



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 14, 2001

Ms. Elizabeth O'Brien
Aspire Pharmaceuticals, Inc.
2915 Weston Road
Weston, FL 33331

Dear Ms. O'Brien:

Your petition requesting the Food and Drug Administration to permit the submission of an abbreviated new drug application for a generic albuterol inhalation aerosol, based upon a bioequivalence study using Proventil was received by this office on 08/14/01. It was assigned docket number 01P-0353/CP 1 and it was filed on 08/14/01. 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,

Helen K. Harris
Dockets Management Branch

01P-0353

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