



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

December 15, 2005

Edward John Allera  
Buchanan Ingersoll PC  
1776 K Street, N.W.  
Washington, DC 20006-2365

**FILE COPY**

Dear Mr. Allera:

Your petition, on behalf of Breckenridge Pharmaceutical, Inc., requesting the Food and Drug Administration to establish criteria, analogous to the criteria for marketing Category I drug products under the Over-the-Counter Drug Review regarding the substitutability of prescription hyoscyamine drug products was received by this office on 12/15/2005. It was assigned docket number 2005P-0493/CP 1 and it was filed on 12/15/2005. 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,

Lyle D. Jaffe  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2005P-0493

ACK 1