



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

September 9, 2003

Mr. Robert W. Pollock
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, New York 11590

FILE COPY

Dear Mr. Pollock:

Your petition requesting the Food and Drug Administration to make a determination that a Hydrocodone Bitartrate and Acetaminophen Tablet, USP 7.5 mg/ 300 mg combination drug product is suitable for submission as an ANDA, was received by this office on 09/04/2003. It was assigned docket number 2003P-0413/CP 1 and it was filed on 09/04/2003. 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
Division of Dockets Management

2003P-0413

ACR1