



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 31, 2002

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, Inc., requesting the Food and Drug Administration to permit an abbreviated new drug application (ANDA) for tableted products containing butalbital and acetaminophen at strengths different from RLD drug. was received by this office on 01/31/02. It was assigned docket number 02P-0056/CP 1 and it was filed on 01/31/02. 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 C. Butler
Dockets Management Branch

02P.0056

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