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

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August 2, 2013

OVERNIGHT COURIER 8/2/13

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, Carisoprodol Tablets, 300 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 the drug product, Carisoprodol Tablets, 300 mg, is suitable for submission in an ANDA. The reference listed drug product (RLD), upon which this petition is based, is Soma® (Carisoprodol) Tablets USP, 250 mg, NDA 011792 held by Meda Pharmaceuticals. This approved NDA also provides for Soma® Tablets in a 350 mg dosage strength. The petitioner seeks a change in strength (from 250 mg to 300 mg) 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 reference listed drug, Soma® Tablets, 250 mg, held by Meda Pharmaceuticals, is a tablet product containing 250 mg of Carisoprodol. See copy of the relevant page from the current Electronic Edition of the *Approved Drug Product with Therapeutic Equivalence Evaluations* (Attachment 1). The proposed drug product also represents a tablet dosage form, but contains 300 mg of Carisoprodol. The petition is thus seeking a change in strength (from 250 mg to 300 mg) from that of the RLD. Please note that the proposed change in strength represents a dosage strength that is clearly contemplated in the approved labeling for the RLD.

The current dosing instructions in the approved labeling of the RLD are as follows:

> "The recommended dose of SOMA is 250 mg to 350 mg three times a day and at bedtime. The recommended maximum duration of SOMA use is up to two or three weeks."

Thus, the additional strength of 300 mg would provide the healthcare practitioner with greater flexibility in dosing patients within the currently approved dosing range.

There are no proposed changes in labeling with the exception of the obvious change in strength sought in this petition and any information specifically related to the manufacturer or distributor. The uses,

indications, warnings and directions for use will remain the same as that of the RLD. Draft labeling for the proposed product is included in Attachment 2, and the approved labeling for the RLD is provided in Attachment 3.

Therefore, the petitioner's request for the Commissioner to find that a change in strength from 250 mg to 300 mg, for Carisoprodol Tablets should raise no questions of safety or effectiveness, and the Agency should approve the petition.

Inapplicability of the Pediatric Research Equity Act ("PREA"). PREA, which is codified at FDC Act § 505B, does not apply to a new strength, such as the one proposed in this Petition. (See FDC Act § 505B(a)(1)(A).) As such, PREA should not serve as an impediment to the Agency's granting of this 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,

Christine Miller

Christine Miller, Pharm.D
Associate Director

CCM/pk

Attachments:
1. Approved Drug Product with Therapeutic Equivalence Evaluations, accessed July 18, 2013
2. Draft Package Insert Labeling Proposed for Carisoprodol Tablets, 300 mg
3. Labeling for the RLD, Soma® Tablets (Meda Pharmaceuticals)

cc: Martin Shimer (OGD)

Soma® is a registered trademark of Meda Pharmaceuticals.

From: (516) 683-1881 Origin ID: RMEA
Westbury Office
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