



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

November 15, 2001

Mr. Paul W. Carr, P.E., R.A.C.
Shotwell & Carr, Inc.
3535 Firewheel Dr.
Suite A
Flower Mound, TX 75028-2628

Dear Mr. Carr:

Your petition on behalf of Atley Pharmaceuticals requesting the Food and Drug Administration to approve an ANDA for a tableted product containing hydrocodone bitartrate & acetaminophen, was received by this office on 11/15/01. It was assigned docket number 01P-0521/CP1 and it was filed on 11/15/01. 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,

Helen K. Harris
Dockets Management Branch

01P-0521

ACK1