



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

August 9, 2005

**FILE COPY**

Anne M. Tomalin  
CanReg, Inc.  
450 North Lakeshore Drive  
Mundelein, Illinois 60060

Dear Ms. Tomalin.:

Your petition requesting the Food and Drug Administration to determine that the drug product, Ursodiol Oral Suspension, 20 mg/ml is suitable for an ANDA was received by this office on 08/09/2005. It was assigned docket number 2005P-0315/CP1 and it was filed on 08/09/2005. 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,

  
Gloria Ortega, Deputy Director  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0315

ACK 1