnston  
Associate  
Lachman Consultant Services, Inc.

cc: Greg Davis, OGD

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