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November 8, 2001

SUITABILITY PETITION

Dockets Management Branch
Food and Drug Administration (HFA-305)
12420 Parklawn Drive (Room 1-23)
Rockville, MD 20857

original

RE: Suitability Petition

Dear Sir/Madam:

Enclosed are four copies of a suitability petition we are filing on behalf of Atley Pharmaceuticals, Inc., Ashland, VA 23005. The petition requests the Commissioner to permit Atley to file an abbreviated new drug application (ANDA) for a tableted product containing Carisoprodol at a strength different from the RLD drug as defined in the attached petition.

Sincerely,

Paul W. Carr

Paul W. Carr, P.E., R.A.C.
Regulatory Consultant

Enclosure

cc: Atley Pharmaceuticals, Inc.

PWC:pbh

OIP-0526

CP1

SUITABILITY PETITION

Petition Filed By:

Atley Pharmaceuticals, Inc.
14433 North Washington Highway
Ashland, VA 23005

Proposed Product:

Oral Tablet Dosage Form Containing
200 mg Carisoprodol

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SUITABILITY PETITION

The undersigned submits this Suitability Petition under Section 505 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 355(j)(2)(C), which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR §5.10. Petitioner requests the Commissioner of Food and Drugs to make a determination that the drug product hereinafter described is suitable for consideration under an abbreviated new drug application (ANDA).

A. Action Requested

Atley Pharmaceuticals, Inc. ("Atley") requests a determination that a drug product containing 200 mg Carisoprodol tablet form for oral administration is suitable for evaluation under an ANDA.

We also request the Food and Drug Commissioner to grant a waiver from the requirements of a pediatric study for a change in dosage form strength on the basis that this active ingredient is currently approved by the Food and Drug Administration at a strength of 350 mg, for the noted disease conditions, but the labeling allows the physician to properly prescribe the appropriate strength depending on the severity of the condition. We understand the agency's desire to seek information regarding the use of this drug in various pediatric populations. However, in this case the product labeling already includes approved uses and dosing instructions for the most significant patient population. We propose that the concept of a standardized dosage adjustment for safety or efficacy, which is the usual goal of pediatric studies, is not relevant to this drug. In accordance with 21 CFR 314.55(c) the Commissioner may grant full or partial waiver of the study requirements on his own initiative **or** at the request of the applicant.

B. Statement of Grounds

The FFDCA allows an ANDA applicant to petition FDA for permission to file an ANDA for a drug product whose strength differs from that of the listed drug. See 21 U.S.C. §355(j)(2)(C); 57 Fed. Reg. 17950-17952(1992).

In the case of the proposed product there is one reference listed drug (RLD) product for Carisoprodol tablets published in, "*Approved Drug Products with Therapeutic Equivalence Evaluations,*" (The Orange Book) with a strength of 350 mg Carisoprodol assigned to Wallace Laboratories. We are attaching a table which lists the RLD product in addition to listing several products that have been approved or for which suitability petitions have been accepted (Attachment 1). In addition, Wallace Laboratories is the sponsor of an RLD product containing 325 mg aspirin and 200 mg carisoprodol, providing clear evidence of the activity of a product containing 200 mg carisoprodol. A copy of this labeling is also found in Attachment 3.

The proposed product is similar to the reference (RLD) product in that the proposed product contains carisoprodol indicated as an adjunct to rest, physical therapy, and other measures for the relief of pain, muscle spasm, and limited mobility associated with acute painful musculosketal conditions.

The legal basis under which this application proceeds is as promulgated in the FFDCA, noted above, which allows the Commissioner to accept a generic drug application for a drug which differs in dosage strengths from the pioneer or reference drug product. The petitioner is not aware of any information that would be unfavorable to the granting of the requested action.

C. Environmental Impact

Atley hereby requests a categorical exclusion from the requirement of preparing an environmental assessment. As provided in 21 CFR 25.31, neither an environmental assessment nor an environmental impact statement is required. To the best of the petitioner's knowledge, no extraordinary circumstances exist that may significantly affect the human environment as discussed under 21 CFR 25.21.

D. Economic Impact

As provided in 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. Identification of RLD

Atley is attaching labeling for the RLD product to which they are comparing the proposed drugs. The product is as follows:

Application No.	Name of Drug	Company
011792	Soma®	Wallace Laboratories, Inc.

F. Labeling

Attachment 2 provides copies of the proposed generic product labeling and Attachment 3 provides copies of the reference drug labeling.

