

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

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

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May 5, 2004

OVERNIGHT COURIER 5/5/04

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, Pravastatin Sodium Tablets 30 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 Pravastatin Sodium Tablets 30 mg are suitable for submission in an ANDA. The listed reference drug product upon which this petition is based is Pravachol® (pravastatin sodium) Tablets 80 mg. The product is also approved in strengths of 10 mg, 20 mg and 40 mg. Therefore, the petitioner seeks a change in strength (from the currently approved 10 mg, 20 mg, 40 mg and 80 mg tablets to include a 30 mg strength) from that of the listed drug product.

B. Statement of Grounds

The reference-listed drug (RLD) product is Pravachol® (pravastatin sodium) Tablets, 80 mg, which is also currently available in approved tablet strengths of 10 mg, 20 mg and 40 mg. A copy of the listing from the *Approved Drug Product with Therapeutic Equivalence Evaluations* 24th edition, page 3-295 is included in Attachment 1. The proposed drug product represents a tablet that will contain an intermediate strength of the drug (30 mg). This intermediate strength is believed to be consistent with the currently approved RLD product's labeling and will provide both greater flexibility for the physician in titrating a patient to the appropriate dose and will represent a more convenient single tablet dosage unit to provide the specific dose prescribed by the physician for an individual patient. The petition is thus seeking a change in strength (from the approved 10 mg, 20 mg, 40 mg and 80 mg tablet products to include a 30 mg strength) from that of the reference-listed drug.

The RLD was recently revised and now states that the recommended starting dose is 40 mg. Clearly, the labeling contemplates dosage adjustments based on patient response, use in certain other medical conditions or when the drug is taken in combination with certain other medications. The proposed dosage strength of 30 mg clearly falls within the currently approved strengths, and therefore, should not raise questions of safety or efficacy.

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The petitioner is seeking the requested changes in strength from the RLD drug product to provide the physician greater flexibility in administering an alternate dosage strength that is consistent with doses clearly contemplated in the approved labeling of the RLD. The goal being to reduce the number of tablets a patient would need to take for a single dose. This will improve patient convenience, compliance and make it easier to achieve the required dose for those patients for whom a dose of 30 mg was found appropriate by the prescribing physician.

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. 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 the How Supplied section which lists the additional available strength sought by this petition. There are no changes in the indications or dosage and administration sections necessary as the approved labeling of the RLD already contemplates the use of the proposed dosage strengths.

Therefore, the petitioner requests that the Commissioner find that a change in strength from 10 mg, 20 mg, 40 mg and 80 mg tablets to include a 30 mg strength tablet for this product 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

RWP/pk

- Attachments:
1. *Approved Drug Product with Therapeutic Equivalence Evaluations 24th edition, page 3-295*
 2. *Copy of Approved Labeling and Draft Labeling for the Proposed Product*

cc: Emily Thakur (OGD)

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