Natrona County

Casper, *Fort Caspar*, 14 Fort Caspar Road.
Casper vicinity, *Pathfinder Dam*, 45 miles southwest of Casper.

Park County

Cody vicinity, *Buffalo Bill Dam (Shoshone Dam)*, 7 miles west of Cody.

Sheridan County

Ranchester, *Connor Battlefield (Tongue River Battlefield)*, City Park on the Tongue River.

Sublette County

Big Piney vicinity, *Wardell Buffalo Trap*, 6 miles east and 2 miles north of Big Piney.

ERNEST ALLEN CONNALLY,
Director, Office of Archeology and Historic Preservation.

[FR Doc.71-13122 Filed 9-7-71;8:45 am]

Office of the Secretary

UNIFORM RELOCATION ASSISTANCE AND REAL PROPERTY ACQUISITION POLICIES ACT OF 1970

Interim Regulations and Procedures for Implementation

The Interim regulations and procedures of this Department for implementing the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Public Law 91-646, 84 Stat. 1894, were published in the FEDERAL REGISTER on April 16, 1971, 36 F.R. 7265. The following amendments are made to these regulations and procedures in order to establish a time period within which claims for reimbursement under the Act must be filed by displaced persons.

Although it is the policy of the Department of the Interior to give notice of proposed rule making and to invite the public to participate in the rule making process (see Statement of Policy, 36 F.R. 8336), public participation in this notice would be unnecessary and contrary to the public interest because the proposed amendment to the notice covers minor technical matters, and the amendments relate to interim provisions prior to the adoption of final regulations.

Paragraph 4 is amended to read as follows:

4. *Qualifications.* A. In order to qualify for benefits under the Act as a displaced person, either of two conditions must be fulfilled:

(1) The person must have received a written notice to vacate which notice may be given before or after initiation of negotiations for acquisition of the property as prescribed by regulations issued by the head of the Bureau or Office; or

(2) The subject real property must in fact have been acquired, and the person must have moved as a result of its acquisition (except in those instances covered by sections 217 and 219 of the Act).

B. Filing of claims:

(1) *General.* All claims under the Act of a displaced person shall be submitted to the land acquiring agency of the Department, and supported by such documentation as may be required by the specific provisions of these regulations and by the departmental form applicable to the payment claimed. In the case of a project or program undertaken with Federal financial assistance, all claims of a displaced person shall be submitted to the State agency, and supported by such documentation as may be required by the State.

(2) *Time for filing claims.* Any claim under the Act of a displaced person shall be submitted to the acquiring agency of the Department within a period of 18 months after such person was required to move from the property in accordance with paragraph 4A, or within 6 months after the publication of this notice, whichever is later. In the case of a project or program undertaken with federal financial assistance any claim of a displaced person shall be submitted to the State agency within a period of 18 months after such person was required to move from the property in accordance with paragraph 4A, or within 6 months after the publication of this notice, whichever is later.

WARREN F. BRECHT,
Deputy Assistant Secretary of the Interior.

SEPTEMBER 1, 1971.

[FR Doc.71-13119 Filed 9-7-71;8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 10849; Docket No. FDC-D-244; NDA 10-849, etc.]

CERTAIN LONG-ACTING SYSTEMIC SULFONAMIDES

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs:

1. Kynex Acetyl Pediatric Suspension containing acetyl sulfamethoxypyridazine equivalent to 250 mg. of sulfamethoxypyridazine per 5 ml. (NDA 11-389), and

2. Kynex Tablets containing 0.5 gm. sulfamethoxypyridazine per tablet (NDA 10-849); both marketed by Lederle Laboratories, Division American Cyanamid Co., West Middletown Road, Pearl River, New York 10956.

3. Midicel Acetyl Suspension containing acetyl sulfamethoxypyridazine equivalent to 250 mg. of sulfamethoxypyridazine per 5 ml. (NDA 11-892), and

4. Midicel Tablets containing 0.5 gm. sulfamethoxypyridazine per tablet (NDA 11-305); both marketed by Parke, Davis and Co., Joseph Campaus Avenue at the River, Detroit, Michigan 48232.

5. Madribon Chewable Tablets containing 250 mg. sulfadimethoxine per tablet (NDA 11-625),

6. Madribon Pediatric Drops containing 250 mg. sulfadimethoxine per ml. (NDA 11-766),

7. Madribon Suspension containing 250 mg. sulfadimethoxine per 5 ml. (NDA 11-625), and

8. Madribon Tablets containing 0.5 gm. sulfadimethoxine per tablet (NDA 11-625); all marketed by Roche Laboratories, Division Hoffmann-LaRoche, Inc., Kingsland Road, Nutley, New Jersey 07110.

The drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new-drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new-drug application is required from any person marketing such drugs without approval.

The Food and Drug Administration is prepared to approve new drug applications and supplements to previously approved new drug applications under conditions described in this announcement.