Following is a description of the differences between the proposed generic product labeling and the RLD package inserts. [Please note: Atley is still in the process of designing the product container labeling and there are several examples in Attachment 2. However, the text will remain the same.]

PACKAGE INSERT

1. Add "Rx Only" to the beginning of the text
2. Replaced "Soma® " Tablets trade name with the Atley trade name of "Carisoprodol 200".
3. Removed "National PharmaPak Services, Inc., Zanesville, OH 43701."

- **Description**

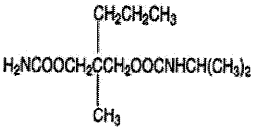
  A. Replaced the trade name "Soma®" with "Carisoprodol 200"

  B. Changed the descriptive text as follows:

FROM:

DESCRIPTION

SOMA® (carisoprodol) Tablets, USP is available as 350 mg round, white tablets. Chemically, carisoprodol is N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate. Carisoprodol is a white crystalline powder, having a mild, characteristic odor and a bitter taste. It is very slightly soluble in water; freely soluble in alcohol, in chloroform and in acetone; its solubility is practically independent of pH. Carisoprodol is present as a racemic mixture. The molecular formula is $C_{12}H_{24}N_2O_4$, with a molecular weight of 260.33. The structural formula is:

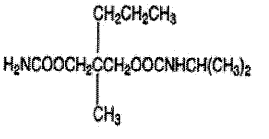


Other ingredients: alginic acid, magnesium stearate, potassium sorbate, starch, tribasic calcium phosphate.

TO THE FOLLOWING:

DESCRIPTION

Carisoprodol 200 Tablets, USP is available as 200 mg round, white tablets. Chemically, carisoprodol is N-isopropyl-2-methyl-2-propyl-1,3-propanediol dicarbamate. Carisoprodol is a white, crystalline powder, having a mild, characteristic odor and a bitter taste. It is very slightly soluble in water; freely soluble in alcohol, in chloroform, and in acetone; its solubility is practically independent of pH. Carisoprodol is present as a racemic mixture. The molecular formula is $C_{12}H_{24}N_2O_4$, with a molecular weight of 260.33. The structural formula is:



In addition, each tablet contains the following inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, microcrystalline cellulose, and stearic acid.

- **Additional Text Changes**

  WARNINGS

  - **Usage in Children** – Changed Trade Name "Soma" to "Carisoprodol 200"

- **How Supplied**

  A. Changed statement from:

TO READ AS FOLLOWS:

HOW SUPPLIED

'SOMA' (carisoprodol) Tablets, USP 350 mg: Round, convex, white tablets, inscribed with 'SOMA' on one side and 37WALLACE2001 on the other side, are available in bottles of 100 (NDC 0037-2001-01) and 500 (NDC 0037-2001-03), and unit-dose packages of 100 (NDC 0037-2001-85).

Storage: Store at controlled room temperature 15°-30°C (59°-86°F).

Dispense in a tight container.

WALLACE LABORATORIES
Division of
CARTER-WALLACE, INC.
Cranbury, New Jersey 08512

Rev. 9/94

120601196

HOW SUPPLIED

Carisoprodol 200 Tablets, is supplied as a white, elongated octagonal, convex tablet embossed with [Embossment to be added later]

Bottles of 100
NDC XXXXXXXXX
Bottles of 500
NDC XXXXXXXXX
Unit Dose Packages of 100
NDC XXXXXXXXX

Storage: Store at controlled room temperature 15°-30°C (59°-86°F).

Dispense in a tight container.

Manufactured For:
Atley Pharmaceuticals, Inc.
Ashland, VA 23005

Manufactured By:
PharmaFab
Grand Prairie, TX 75050

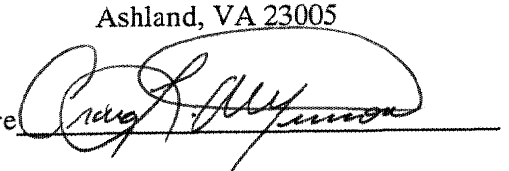
PIN ISS

Rev. Oct. 2001 Made in USA

G. 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 us that are unfavorable to the petition.

Typed Name: Atley Pharmaceuticals, Inc.
14433 N. Washington Highway
Ashland, VA 23005

Signature 

Title: By: Craig L. Attkisson, Its President

Name of Petitioner: Atley Pharmaceuticals, Inc.
Mailing Address: 14433 N. Washington Highway
Ashland, VA 23005

Telephone No: (804) 752-8400