

**LACHMAN CONSULTANT SERVICES, INC.**  
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE, WESTBURY, NY 11590  
(516) 222-6222 • FAX (516) 683-1887

November 16, 2004

**OVERNIGHT COURIER 11/16/04**

Division of Dockets Management  
Food and Drug Administration (HFA-305)  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
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 in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Selegiline Hydrochloride Orally Disintegrating Tablets, 5 mg, is suitable for consideration in an abbreviated new drug application (ANDA).

**A. Action Requested**

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Selegiline Hydrochloride Orally Disintegrating Tablets, 5 mg, is suitable for submission in an ANDA. The listed reference drug product upon which this petition is based is Selegiline Hydrochloride Tablets, 5 mg. The petitioner thus seeks a change in dosage form (from an immediate-release capsule to an orally disintegrating tablet) from that of the listed drug product.

**B. Statement of Grounds**

The reference listed drug (RLD) product, Selegiline Tablets, 5 mg, approved in ANDA 74-871, is currently available in immediate-release tablet in a 5 mg strength of Selegiline Hydrochloride. A copy of the listing from the electronic version of the *Approved Drug Product with Therapeutic Equivalence Evaluations* (Orange Book) 24<sup>th</sup> edition is included in Attachment 1 (page 3-313). {NOTE: At the time of submission of this petition, the electronic Orange Book did not designate which of the marketed products was the RLD. This was discussed with the Office of Generic Drugs and on November 12, 2004, a member of the Orange Book staff called to indicate that the above-referenced ANDA would be designated as the RLD. The proposed drug product represents an orally disintegrating tablet that will contain the same strength of selegiline hydrochloride, 5 mg, as the RLD, but in a different dosage form (orally disintegrating tablet).

The proposed orally disintegrating tablet is designed to provide for ease of administration for patients who cannot or who find it difficult to swallow immediate-release tablets. The product is designed to be dissolved rapidly on the tongue, and swallowed without the need for water. The new proposed dosage form will provide a more convenient dosage form for those patients

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identified above and for those patients who are elderly and infirm, a common characteristic for Parkinson's patients, and find it difficult to swallow a tablet or are not in a position to have water available when dosing is necessary. The availability of an orally disintegrating tablet may be of specific benefit in Parkinson's patients who may find it easier due to their illness to utilize such a product.

Copies of labeling of the reference-listed drug product upon which this petition is based and draft labeling for the proposed product are included in Attachment 2 and Attachment 3, respectively. Please note that the draft labeling for the proposed product will be revised to include the inactive ingredients and a complete "How Supplied" section when the ANDA is submitted. The proposed labeling is the "same as" the approved RLD labeling with the exception of changes allowed because the manufacturer of the generic product differs from that of the RLD and in regard to those changes necessary due to the approval of this petition (i.e., method of dosing [the ability to dissolve the tablet on the tongue]). There are no changes in the indications, uses or dosing regimen of the proposed product. The ANDA applicant will demonstrate that the proposed orally disintegrating tablet is bioequivalent to the RLD.

### **Pediatric Waiver Request**

In December of 2003, Congress passed the Pediatric Research Equity Act of 2003 (PREA) that amended the Federal Food, Drug and Cosmetic Act to provide the Agency authority to require drug firms to study certain drugs in pediatric patients, if the Agency felt that such a study would provide beneficial health data for that patient population. The act also provides a provision for a waiver from such requirement if:

- (iii) the drug or biological product;
- (I) does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients; and
- (II) is not likely to be used in a substantial number of pediatric patients.

The petitioner hereby requests that a waiver from the conduct of pediatric studies be granted for the approval of this petition to permit a subsequent ANDA filing.

Selegiline Hydrochloride does not appear on the historical List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population.<sup>1</sup> While the RLD is available in an immediate-release capsule dosage form, it was additionally approved by the Agency in an immediate-release tablet dosage form (Eldepryl®, NDA 19-334) also in a strength of 5 mg. The labeling of the RLD states:

"Selegiline is indicated as an adjunct in the management of Parkinsonian patients being treated with levodopa/carbidopa who exhibit deterioration in the quality of their response to this therapy."

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<sup>1</sup> The list was accessed on September 1, 2004 from the following web address  
<http://www.fda.gov/cder/pediatric/peddrugsfinal.htm>

Postgraduate Medicine Online reports that the mean age of onset of Parkinson's disease is 55-60 years of age.<sup>2</sup> Clearly this is not a disease associated with children, and therefore, selegiline hydrochloride is not likely to be utilized or prescribed in the pediatric population. The proposed product could not have a meaningful therapeutic benefit over existing therapies for pediatric patients because the disease does not affect pediatric patients. For this reason alone, this proposed product should be granted a full waiver under PREA.

Therefore, based on the reasons cited above, the petitioner requests that the Commissioner find that a change in dosage form from an immediate-release capsule to an orally disintegrating tablet containing Selegiline Hydrochloride, 5 mg, raises no questions of safety or effectiveness, and the Agency should then approve the petition.

**C. Environmental Impact**

The petitioner claims a categorical exclusion under 21 CFR 25.31.

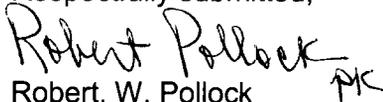
**D. Economic Impact**

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.

**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,

 Robert W. Pollock PK

Vice President  
Lachman Consultant Services, Inc.  
1600 Stewart Avenue  
Westbury, New York 11590

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- Attachments:
1. *Approved Drug Product with Therapeutic Equivalence Evaluations* (Orange Book) 24<sup>th</sup> Edition, page 3-313
  2. Labeling of the Reference-Listed Drug Product
  3. Draft Labeling for the Proposed Product

cc: Emily Thomas (OGD)

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<sup>2</sup> Postgraduate Medicine, Conley, S.C.; Kirchner, J.T., Vol. 106, No. 1, July 1999, [http://www.postgradmed.com/issues/1999/07\\_99/conley.htm](http://www.postgradmed.com/issues/1999/07_99/conley.htm) accessed September 3, 2004