



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FILE COPY

March 22, 2001

Ms. Kaye B. McDonald
Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605

Dear Ms. McDonald:

Your petition requesting the Food and Drug Administration to declare that an ANDA may be submitted for combination hydrocodone bitartrate and acetaminophen elixir products in strengths of 10mg/500mg per 15 ml, was received by this office on 03/22/01. It was assigned docket number 01P-0144/CP1 and it was filed on 03/22/01. 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-0144

ACK1