



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

**FILE COPY**

March 16, 2001

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

Dear Ms. McDonald:

Your petition requesting the Food and Drug Administration to seek the determination of the suitability of a higher strength elixir containing 10mg of hydrocodone bitartrate and 650mg of acetaminophen for an ANDA, was received by this office on 03/14/01. It was assigned docket number 01P-0130/CP 1 and it was filed on 03/14/01. 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,

Jennie Butler  
Dockets Management Branch

**01P-0130**

**ACK 1**