



DEPARTMENT OF HEALTH & HUMAN SERVICES

---

Food and Drug Administration  
Rockville MD 20857

April 7, 2000

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

Dear Ms. McDonald:

Your petition requesting the Food and Drug Administration to determine that an abbreviated new drug application is suitable for elixirs containing 10 mg hydrocodone bitartrate/325 mg acetaminophen per 15 mL, 10 mg hydrocodone bitartrate/500 mg acetaminophen per 15 mL, and 10 mg hydrocodone bitartrate/650 mg acetaminophen per 30 mL was received by this office on 04/07/00. It was assigned docket number 00P-1243/CF 1 and it was filed on 04/07/00. 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 black ink, appearing to read "Lyle D. Jaffe".

Lyle D. Jaffe  
Dockets Management Branch

00P-1243

ACK 1