



# FILE COPY

November 5, 2001

Darlene M. Ryan, Manager  
ANDAFAB ONE LP  
2940 North Highway 360  
Suite 100  
Grand Prarie, TX 75050

Dear Ms. Ryan:

Your petition requesting the Food and Drug Administration to permit the filing of an abbreviated new drug application for a tableted product containing 10 mg hydrocodone bitartrate/400 mg acetaminophen and 7.5 mg hydrocodone bitartrate/400 mg acetaminophen was received by this office on 11/02/01. It was assigned docket number 01P-0504/CP 1 and it was filed on 11/05/01. 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,

Lyle D. Jaffe  
Dockets Management Branch

cc: Paul W. Carr, P.E., R.A.C.  
Regulatory Consultant  
Shotwell & Carr, Inc.  
3535 Firewheel Drive, Suite A  
Flower Mound, TX 75028-2628

01P-0504

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