DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

October 14, 2003

FILE COPY

Mr. Ira R. Berry
International Regulatory Business Consultants, Ltd.
2115 Millburn, Suite 108
Maplewood, New Jersey 07040

Dear Mr. Berry:

Your petition requesting the Food and Drug Administration to make a determination that the drug product containing hydrocodone bitartrate 5 mg and acetaminophen 325 mg in liquid form for oral administration is suitable for evaluation under an ANDA, was received by this office on 10/09/2003. It was assigned docket number 2003P-0475/CP 1 and it was filed on 10/10/2003. 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-0475

ACK 1