



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 1 2002

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Ms. Elizabeth O'Brien
Sr. Manager, Regulatory Affairs
Aspire Pharmaceuticals, Inc.
2915 Weston Road
Weston, FL 33331

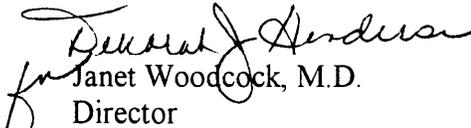
Re: Docket No. 01P-0353/CP1

Dear Ms. O'Brien:

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that we are still considering the issue raised in your petition, dated August 13, 2001, requesting that the Food and Drug Administration (FDA) permit the submission of an abbreviated new drug application (ANDA) for a generic albuterol inhalation aerosol, 0.09 mg/inhalation, based on a bioequivalence study using Proventil Albuterol Inhalation as an alternative reference listed drug to the FDA-designated reference product, Ventolin.

We expect to conclude our evaluation shortly and will respond to your petition once that process is completed.

Sincerely yours,


for Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

01P-0353

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