



Food and Drug Administration
Rockville MD 20857

MAY 13 2002

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William Stahovec
Manager, Regulatory Affairs
Aspire Pharmaceuticals, Inc.
4011 SW 47th Avenue
Suite 1107
Fort Lauderdale, FL 33314

Re: Docket No. 01P-0315/CP1

Dear Mr. Stahovec:

This formally responds to your citizen petition, dated July 23, 2001, requesting that the Food and Drug Administration (FDA) 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acetaminophen and codeine phosphate tablets, 500 milligrams (mg)/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and has determined that Roxane Laboratories' acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the FDA to maintain Roxane Laboratories' acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, in the "Discontinued Drug Product List" of *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice announcing the FDA's determination. If you require any further information, please call me at 301-594-2041.

Sincerely yours,

Carol Drew
Office of Regulatory Policy (HFD-7)
Center for Drug Evaluation and Research

OIP-0315
Enclosure

LET 2

Attachment J.—Certification Regarding Environmental Tobacco Smoke

Public Law 103227, Part C Environmental Tobacco Smoke, also known as the Pro Children Act of 1994, requires that smoking not be permitted in any portion of any indoor routinely owned or leased or contracted for by an entity and used routinely or regularly for provision of health, day care, education, or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law does not apply to children's services provided in private residences, facilities funded solely by Medicare or Medicaid funds, and portions of facilities used for inpatient drug or alcohol treatment. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1000 per day and/or the imposition of an administrative compliance order on the responsible entity. By signing and submitting this application the applicant/grantee certifies that it will comply with the requirements of the Act.

The applicant/grantee further agrees that it will require the language of this certification be included in any subawards which contain provisions for the children's services and that all subgrantees shall certify accordingly.

Attachment K.—*Title 45 of the Code of Federal Regulations*

Part 16—Department of Grant Appeals Process

Part 74—Administration of Grants (grants and subgrants to entities)

Part 75—Informal Grant Appeal Procedures

Part 76—Debarment and Suspension from Eligibility for Financial Assistance

Subpart F—Drug Free Workplace Requirements

Part 80—Non-Discrimination—Under Programs Receiving Federal Assistance through the Department of Health and Human Services Effectuation of Title VI of the Civil Rights Act Of 1964

Part 81—Practice and Procedures for Hearings Under Part 80 of this Title

Part 83—Regulation for the Administration and Enforcement of Section 799A and 845 of the Public Health Service Act

Part 84—Non-discrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance

Part 85—Enforcement of Non-Discrimination on the Basis of Handicap in Programs or Activities Conducted by the Department of Health and Human Services

Part 86—Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting from Federal Financial Assistance

Part 91—Non-discrimination on the Basis of Age in Health and Human Services Programs or Activities Receiving Federal Financial Assistance

Part 92—Uniform Administrative Requirements for Grants and Cooperative Agreements to States and Local Governments (**Federal Register**, March 11, 1988)

Part 93—New Restrictions on Lobbying

Part 100—Intergovernmental Review of Department of Health and Human Services Programs and Activities

[FR Doc. 02-11217 Filed 5-6-02; 8:45 am]

BILLING CODE 4184-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 02F-0181]

Safe Foods Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Safe Foods Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of cetylpyridinium chloride as an antimicrobial agent in poultry processing.

DATES: DATES: Submit written comments on the petitioner's environmental assessment by June 6, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3071.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2A4736) has been filed by Safe Foods Corp., c/o Keller and Heckman LLP, 1001 G St. NW., Washington, DC 20001. The petition proposes to amend the food additive regulations in part 173 Secondary Direct Food Additives Permitted in Food for Human Consumption (21 CFR part 173) to provide for the safe use of cetylpyridinium chloride as an antimicrobial agent in poultry processing.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment

submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (see ADDRESSES) for public review and comment. Interested persons may submit to the Dockets Management Branch written comments by June 6, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: April 11, 2002.

Laura M. Tarantino,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 02-11255 Filed 5-6-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 01P-0315]

Determination That Acetaminophen and Codeine Phosphate Tablets, 500 Milligrams (mg)/15 mg, 500 mg/30 mg, and 500 mg/60 mg, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for acetaminophen and codeine phosphate

tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg.

FOR FURTHER INFORMATION CONTACT:

Carol E. Drew, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

There are no NDAs for acetaminophen and codeine phosphate tablets. The initial acetaminophen/codeine combination drug product was accepted as an ANDA based on a **Federal Register** notice finding TRIGESIC with codeine to be effective for the relief of mild to moderate pain. (See 38 FR 3210, February 2, 1973.) FDA made this effectiveness determination under the 1962 amendments to the act, which

required a demonstration of the effectiveness of new drugs, including those approved prior to 1962. FDA contracted with the National Academy of Science/National Research Council to carry out the Drug Efficacy Study assessing the evidence of effectiveness available for new drugs approved prior to 1962. TRIGESIC with codeine contained codeine, acetaminophen, aspirin, and caffeine. The initial ANDA for acetaminophen and codeine tablets was considered to be similar and related to TRIGESIC with codeine tablets, and therefore was accepted as an ANDA.

Roxane Laboratories (Roxane) filed a suitability petition (86P-0161/CP) on April 14, 1986, requesting permission to file ANDAs for three different strengths of acetaminophen and codeine phosphate tablets. Its suitability petition was approved on May 8, 1986. Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, are the subject of ANDAs 89-511, 89-512, and 89-513, respectively. FDA approved ANDAs 89-511, 89-512, and 89-513, held by Roxane, on April 24, 1989, at which time they became "listed drugs" within the meaning of 21 CFR 314.3. On October 23, 1997, Roxane requested withdrawal of approval of ANDAs 89-511, 89-512, and 89-513. FDA withdrew approval of these ANDAs on June 11, 1998.

On July 23, 2001, Aspire Pharmaceuticals, Inc., submitted a citizen petition (Docket No. 01P-0315/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. Two grounds support the agency's finding. First, there are drug products with a combination of acetaminophen and codeine phosphate being marketed today with greater than 500 mg of acetaminophen. Second, when FDA's Center for Drug Evaluation and Research Suitability Petition Committee first considered Roxane's suitability petition for its acetaminophen and codeine phosphate drug products, it concluded that the drug products did not need any safety or efficacy studies to support their approval because the proposed change in strength of the acetaminophen component fell within acceptable limits established by the Monograph for Over-

the-Counter Internal Analgesic, Antipyretic, and Antirheumatic Drug Products.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously in this document, Roxane's acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been withdrawn from marketing for reasons other than safety or effectiveness. ANDAs that refer to acetaminophen and codeine phosphate tablets, 500 mg/15 mg, 500 mg/30 mg, and 500 mg/60 mg, may be approved by the agency.

Dated: April 29, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-11206 Filed 5-6-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Comparability Studies for Human Plasma-Derived Therapeutics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Plasma Protein Therapeutics Association (PPTA), entitled "Comparability Studies for Human Plasma-Derived Therapeutics." The workshop will discuss current guidance, critical issues, and approaches for establishing the comparability of human plasma derivatives in order to support changes in manufacturing processes, equipment, or facilities.

Date and Time: The public workshop will be held on May 30, 2002, from 8 a.m. to 5:30 p.m., and on May 31, 2002, from 9 a.m. to 12 noon.

Location: The workshop will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact: HelmsBriscoe Resource One, 12530 Browns Ferry Rd., Herndon, VA