DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

6837 '03 OCT 14 A9:32

OCT 10 2003

Anabolic Laboratories, Inc.
Attention: Robert van Osdel
17802 Gillette Avenue
Irvine, CA 92614-6502

Docket No. 2003P-0436/CP1

Dear Mr. Osdel:

This is in response to your Abbreviated New Drug Application (ANDA) suitability petition filed on September 22, 2003, regarding oral dosage forms containing Hydrocodone Bitratrate and Acetaminophen, 5 mg/300 mg, 7.5 mg/300 mg, 10 mg/300 mg. Your petition is incomplete as submitted. Please refer to 21 C.F.R 314.93 regarding the type of information that should be included in a petition submitted pursuant to section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act. The Food and Drug Administration (FDA) has the following comments with respect to your petition.

1. A petition was previously approved for Hydrocodone Bitartrate and Acetaminophen Tablets, 10 mg/300 mg (See Docket # 01P-0441/CP1). Once a petition is approved, any ANDA applicant may refer to that petition as the basis of submission for an ANDA.

2. Two petitions are pending for Hydrocodone Bitartrate and Acetaminophen Tablets, 5 mg/300 mg and 7.5 mg/300 mg (See Docket #s 03P-0413/CP1 and 03P-0414/CP1). These petitions will be evaluated by the FDA. It is not necessary for another petitioner to submit an additional petition for the same request.

3. You should identify a listed drug for each drug product for which you are requesting a change. You have identified at least two listed drugs for each requested product.

4. You should identify the dosage form you are requesting. You did not identify a dosage form for your proposed products.

5. You should identify the changes you are requesting from the listed drug.

The file is closed until you either amend your petition with the requested information, or withdraw your petition. If you have any questions regarding this petition, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 301-827-5845.

2003P-0436

LET 1

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,

Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research