Aspire
PHARMACEUTICALS, INC.

August 13, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857

CITIZEN PETITION

ACTION REQUESTED

The undersigned submits this petition pursuant to 21 CFR §314.93 to request the Commissioner of Food and Drugs to permit the submission of an abbreviated new drug application for a generic albuterol inhalation aerosol, 0.09 mg/inhalation, based upon a bioequivalence study using Proventil® Albuterol Inhalation Aerosol, 0.09 mg/inhalation which is a listed drug, as the reference product instead of the FDA-designated reference product, Ventolin®, as required under 21 CFR Subpart B §320.20(b)(1).

STATEMENT OF GROUNDS

21 CFR Subpart B §320.21(b)(1) states:

> "(b) Any person submitting an abbreviated new drug application to FDA shall include in the application either:
>
> (1) Evidence demonstrating that the drug product that is the subject of the abbreviated new drug application is bioequivalent to the reference listed drug (defined in 314.3(b); or..."

Pursuant to 21 CFR §314.3(b), a reference listed drug is defined as the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its abbreviated application.

Permission is being sought for this exception in order to aid with projected market shortages involving albuterol inhalation aerosols. Approval of this action will allow Aspire to pursue approval for a product therapeutically equivalent to Proventil®. Currently, Aspire maintains regulatory control of an approved albuterol inhalation aerosol that is rated AB equivalent to Ventolin®, the Orange Book reference listed drug. Aspire believes our product will be shown to be equivalent to Proventil® in appropriately designed bioequivalence studies. By demonstrating bioequivalence of this product to Proventil®, Aspire will allow for patients currently using Proventil® Albuterol Inhalation Aerosol to obtain a generic version of the product at a reduced cost versus the innovator

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AN ANDRX COMPANY
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product, and will allow for patients currently using Proventil® to received uninterrupted equivalent therapy in the instance that Proventil® is not readily available on the market.

ENVIRONMENTAL IMPACT

Aspire requests categorical exclusion of an environmental assessment, as defined in 21 CFR §25.24(c)(1) pursuant to 21 CFR §25.31 for its albuterol inhalation aerosol.

ECONOMIC IMPACT

Pursuant to 21 CFR §10.30(b)(3), this section is not required unless requested by the Commissioner following a review of this petition.

CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes information known to the petitioner which are unfavorable to the petition.

Enclosed are copies of the current Orange Book listing for albuterol inhalation aerosols, current approved labeling for Proventil® and proposed draft labeling for Aspire's albuterol inhalation aerosol. Thank you for your consideration in reviewing this petition. Should any additional information be required, please contact the undersigned via telephone at (954) 217-4239 or via facsimile at (954) 217-4379.

Sincerely,

Elizabeth A O'Brien

Elizabeth O'Brien, M.S., RAC
Sr. Manager, Regulatory Affairs
Aspire Pharmaceuticals, Inc.
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Citizen Petition Attachments

Relevant Electronic Orange Book Pages	Attachment 1
Proventil® Current Innovator Labeling	Attachment 2
Aspire Proposed Draft Labeling	Attachment 3

Note: Aspire Pharmaceuticals, Inc. and Andrx Pharmaceuticals, Inc. are both divisions of Andrx Corporation.