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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 60 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 60 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 currently 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 60 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. The product 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 60 mg drug product represents a tablet that will contain a strength of the drug that falls squarely between the reference-listed drug products approved 40 mg and 80 mg strength products. While the current labeling of the RLD states that "[i]f a daily dose of 40 mg does not achieve desired cholesterol levels, 80 mg once daily is recommended", the proposed 60 mg intermediate strength product 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 based on the patients response and will represent a more convenient single tablet dosage unit to provide the specific dose prescribed by the physician for an individual patient. This may improve patient convenience, compliance and make it easier to achieve the required dose for those patients for whom a dose of 60 mg was found appropriate by the prescribing physician.

Additionally, the labeling of 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 60 mg clearly falls within two of the currently approved strengths of the RLD (40 mg and 80 mg), and therefore, should not raise questions of safety or efficacy.

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