CITIZEN PETITION

PETITION TO REQUEST A CHANGE FROM A LISTED DRUG

Date: September 30, 2003

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

PETITION FILED BY:

Anabolic Laboratories, Inc.
Irvine, CA 92614-6502

PROPOSED PRODUCTS:
Oral dosage forms containing
7.5 mg Cyclobenzaprine HCl

Introduction

The undersigned submits this petition under provisions of Section 505(j)(2)(C) of the Food, Drug and Cosmetic Act ("FDCA") as implemented by 21 CFR §314.93 and according to Part §10.20 of the same title. The petitioner requests the Commissioner of Food and Drugs to make a determination that the drug products described hereinafter, with a slightly different strength than the listed drugs, are suitable for marketing under an Abbreviated New Drug Application ("ANDA") because:

a) Investigations are not necessary to show the safety and effectiveness of the proposed drugs or any of the active ingredients or the strength; and

b) There are no active ingredients which may not be adequately evaluated for approval as safe and effective on the basis of the information to be submitted in an abbreviated application.

Action Requested

The petitioner requests the Commissioner of Food and drugs to make a determination that a drug product containing 7.5 mg of Cyclobenzaprine HCl is suitable for evaluation under an ANDA.

Statement of Grounds

Currently, FDA has approved FLEXERIL®[1] (Cyclobenzaprine HCl) in two dosage strengths for the treatment of skeletal muscle spasm of local origin. The two dosage strengths are 10 mg and 5 mg. Both dosage levels have been found safe and effective for their labeled indication.

The petitioner wishes to provide treating physicians with an intermediate dosing alternative with a 7.5 mg dosage of Cyclobenzaprine. Section 505(j)(2)(C) of the FDCA directs FDA to approve a petition requesting a change

[1] FLEXERIL is a registered trademark of ALZA Corporation

from a listed drug as suitable for evaluation under an ANDA unless FDA finds that investigations must be conducted to show the safety and effectiveness of the strength of the proposed drug product that differs from the strength of the listed drug product. The petitioner considers that new investigations should not be necessary to evaluate the safety and effectiveness of the proposed drug product because dosages both higher and lower of the same drug product have already been determined to be safe and effective. Also, the petitioner believes that bioequivalence of the proposed 7.5 mg dose can be demonstrated against the listed drug utilizing both the 10 mg and 5 mg dosages.

The following are listed as reference drugs ("RLD") by FDA in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"):

Table 1: Reference Listed Drugs

Application Number	**Description**	**Strength**	**Company**
017821	Cyclobenzaprine HCl	10 mg	McNeil Consumer & Specialty Pharmaceuticals
	Cyclobenzaprine HCl	5 mg	

The most current labeling for the listed drugs was approved on February 3, 2003. A copy of the listed drugs labeling is provided in an attachment to this petition. Also, a copy of a draft label for the proposed drug is provided in an attachment to this petition.

Environmental Impact

The petitioner 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

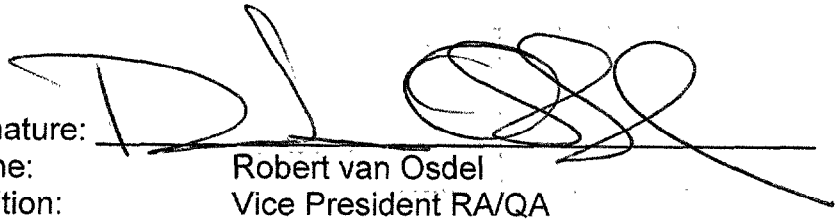
circumstances exist that may significantly affect the human environment as discussed under 21 CFR §25.21.

Economic Impact

As provided in 21 CFR §10.30(b), the petitioner agrees to submit economic impact information only if requested by the Commissioner of Food and Drugs following review of the petition.

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.

Signature: 
Name: Robert van Osdel
Position: Vice President RA/QA

Name of Petitioner: Anabolic Laboratories, Inc.
Address: 17802 Gillette Avenue
Irvine, CA 92614-6502
949-863-0340

ATTACHMENTS