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

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February 15, 2008

OVERNIGHT COURIER 02/15/08

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Amendment to Citizen Petition 2006P-0002
Change in Listed Drug

Dear Sir or Madam:

The undersigned submits this petition amendment, 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. The petition was submitted to request the Commissioner of the Food and Drug Administration to declare that the drug product, Methocarbamol Tablets USP, 1000 mg, is suitable for consideration in an abbreviated new drug application (ANDA). This amendment simply changes the Listed Drug product to the 500 mg strength. The basis for the strength change sought in the petition is the same, and as suggested in the original petition, is consistent with the approved labeling of Methocarbamol Tablets relative to the 1000 mg strength requested in this petition (see original petition relative to dosing recommendations). This is merely an administrative change that was requested by the Agency. The substance of the request made in this petition remains the same.

A. Action Requested in Amendment

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Methocarbamol Tablets USP, 1000 mg, is suitable for submission as an ANDA. The listed reference drug product (RLD), upon which this petition is based is hereby revised to Robaxin-500® Tablets (methocarbamol), 500 mg, NDA 11-011 currently held by Schwarz Pharma. In the original petition, we cited the 750 mg approved product as the listed drug, but relied on the FDA's approval of the 500 mg tablet strength as the basis for supporting the 1000 mg tablet strength and the relevant dosing instructions. Thus, this amendment only requests that the Listed Drug be revised to the 500 mg strength. The rationale for the change remains the same with the exception of the administrative change to the listed drug. A copy of the listing for the 500 mg tablet as a listed drug is included in Attachment A. This information was also included in the original petition. Because there would be no changes in the labeling of the proposed product or the Listed Drug product submitted in the original petition, new draft labeling is not being submitted.

B. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

AMD

C. 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.

D. 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 is unfavorable to the petition.

Respectfully submitted,

Robert W. Pollock
Senior Vice President

RWP/pk

cc: Cecelia Parise (OGD)
Craig Kiester (OGD)

Attachment: Listing for 500 mg Tablet

A43P8046

Search results from the "OB_Rx" table for query on "011011."

Active Ingredient:	METHOCARBAMOL
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	ROBAXIN
Applicant:	SCHWARZ PHARMA
Strength:	500MG
Application Number:	011011
Product Number:	004
Approval Date:	Approved Prior to Jan 1, 1982
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AA**
Patent and Exclusivity Info for this product:	View

Active Ingredient:	METHOCARBAMOL
Dosage Form;Route:	TABLET; ORAL
Proprietary Name:	ROBAXIN-750
Applicant:	SCHWARZ PHARMA
Strength:	750MG
Application Number:	011011
Product Number:	006
Approval Date:	Approved Prior to Jan 1, 1982
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	**AA**
Patent and Exclusivity Info for this product:	View

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