



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

January 04, 2002

Dave Ambrose
Ambi Pharmaceuticals, Inc.
16206-A Flight Path Drive
Brooksville, FL 34604

Dear Mr. Ambrose:

Your petition requesting the Food and Drug Administration to determine that a drug product containing 200 mg actaminophen, 10 mg hydrocodone bitartrate, 7.5 mg hydrocodone bitartrate and 5 mg hydrocodone bitartrate in tablet form for oral administration is suitable for evaluation under an ANDA, was received by this office on 01/04/02. It was assigned docket number 02P-0004/CP 1 and it was filed on 01/04/02. 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,

A handwritten signature in cursive script that reads "Jennie Butler".

Jennie Butler
Dockets Management Branch

02P-0004

ACK 1