

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

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February 28, 2007

OVERNIGHT COURIER 2/28/07

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, Metoprolol Tartrate Tablets USP, 37.5 mg and 75 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 Metoprolol Tartrate Tablets USP, 37.5 mg and 75 mg, are suitable for submission as an ANDA. The reference-listed drug product (RLD), upon which this petition is based, is Metoprolol Tartrate Tablets, ANDA 76-704 held by Mylan Pharmaceuticals, Inc. The petitioner also references Metoprolol Tartrate Tablets, 25 mg and 50 mg, in support of this petition. Therefore, the petitioner seeks a change in strength (from 100 mg to include a 37.5 mg and 75 mg strength) from that of the listed drug product.

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The RLD, Metoprolol Tartrate Tablets, by Mylan Pharmaceuticals, Inc. is a tablet product containing 100 mg of metoprolol tartrate. See copy of the page from the current Electronic Edition of the *Approved Drug Products with Therapeutic Equivalence Evaluations* (Attachment 1). The proposed drug product also represents a tablet dosage form, but containing 37.5 mg or 75 mg of metoprolol tartrate. The petition is thus seeking a change in strength (from 100 mg to include a 37.5 mg or 75 mg strength) from that of the RLD.

Please note that the proposed changes in strength represent dosage strengths that are contemplated in the approved labeling for the RLD. The usual initial dosage for hypertension and angina pectoris is 100 mg daily, given in single or divided doses. The labeling clearly indicates that the dose for both hypertension and angina pectoris should be individualized. All three of the approved strengths, 25 mg, 50 mg and 100 mg, are available as scored tablets allowing for flexibility in dosing, in order to provide an individualized dose that is well tolerated by the patient. Additionally, for myocardial infarction, the labeling states, "Patients who appear not to tolerate the full intravenous dose should be started on metoprolol

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tartrate tablets either 25 mg or 50 mg every 6 hours (depending on the degree of intolerance)...” The 37.5 mg, an intermediate strength, would provide greater flexibility to the healthcare practitioner in achieving the best-tolerated dose for the patient. The proposed 37.5 mg and 75 mg strengths would allow for greater flexibility by providing the healthcare practitioner with appropriate intermediate doses, as determined by patient response, for hypertension, angina pectoris, and myocardial infarction.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition. The uses, indications, warnings and directions for use will remain the same as that of the RLD. Draft labeling for the proposed products is included in Attachment 2, and the RLD’s approved labeling is provided in Attachment 3.

Therefore, the petitioner’s request for the Commissioner to find that a change in strength from 100 mg to 37.5 mg and 75 mg for Metoprolol Tartrate Tablets, USP should raise no questions of safety or effectiveness, and the Agency should 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*
Senior Vice President
Lachman Consultant Services, Inc.

RWP/pk

- Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, accessed February 26, 2007
 2. Draft Labeling Proposed for Metoprolol Tartrate Tablets USP, 37.5 mg and 75 mg
 3. Labeling for the Reference-Listed Drug Metoprolol Tartrate Tablets, USP by Mylan Laboratories, Inc., revised June 2004

cc: Craig Kiester (OGD)

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