SULFADIMETHOXINE, SULFAMETHOXYPYRIDAZINE AND ACETYL SULFAMETHOXYPYRIDAZINE

A. *Effective classification.* The Food and Drug Administration has considered the Academy reports, as well as other available evidence, and concludes that:

1. These drugs are effective in chancroid; trachoma; inclusion conjunctivitis; nocardiosis; urinary tract infections (primarily pyelonephritis, pyelitis and cystitis) due to susceptible organisms (usually *Escherichia coli, Klebsiella*, the enterobacter, *Staphylococcus aureus, Proteus mirabilis* and less frequently *Proteus vulgaris*), in the absence of obstructive uropathy or foreign bodies; toxoplasmosis, as adjunctive therapy with pyrimethamine; malaria due to chloroquine-resistant strains of *Plasmodium falciparum*, when used as adjunctive therapy; acute otitis media due to *Haemophilus influenzae* when used concomitantly with adequate doses of penicillin; and for the prophylaxis of rheumatic fever as an alternative to penicillin.

2. These drugs are probably effective in recurrent and chronic infections of the urinary tract.

3. These drugs are possibly effective for the treatment of pneumococcal infections; gas gangrene; lymphogranuloma venereum; shigellosis; for suppressive therapy in patients with indwelling catheters, ureterostomies, urinary stasis, cord bladder, and before and after genitourinary surgery and instrumentation; and in acute and chronic otitis media except when caused by *H. influenzae*, as qualified under "effective" indications.

4. Except as noted above, these drugs lack substantial evidence of effectiveness as therapeutic agents in common infections; actinomycosis; gonococcal, streptococcal, staphylococcal, salmonella, and pseudomonas infections; infections other than acute otitis media as described above due to *H. influenzae;* infections due to *Klebsiella pneumoniae* and the meningococci bacterial upper respiratory infections; or acne vulgaris.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Preparations of sulfamethoxypyridazine or its acetyl derivative and sulfadimethoxine are in tablet, suspension or chewable tablet form suitable for oral administration and contain per dosage unit an amount appropriate for administration in the dosage ranges described in the labeling conditions in this announcement.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the Act and regulations promulgated thereunder and those parts of its labeling indicated below are substantially as follows:

WARNING

Fatalities Have Occurred Due to the Development of Stevens-Johnson Syndrome (Erythema Multiforme Exudativum) Following the Use of _____. Therefore, the Patient Must Be Closely Observed, and Should a Rash Develop During Therapy With _____ the Drug Should Be Discontinued Immediately.

_____ Is a Sulfonamide Which Maintains a Long-Lasting Blood Level Due to Slow Excretion. Because of the Long-Lasting Blood Levels, a Smaller Dosage Than Is Normally Employed With Shorter-Acting Sulfonamides Should Be Administered.

Less Toxic, Shorter-Acting Sulfonamides Are Effective for All Indications Listed for This Drug. Use of Shorter-Acting Sulfonamides Should Be Ruled Out Before the Long-Acting Sulfonamides Are Employed.

DESCRIPTION

A statement should be included that these sulfonamides exist in the blood in various forms and that the "free" form is considered to be the therapeutically active form. Data should be included giving "free" and "total" sulfonamide levels in the blood from an average dose of the drug. (Additional descriptive information to be included by the manufacturer or distributor should be confined to an appropriate description of the physical and chemical properties of the drug and the formulation.)

ACTIONS

The systemic sulfonamides are bacteriostatic agents having a similar spectrum of activity. Sulfonamides competitively inhibit bacterial synthesis of folic acid (pteroylglutamic acid) from aminobenzoic acid. Resistant strains are capable of utilizing folic acid precursors or preformed folic acid.

INDICATIONS

Chancroid.
Trachoma.
Inclusion conjunctivitis.
Nocardiosis.

Urinary tract infections (primarily pyelonephritis, pyelitis and cystitis) due to susceptibile organisms (usually *E. coli, Klebsiella,* the enterobacter, *S. aureus, P. mirabilis,* and less frequently, *P. vulgaris*) in the absence of obstructive uropathy or foreign bodies.

Toxoplasmosis as adjunctive therapy with pyrimethamine.

Malaria due to chloroquine-resistant strains of *P. falciparum* when used as adjunctive therapy.

In acute otitis media due to *H. influenzae* when used concomitantly with adequate doses of penicillin.

Prophylaxis of rheumatic fever as an alternative to penicillin.

These long-acting sulfonamides may also be effective in recurrent and chronic infections of the urinary tract.

IMPORTANT NOTE: In vitro sulfonamide sensitivity tests are not always reliable. The test must be carefully coordinated with bacteriologic and clinical response. When the patient is already taking a sulfonamide, followup cultures should have aminobenzoic acid added to the culture media.

The currently increasing frequency of resistant organisms is a limitation of the usefulness of antibacterial agents including the sulfonamides.

