



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 10 2002

4856 '02 JAN 18 P2:29

William Stahovec
Manager, Regulatory Affairs
Aspire Pharmaceuticals, Inc.
4011 47th Avenue
Fort Lauderdale, FL 33314

Re: Docket No. 01P-0315/CP1

Dear Mr. Stahovec:

Pursuant to 21 CFR 10.30 (e)(2), this letter informs you that we are still considering your citizen petition request to determine whether Roxane Laboratories' acetaminophen and codeine phosphate tablets, 500 milligrams (mg)/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were withdrawn from sale for reasons of safety or effectiveness.

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "J. Woodcock".

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

01P-0315

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