

## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration Rockville, MD 20857

FILE COPY

October 1, 2003

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

Dear Mr. Osdal:

Your petition requesting the Food and Drug Administration to permit an Abbreviated New Drug Application (ANDA) suitability for a containing 7.5 mg of Cyclobenzaprine HCI, was received by this office on 10/1/2003. It was assigned docket number 2003P-0461/CP 1 and it was filed on 10/1/2003. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie Butler, Director

Division of Dockets Management

2003P.046/

ACK-1