Wide variation in blood levels may result with identical doses. Blood levels should be measured in patients receiving sulfonamides for serious infections. Free sulfonamide blood levels of 5–15 mg. per 100 ml. may be considered therapeutically effective for most infections with blood levels of 12–15 mg. per 100 ml. optimal for serious infections; 20 mg. per 100 ml. should be the maximum total sulfonamide level as adverse reactions occur more frequently above this level.

CONTRAINDICATIONS

Hypersensitivity to sulfonamides.

Infants less than 2 months of age (except in the treatment of congenital toxoplasmosis as adjunctive therapy with pyrimethamine).

Pregnancy at term and during the nursing period because sulfonamides pass the placenta and are excreted in the milk and may cause kernicterus.

WARNING: USE IN PREGNANCY

The safe use of sulfonamides in pregnancy has not been established. The teratogenicity potential of most sulfonamides has not been thoroughly investigated in either animals or humans. However, a significant increase in the incidence of cleft palate and other bony abnormalities of offspring has been observed when certain sulfonamides of the short-, intermediate-, and long-acting types were given to pregnant rats and mice at high oral doses (7 to 25 times the human therapeutic dose).

WARNING—SEE BOX WARNING

Sulfonamides will not eradicate group A streptococci and have not been demonstrated to prevent such sequelae of these infections as rheumatic fever and glomerulonephritis.

Deaths associated with the administration of sulfonamides have been reported from hypersensitivity reactions, agranulocytosis, aplastic anemia, and other blood dyscrasias.

The presence of clinical signs such as sore throat, fever, pallor, purpura, or jaundice may be early indications of serious blood disorders.

Complete blood counts should be done frequently in patients receiving sulfonamides.

The frequency of renal complications is considerably lower in patients receiving the more soluble sulfonamides. Urinalysis with careful microscopic examination should be obtained frequently in patients receiving sulfonamides.

PRECAUTIONS

Sulfonamides should be given with caution to patients with impaired renal or hepatic function and to those with severe allergy or bronchial asthma.

In glucose-6-phosphate dehydrogenase deficient individuals, hemolysis may occur. This reaction is frequently dose-related.

Adequate fluid intake must be maintained in order to prevent crystalluria and stone formation.

ADVERSE REACTIONS

Blood dyscrasias. Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia, methemoglobinemia.

Allergic reactions. Erythema multiforme (Stevens-Johnson Syndrome), generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritis, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia, and allergic myocarditis.

Gastrointestinal reactions. Nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis, and stomatitis.

C.N.S. reactions. Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo, and insomnia.

Miscellaneous reactions. Drug fever, chills, and toxic nephrosis with oliguria and anuria. Periarteritis nodosum and L. E. phenomenon have occurred.

The sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides), and oral hypoglycemic agents. Goiter production, diuresis, and hypoglycemia have occurred rarely in patients receiving sulfonamides. Cross-sensitivity may exist with these agents.

DOSAGE AND ADMINISTRATION

Systemic Sulfonamides are Contraindicated in infants under 2 months of age, except in treatment of congenital toxoplasmosis as adjunctive therapy with pyrimethamine.

A. *Sulfamethoxypyridazine.—Usual dose.* Adults: 1 gm. the first day, then 0.5 gm. daily.

Children: 30 mg./kg. the first day, then 15 mg./kg. daily.

B. *Sulfadimethoxine.—Usual dose.* Adults: 2 gm. the first day, then 1 gm. daily.

Children: 60 mg./kg. the first day, then 30 mg./kg. daily.

Therapy should continue until the patient is asymptomatic for 48 to 72 hours. Adequate fluid intake must be maintained during and for at least 24 to 48 hours after treatment.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study" published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273), as follows:

a. For holders of "deemed approved" new drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for updating information, and adequate data to show the biologic availability of the drug in the formulation which is marketed as described in paragraph (a)(1)(i), (ii), and (iii) of the notice of July 14, 1970. For preparations claiming sustained action, timed release or other delayed or prolonged effect, such data should show that the drug is available at a rate of release which will be safe and effective.

b. For any person who does not hold an approved or effective new drug application, the submission of abbreviated new drug application, to include adequate data assure the biologic availability of the drug in the formulation

which is or is intended to be marketed, as described in paragraph (a)(3)(ii) of that notice. For preparations claiming sustained action, timed release or other delayed or prolonged effect, such data should show that the drug is available at a rate of release which will be safe and effective.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

d. For indications for which the drug has been classified as probably effective (included in the "Indications" section above) and possibly effective (not included in the indications section), continued use as described in paragraphs (c), (d), (e), and (f) of that notice.

D. *Opportunity for a hearing.* 1. The Commissioner of Food and Drugs proposes to issue an order under the provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act withdrawing approval of all new-drug applications and all amendments and supplements thereto providing for the indications for which substantial evidence of effectiveness is lacking as described in paragraph A.4 of this announcement. An order withdrawing approval of the applications will not issue if such applications are supplemented, in accord with this notice, to delete such indications. Promulgation of the proposed order would cause any drug for human use offered for the indications for which substantial evidence of effectiveness is lacking, to be a new drug for which an approved new-drug application is not in effect. Any such drug then on the market would be subject to regulatory proceedings.

