Aspire
PHARMACEUTICALS, INC.

July 23, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, HFA-305
Room 1061
Rockville, MD 20852

01P-0315

CITIZEN PETITION

The undersigned submits this petition under 21 CFR 10.25(a) and 10.30 and pursuant to 21 CFR 314.122 (Section 505(j)(2)(C) of the FD & C Act) to request the Commissioner of Food and Drugs to make a determination as to whether a product was withdrawn from sale in the United States for reasons other than safety or effectiveness.

A. Action Requested

By this petition, the undersigned requests that the Commissioner of Food and Drugs makes the determination that Roxane Laboratories' Acetaminophen and Codeine Phosphate Tablets, 500 mg/15 mg, 500 mg/30 mg and 500 mg/60 mg, were withdrawn from sale in the United States for reasons other than safety or effectiveness.

B. Statement of Grounds

Aspire Pharmaceuticals plans to manufacture and distribute Acetaminophen and Codeine Phosphate Tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, pending approval by the FDA. These are the same as Roxane Laboratories' products of the same strengths and dosage forms. Dosage form and administration route are also the same as Tylenol® with Codeine Tablets which recommends a single dose range for acetaminophen of 300 mg–1000 mg and a maximum 24 hour dose of 4000 mg. A copy of the product labeling for Tylenol® with Codeine Tablets containing prescribing information is included as Attachment A.

Abbreviated New Drug Applications were submitted for Acetaminophen and Codeine Phosphate Tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg by Roxane Laboratories. The applications were approved on April 25, 1989. As required under 505(j)(2)(C) of the Food, Drug, and Cosmetic Act, Roxane also filed a Citizen Petition (Docket No. 86P-0161/CP) requesting the Commissioner of Food and Drugs to make a determination as to whether the drug product was suitable for an ANDA application as a similar or related product. The petition was approved on May 8, 1986. The letter from the FDA to Roxane states "Since the proposed change in strength of the acetaminophen component falls within acceptable limits established by the Monograph for OTC Internal Analgesics, Antipyretic and Antirheumatic Products, the Agency has determined that the proposed change in strength does not pose questions of safety or effectiveness, and concludes, therefore, that investigations are not necessary in this instance." A copy of this letter is included as Attachment B.

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AN ANDRX COMPANY
4011 SW 47th Avenue, Suite 1107, Fort Lauderdale, Florida 33314 • Office (954) 581-7500 • Fax: (954) 584-1442

Roxane Laboratories requested that the applications be withdrawn. A letter from the FDA to Roxane Laboratories, dated November 19, 1997, acknowledges receipt of this request and states that "These withdrawals will not prejudice any future filing of the Applications." A copy of this letter is included as Attachment C. Consequently, Roxane Laboratories Acetaminophen and Codeine Phosphate Tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg are listed in the discontinued section of *Approved Drug Products with Therapeutic Equivalence Evaluations*.

C. Environmental Impact

Aspire Pharmaceuticals, Inc., claims that it is entitled to a categorical exclusion, as defined in 21 CFR § 25.24(c)(1), from the filing of an environmental assessment as listed in § 25.31 for its Acetaminophen and Codeine Phosphate Tablets.

The undersigned certifies that our formulation will not be administered at higher dose levels, for longer duration or for different indications than were previously in effect for the approved formulation of Acetaminophen and Codeine Phosphate Tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg by Roxane.

D. Economic Impact

This information will be submitted if requested by the agency.

E. 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 representative data and information known to the petitioner that may be unfavorable to the petition.

William Stahovec 7-23-01

William Stahovec
Manager, Regulatory Affairs
Aspire Pharmaceuticals, Inc.
4011 SW 47th Avenue
Suite 1107
Ft. Lauderdale, FL 33314
(954) 585-1846