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
200 mg Carisoprodol/ 325 mg Acetaminophen/
200 mg Carisoprodol/ 325 mg Acetaminophen/ 16 mg Codeine

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 different ingredient 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 two drug products containing a combination of 200 mg Carisoprodol and 325 mg of Acetaminophen; and 200 mg Carisoprodol, 325 mg of Acetaminophen, and 16 mg Codeine Phosphate are suitable for evaluation under an ANDA.

Statement of Grounds

Acetaminophen is an appropriate and effective replacement for Aspirin in treatment of minor muscle pain and is considered as effective as Aspirin at the same dosage levels.

Pain of skeletal muscle origin remains a substantial problem for many patients. Multimodal analgesic combinations, such as Acetaminophen, Codeine Phosphate and Carisoprodol, can provide a method to improve pain treatment by offering improved pain relief and minimized adverse effects.

Several multimodal pain treatments used for skeletal muscle pain combine a muscle relaxant with a centrally acting opiate, such as Codeine, and a peripherally acting analgesic such as Aspirin or Acetaminophen.

In publishing a tentative final OTC monograph for internal analgesic drug products on November 16, 1988, FDA presented a substantial amount of information in the preamble based on reviewed scientific literature. At one point, FDA recommended an indication for OTC internal analgesic products include the temporary relief of minor aches and pains associated with muscular aches and pains, among others. Moreover, that the terms "muscular aches" and backache" adequately represent most musculoskeletal aches and pains. Further in the preamble, FDA discussed the similarity of Aspirin and Acetaminophen: "The agency believes at this time that it is reasonable for acetaminophen and aspirin to have the same dosage and frequency of administration because, based upon the data submitted to the Panel, the safe and effective OTC dosage ranges for acetaminophen and Aspirin are the same ... Also, aspirin and Acetaminophen are indicated for the same OTC uses, have been extensively promoted as comparable OTC analgesics (with different side effects), and are widely and interchangeably used by consumers."

Section 505(j)(2)(C) of the FDCA directs FDA to approve a petition requesting a change 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 proposed drug with a different active ingredient that differs from the ingredient 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. The two proposed drug products differ from the listed drug products only in the analgesic ingredient and FDA has already established that Aspirin (in the listed drug) is interchangeable with the Acetaminophen in the proposed drug. The dosage of the Acetaminophen is the same as the Aspirin it is proposed to replace.

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**
012365	Aspirin/ Carisoprodol	325 mg/ 200 mg	Medpointe Pharm HLC
012366	Aspirin/ Carisoprodol/ Codeine Phosphate	325 mg/ 200 mg/ 16 mg	

The last labeling revision reviewed and approved by FDA for the listed drug containing Aspirin and Carisoprodol (325 mg/200 mg) was approved on January 10, 1986. The last labeling revision reviewed and approved by FDA for the listed drug containing Aspirin, Carisoprodol, and Codeine Phosphate (325 mg/200 mg/16 mg) was approved on January 16, 1986. Copies of labeling for these listed drugs are provided in an attachment to this petition. Also, a copy of draft labeling for the proposed drugs is provided in an attachment to this petition.

Acetaminophen has been in clinical use in the United States since the 1950s. Both combinations listed above were approved by FDA after review of safety data in 1960. Accordingly, there is no safety issue with either proposed active ingredient at the strengths proposed. Also, since Acetaminophen has been approved by FDA as effective for pain relief at levels of 325 mg in combination with Codeine (Vicodin) the petitioner considers there can be no effectiveness issues.

Environmental Impact

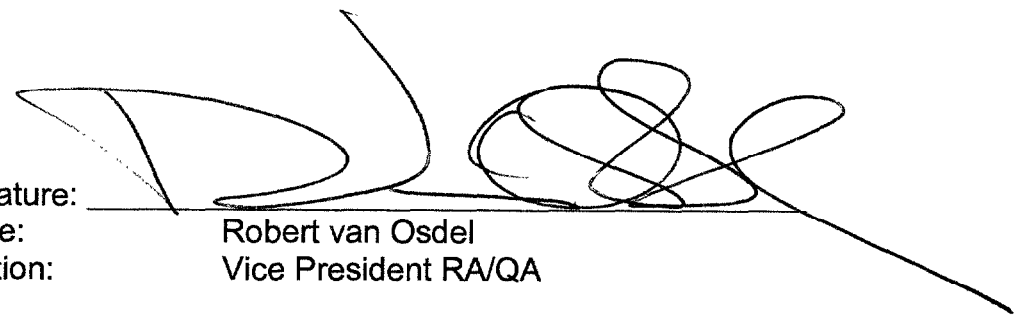
The petitioner requests a categorical exclusion from the requirement of preparing an environmental assessment. As provided in 21 CFR §25.31, neither an environmental assessment nor an environmental impact statement is required. To the best of the petitioner's knowledge, no extraordinary circumstances 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: _____

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