2. In accordance with the provisions of section 505 of the Act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Part 130), the Commissioner will give the holders of any such applications, and any interested person who would be adversely affected by such an order, an opportunity for a hearing to show why such indications should not be deleted from labeling. A request for a hearing must be filed within 30 days after the date of publication of this notice in the FEDERAL REGISTER. A request for a hearing may not rest upon mere allegations or denials but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing, together with a well-organized and full-factual analysis of the clinical and other investigational data the objector is prepared to prove in a hearing. Any data submitted in response to this notice must be previously unsubmitted and include data from adequate and well-controlled clinical investigations (identified for ready review) as described in § 130.12(a)(5) of the regulations published in the FEDERAL REGISTER of May 8, 1970 (35 F.R. 7250). Carefully conducted and documented clinical studies obtained under uncontrolled or partially controlled situations are not acceptable as a sole basis for approval of claims of effectiveness, but such studies may be considered on their merits for corroborative support of efficacy and evidence of safety. If a hearing is requested and is justified by the response to this notice, the issues will be defined, a hearing examiner will be named, and he shall issue a written notice of the time and place at which the hearing will commence.

Representatives of the Administration are willing to meet with any interested person who desires to have a conference concerning proposed changes in the labeling set forth herein. Requests for such meetings should be made to the Office of Scientific Evaluation (BD-100), at the address given below, within 30 days after the publication of this notice in the FEDERAL REGISTER.

A copy of the Academy's report has been furnished to each firm referred to above. Any other interested person may obtain a copy by request to the appropriate office named below.

Communications forwarded in response to this announcement should be identified with the reference number DESI 10849, directed to the attention of the appropriate office listed below, and addressed (unless otherwise specified) to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.

Original abbreviated new drug applications (identify as such): Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

Request for Hearing (identify with Docket number): Hearing Clerk, Office of General Counsel (GC-1), Room 6-62, Parklawn.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: August 16, 1971.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.71-13143 Filed 9-7-71;8:51 am]

[DESI 7871]

CERTAIN OTC TOPICAL ANTIHISTAMINES

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following drugs for topical use:

1. Benadryl Cream containing diphenhydramine hydrochloride; Parke, Davis & Co., Joseph Campau at the River, Detroit, Mich. 48232. (NDA 5-845).

2. Ziradryl Lotion containing diphenhydramine hydrochloride, zirconium carbonate and camphor; Parke, Davis & Co. (NDA 5-845).

3. Ziradryl Cream containing diphenhydramine hydrochloride and zirconium carbonate; Parke, Davis & Co. (NDA 5-845).

4. Caladryl Cream containing diphenhydramine hydrochloride and calamine; Parke, Davis & Co. (NDA 5-845).

5. Caladryl Lotion containing diphenhydramine hydrochloride, calamine, and camphor; Parke, Davis & Co. (NDA 5-845).

6. Pyribenzamine Cream and Ointment containing tripelennamine hydrochloride; Ciba Pharmaceutical Co., 556 Morris Avenue, Summit, N.J. 07901 (NDA 5-914).

7. Thephorin Ointment and Lotion containing phenindamine tartrate; Roche Laboratories, Division of Hoffmann-LaRoche, Inc., 340 Kingsland Avenue, Nutley, N.J. 07110 (NDA 6-303).

8. Perazil Cream containing chlorcyclizine hydrochloride; Burroughs Wellcome & Co., Inc., 3030 Cornwallis Road, Research Triangle Park, N.C. 27709 (NDA 7-871).

9. Bristamin Lotion containing phenyltoloxamine dihydrogen citrate; Bristol Laboratories, Inc., Division Bristol-Myers Co., Thompson Road, Syracuse, N.Y. (NDA 8-084).

10. Pyribenzamine Cream with zirconium containing tripelennamine hydrochloride and zirconium oxide; Ciba Pharmaceutical Co. (NDA 8-418).

11. Prantal Cream containing diphemanil methylsulfate; Schering Corp., 1011 Morris Avenue, Union, N.J. 07083 (NDA 8-961).

12. Dermaval Cream containing calamine, zinc oxide, camphor, phenol, menthol, and pyrilamine maleate; The Vale Chemical Co., Inc., 1201 Liberty Street, Allentown, Pa. 18102 (NDA 8-981).

13. Histacalma Cream containing zinc oxide, methapyrilene hydrochloride, benzocaine, and camphor: Rexall Drug Co., Rexall Square, Beverly at La Cienega, Los Angeles, Calif. 90054 (NDA 9-075).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). The effectiveness classification and marketing status are described below.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that:

1. There is a lack of substantial evidence that these drugs are effective for prophylaxis against dermatitis due to poison ivy, poison oak, poison sumac, and other plants of the Rhus genus.

