



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

August 26, 2002

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 (ANDA) is suitable for an analgesic oral suspension containing 7.5 mg hydrocodone bitartrate and 200 mg ibuprofen per 15 mL, was received by this office on 08/26/02. It was assigned docket number 02P-0386/CP 1 and it was filed on 08/26/02. 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,

Lyle D. Jaffe
Dockets Management Branch

02P.0386

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