2. These drugs are possibly effective for other labeled indications for dermatologic use.

B. *Marketing status.* 1. Within 60 days of the date of publication of this announcement in the FEDERAL REGISTER, the holder of any approved new-drug application for a drug which is classified in paragraph A above as lacking substantial evidence of effectiveness is requested to submit a supplement to his application, as needed, to provide for revised labeling which deletes those indications for which substantial evidence of effectiveness is lacking. Such a supplement should be submitted under the provisions of § 130.9 (d) and (e) of the new drug

regulations (21 CFR 130.9 (d) and (e)) which permit certain changes to be put into effect at the earliest possible time, and the revised labeling should be put into use within the 60-day period. Failure to do so may result in a proposal to withdraw approval of the new-drug application.

2. If any such preparation is on the market without an approved new-drug application, its labeling should be revised if it includes those claims for which substantial evidence of effectiveness is lacking as described in paragraph A above. Failure to delete such indications and put the revised labeling into use within 60 days after the date of publication hereof in the FEDERAL REGISTER may cause the drug to be subject to regulatory proceedings.

3. The notice "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER, July 14, 1970 (35 F.R. 11273), describes in paragraphs (d), (e), and (f) the marketing status of a drug labeled with those indications for which it is regarded as possibly effective.

A copy of the Academy's report has been furnished to each firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 7871, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.
Original new-drug applications: Office of Scientific Evaluation (BD-100), Bureau of Drugs.
Request for the Academy's report: Drug Efficacy Study Information Control (D-67), Bureau of Drugs.
All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: August 18, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-13142 Filed 9-7-71;8:51 am]

[DESI 6615]

DEODORANT/ANTIPERSPIRANT

Drugs for Human Use; Drug Efficacy Study Implementation

The Food and Drug Administration has evaluated reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group, on the following antiperspirant/deodorant drugs for topical use:

1. Ice-Blue Secret Cream Deodorant and Antiperspirant containing zirconium oxychloride, aluminum chlorhydroxide, and hexachlorophene; Procter and Gamble, Winton Hill Technical Center, 6000 Center Hill Road, Cincinnati, Ohio 45224 (NDA 12-984).

2. Ice-Blue Secret Roll-On Deodorant and Antiperspirant containing, zirconium oxychloride, aluminum chlorhydroxide, and hexachlorophene; Procter and Gamble (NDA 12-983).

3. Old Spice Spray Deodorant containing dibromsalan and aluminum chlorhydroxide; Shulton, Inc., 697 Route 46, Clifton, New Jersey 07015 (NDA 12-760).

4. Veto Cream Deodorant containing aluminum sulfamate; Colgate-Palmolive Co., 300 Park Avenue, New York, New York 10022 (NDA 6-615).

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new-drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new-drug application is required from any person marketing such drug without approval.

A. *Effectiveness classification.* The Food and Drug Administration has considered the Academy's reports, as well as other available evidence, and concludes that preparations containing zirconium oxychloride, aluminum chlorhydroxide, and hexachlorophene; dibromsalan and aluminum chlorhydroxide; or aluminum sulfamate are effective as deodorant/antiperspirants.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new-drug applications and abbreviated supplements to previously approved new-drug applications under conditions described herein.

1. *Form of drug.* These preparations are in a form suitable for topical application.

2. *Labeling conditions.* a. The drug is labeled to comply with all requirements of the Act and regulations promulgated thereunder, and its labeling bears adequate directions and warnings under which a layman can use the drug safely and for the purpose for which it is intended.

b. The statement of identity, which includes the general pharmacological category or the principal intended action, required by § 1.102a (21 CFR 1.102a), appears in bold face type on the principal display panel.

c. The indications for use are: "Antiperspirant and deodorant" or "As an aid in the reduction of underarm odors and sweating."

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled "Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study," published in the FEDERAL REGISTER July 14, 1970 (35 F.R. 11273), as follows:

a. For holders of "deemed approved" new drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1962), the submission of a supplement for revised labeling and an abbreviated supplement for updating information as described in paragraph (a)(1)(i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new drug application, the submission of an abbreviated new drug application as described in paragraph (a)(3)(i) of that notice.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

A copy of the Academy's report has been furnished to each firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 6615, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20852:

Supplements (identify with NDA number): Office of Scientific Evaluation (BD-100), Bureau of Drugs.
Original abbreviated new drug applications (identify as such): Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.
Requests for the Academy's report: Drug Efficacy Study Information Control (BD-67), Bureau of Drugs.
All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

This notice is issued pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: August 18, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-13140 Filed 9-7-71;8:51 am]

[DESI 7322]

TETRACYCLINE AND CERTAIN OTHER DRUGS FOR SYSTEMIC USE

Drugs for Human Use; Drug Efficacy Study Implementation

In a notice (DESI 7322) published in the FEDERAL REGISTER of September 2, 1970 (35 F.R. 13897) and amended on April 20, 1971 (36 F.R. 7473), the Commissioner of Food and Drugs announced his conclusions pursuant to evaluation of reports received from the National Academy of Sciences-National Research Council, Drug Efficacy Study Group on the following antiinfective drugs for oral and parenteral use:

I. Tetracycline for oral administation: marketed as:

1.a Tetrex Pediatric Drops (NDA 60-049),

b. Tetrex Syrup (NDA 60-049),

c. Bristacycline Capsules (NDA 60-211),

d. Tetracycline Phosphate Complex Capsules (NDA 50–212),
e. Tetrex Capsules (NDA 50–212), and
f. Polycycline for Suspension (NDA 60–032); Bristol Laboratories, Post Office Box 657, Syracuse, N.Y. 13201.
2.a. Tetramed Capsules (NDA 60–103),
b. Tetramed Syrup (NDA 60–117),
c. Tetracycline Hydrochloride Tablets (NDA 60–118),
d. Tetracycline Hydrochloride Capsules (NDA 60–103), and
e. Tetracycline Capsules (NDA 60–103); Continental Vitamin Corp., 150 South Dean Street, Englewood, N.J. 07631.
3. Tetracycline Hydrochloride Capsules; Davis-Edwards Pharmacal Corp., 432 Austin Place, Bronx, N.Y. 10455 (NDA 60–351).
4.a. Tetracycline Hydrochloride Tablets (NDA 90–048),
b. Tetracycline Syrup (NDA 60–275), and
c. Tetracycline Hydrochloride Capsules (NDA 60–059); Ketchum Laboratories, Inc., 800 Hinsdale Road, Brooklyn, N.Y. 11207.
5.a. Achromycin V Pediatric Drops (NDA 50–263),
b. Achromycin for Oral Suspension (NDA 50–269),
c. Achromycin Syrup (NDA 50–263),
d. Tetracycline Hydrochloride Capsules; Davis-Edwards Pharmacal Corp.,
e. Achromycin Soluble Tablets (NDA 50–264),
f. Achromycin (Film Coated) Tablets (NDA 50–264),
g. Achromycin V Syrup (NDA 50–263),
h. Achromycin Pediatric Drops (NDA 50–263),
i. Achromycin V Capsules (NDA 60–432),
j. Achromycin V Capsules with Sodium Metaphosphate (NDA 50–278), and
k. Achromycin Spersoids Dispersible Powder (NDA 50–271); Lederle Laboratories Division, American Cyanamid Co., Pearl River, N.Y. 10965.
6. a. Tetracyn (Film Coated) Tablets (NDA 60–077),
b. Tetracycline Hydrochloride Capsules (NDA 60–082),
c. Tetracyn Capsules (NDA 60–082),
d. Tetracyn Syrup (NDA 60–095),
e. Tetracycline Syrup (NDA 60–095), and,
f. Tetracyn Pediatric Drops (NDA 60–095); Chas. Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017.
7. a. Tetracycline Hydrochloride Tablets (NDA 60–422),
b. Premocycline Syrup (NDA 60–423), and
c. Premocycline Aqueous Pediatric Drops (NDA 60–423); Premo Pharmaceutical Laboratories, Inc., 111 Leuning Street, South Hackensack, N.J. 07606.
8. a. Tetrachel Pediatric Drops and Tetracycline Pediatric Drops (NDA 60–432).
b. Tetrachel Syrup and Tetracycline Syrup (NDA 60–342),
c. Tetrachel Capsules and Tetracycline Hydrochloride Capsules (NDA 60–343), and
d. Tetrachel (Film Coated) Tablets (NDA 60–344): Rachelle Laboratories, Inc., 700 Henry Ford Avenue, Long Beach, Calif. 90810.
9. a. Tetracycline Hydrochloride Capsules (NDA 90–290), and
b. Tetracycline Syrup (NDA 60–291); Rondex Laboratories, Inc., 68 69th Street, Guttenberg, N.J. 07093.
10. a. Tetracycline Hydrochloride Film-coated Tablets (NDA 60–048),
b. Tetracycline Hydrochloride Tablets (NDA 60–048),
c. Tetracycline Hydrochloride Capsules (NDA 60–057), and
d. Tetracycline Phosphate Complex Capsules (NDA 90–481); Societa Prodotti Antibiotici, Milan, Via Biella 8, Italy.
11. a. Steclin Capsules,
b. Sumycin Capsules,
c. Sumycin Aqueous Drops, and
d. Sumycin Syrup; E. R. Squibb and Sons, Inc., Georges Road, New Brunswick, N.J. 08903 (NDA 60–429).
12. a. Panmycin Capsules (NDA 60–347),
b. Panmycin KM Syrup (NDA 60–278),
c. Panmycin Syrup (NDA 60–278),
d. Panmycin Phosphate Capsules (NDA 60–428), and
e. Panmycin Aqua Drops (NDA 60–278): The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002.

II. Tetracycline for intramuscular use, marketed as:
1. a. Tetrex Powder for Intramuscular Injection (NDA 50–215),
b. Polycycline Powder for Intramuscular Injection (NDA 60–044); Bristol Laboratories.
2. Achromycin Powder for Intramuscular Injection (NDA 50–276); Lederle Laboratories.
3. Tetracyn Powder for Intramuscular Injection (NDA 60–285); Chas. Pfizer & Co.
4. Tetrachel Powder for Intramuscular Injection (NDA 60–346); Rachelle Laboratories.
5.a. Steclin Powder for Intramuscular Injection, and
b. Sumycin Powder for Intramuscular Injection; E. R. Squibb & Sons, Inc. (NDA 60–396).
6. Panmycin Powder for Aqueous Injection (NDA 60–333); The Upjohn Co.

III. Tetracycline for intravenous use, marketed as:
1. Bristacycline Sterile Powder for Injection (NDA 60–024); Bristol Laboratories.
2. Achromycin Powder for Intravenous Injection (NDA 50–273); Lederle Laboratories.
3. Tetracyn Powder for Intravenous Injection (NDA 60–096); Chas. Pfizer & Co.
4. Tetrachel Powder for Intravenous Injection (NDA 60–345); Rachelle Laboratories.
5. Steclin Powder for Intravenous Injection (NDA 60–396); E. R. Squibb & Sons, Inc.
6. Panmycin Powder for Intravenous Injection (NDA 60–279); The Upjohn Co.

IV. Oxytetracycline for Oral Administration, marketed as:
1.a. Terramycin Capsules (NDA 7–322),
b. Terramycin Soluble Tablets (NDA 7–966),
c. Terramycin Syrup (NDA 12–050 and 10–501),
d. Terramycin Pediatric Drops (NDA 12–074), and
e. Oxytetracycline Powder for Oral Suspension (NDA 8–257); Chas. Pfizer & Co.
2. Oxytetracycline Tablets (NDA 60–190); Zenith Laboratories, Inc., 150 South Dean Street, Englewood, N.J. 07631.

V. Oxytetracycline for intravenous administration, marketed as:
1. Terramycin Powder for Intravenous Injection; Chas. Pfizer & Co. (NDA 7–651).

VI. Oxytetracycline for intramuscular administration, marketed as:
1. Terramycin Intramuscular Solution; Chas. Pfizer & Co. (NDA 11–375).

VII. Chlortetracycline for oral administration, marketed as:
1.a. Aureomycin Capsules (NDA 50–251),
b. Aureomycin Soluble Tablets (NDA 50–250),
c. Aureomycin Oral Drops (NDA 50–249),
d. Aureomycin Syrup (NDA 50–249), and
e. Aureomycin Spersoids Dispersible Powder (NDA 50–253); Lederle Laboratories.
2. Chlortetracycline Hydrochloride Capsules (NDA 60–104; Zenith Laboratories, Inc.

VIII. Chlortetracycline for intravenous administration, marketed as:
1. Aureomycin Powder for Intravenous Injection; Lederle Laboratories (NDA 50–245).

IX. Demeclocycline for oral administration, marketed as:
1.a. Declomycin Capsules (NDA 50–262),
b. Declomycin (Film Coated) (NDA 50–261),
c. Declomycin Pediatric Drops (NDA 50–257),
d. Declomycin Syrup (NDA 50–257), and
e. Declomycin Powder for Oral Suspension (NDA 50–255); Lederle Laboratories.

X. Rolitetracycline for intravenous and intramuscular administration, marketed as:
1.a. Syntetrin Powder for Intravenous Injection (NDA 50–132), and
b. Syntetrin Powder for Intramuscular Injection (NDA 50–139); Bristol Laboratories.

The notice stated that the drugs were regarded as effective, possibly effective, and lacking substantial evidence of effectiveness for the various labeled indications. The possibly effective indications have been reclassified as lacking substantial evidence of effectiveness in that no new evidence of effectiveness of these drugs has been submitted pursuant to the notice of September 2, 1970.

Under the heading Tetracycline for Intravenous Administration, the possibly effective indication of "C. diphtheriae, as adjunctive therapy with antitoxin" was inadvertently placed in the

indications section of the labeling guidelines. This indication should be deleted from the guidelines.

Batches of such drugs with labeling bearing indications for which substantial evidence of effectiveness is lacking are no longer acceptable for certification or release.

Any person who will be adversely affected by the deletion from labeling of the indications for which the drug has been reclassified from possibly effective to lacking substantial evidence of effectiveness may, within 30 days after the date of publication of this notice in the FEDERAL REGISTER, petition for the issuance of a regulation providing for other certification of the drug for such indications. The petition must be supported by a full factual and well documented medical analysis which shows reasonable grounds for the issuance of such regulation.

A petition for issuance of said regulation should be filed (preferably in quintuplicate) with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-62, 5600 Fishers Lane, Rockville, Maryland 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 507, 52 Stat. 1050-51, as amended, 59 Stat. 463, as amended; 21 U.S.C. 352, 357) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: August 25, 1971.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.71-13141 Filed 9-7-71;8:51 am]

E. I. DU PONT DE NEMOURS AND CO.

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 2B2708) has been filed by E. I. du Pont de Nemours and Co., 1007 Market Street, Wilmington, Del. 19898, proposing that § 121.2524 *Polyethylene terephthalate film* (21 CFR 121.2524) be amended to provide for the additional safe use of polyethylene terephthalate as articles or components of articles intended for use in contact with food.

Dated: August 26, 1971.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc.71-13144 Filed 9-7-71;8:50 am]

NATIONAL MARINE FISHERIES SERVICE

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 1A2671) has been filed by National Marine Fisheries Service, U.S. Department of Commerce, Interior Building, Washington, D.C. 20235, proposing that § 121.1230 *Sodium nitrite used in processing smoked chub* (21 CFR 121.1230) be amended (1) by deleting the temperature 160° F. in subparagraph (c) and replacing it with 150° F. as the continuous temperature prescribed to be maintained throughout each fish during the heating process when sodium nitrite is used as a food additive, and (2) by extending said regulation to allow the addition of sodium nitrite under the same conditions of use in the processing of smoked whitefish.

Dated: August 26, 1971.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc.71-13145 Filed 9-7-71;8:51 am]

NOVO ENZYME CORP.

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 2A2712) has been filed by Novo Enzyme Corp., Post Office Box 189, Mamaroneck, N.Y. 10543, proposing that §121.1199 *Fermentation-derived, milk-clotting enzyme* (21 CFR 121.1199) be amended to provide for the safe use of a milk-clotting enzyme derived from *Mucor miehei*, Cooney et Emerson, in cheese production.

Dated: August 26, 1971.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc.71-13146 Filed 9-7-71;8:51 am]

STEIN, HALL & CO., INC.

Notice of Filing of Petition for Food Additive

Pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786; 21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 1J2702) has been filed by Stein, Hall & Co., Inc., 605 Third Avenue, New York, N.Y. 10016, proposing that § 121.1009 *Polysorbate 80* be amended to provide for the safe use of polysorbate 80 as a defoaming agent in the preparation of the creaming mixture for creamed cottage cheese.

Dated: August 26, 1971.

VIRGIL O. WODICKA,
Director, Bureau of Foods.

[FR Doc.71-13147 Filed 9-7-71;8:51 am]

ATOMIC ENERGY COMMISSION

[Docket No. 50-293]

BOSTON EDISON CO.

Notice of Change of Date and Location of Prehearing Conference

In the matter of Boston Edison Co. (Pilgrim Nuclear Power Station).

On July 12, 1971 the AEC issued a notice of hearing on a facility operating license in the above-entitled matter (36 F.R. 13287). The notice authorized the Atomic Safety and Licensing Board designated therein to set the date and place of a Prehearing Conference.

On August 19, this Board announced that a Prehearing Conference would be held on October 6, 1971. It has become necessary for good cause to defer the conference for one week, which in turn has necessitated a change in location.

Pursuant to the authority delegated to this Board therefore, notice is hereby given that the Prehearing Conference in the above-entitled proceeding will be held at 10 a.m. on Wednesday, October 13, 1971 in the:

Memorial Hall, 83 Court Street, Plymouth, MA 02360.

Dated this 1st day of September 1971, at Washington, D.C.

ATOMIC SAFETY AND LICENSING BOARD,
NATHANIEL H. GOODRICH,
Chairman.

[FR Doc.71-13121 Filed 9-7-71;8:45 am]

CIVIL AERONAUTICS BOARD

[Docket No. 23780; Order 71-9-3]

INTERNATIONAL STUDENT AND YOUTH FARES APPLYING TO U.S. RESIDENTS

Order of Investigation

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 1st day of September 1971.

By tariffs filed pursuant to orders from various governments, special fares are now available for students and/or youths for travel between the United States and various foreign points. These special fares apply in air transportation between the United States and numerous points in Europe, various South American countries, Mexico, the Dominican Republic, and Taiwan. The transatlantic fares are available in most instances to persons 12 years and older. The upper age limit, however, varies from 23 to 30 years. Discounts range up to 72 percent from normal economy fares. For example, these special fares between New York and London are $210 and $190 in peak and offpeak periods, respectively, and, when compared with the normal economy fares of $552 and $452 applicable in such periods, represent discounts of 62 and 58 percent. The youth fare on file with the Board for round-trip transportation between New York and Rome is $199 and is available throughout the year. This fare represents discounts of 72 and 66 percent from the peak and offpeak normal economy fares of $704 and $604, respectively. Fares between the United States and Mexico established pursuant to an order from the Mexican Government are generally a uniform $150 round trip for all passengers between the ages of 12 through 25 and represent discounts of up to 50 percent from normal fares.