14. Penicillin 100,000 (also 200,000, 250,000, and 300,000) Units with Triple Sulfonamides Tablets; marketed by Zenith Laboratories, Inc., 150 South Dean Street, Englewood, N.J. 07631.

15. Penicillin with Triple Sulfas Tablets; marketed by Supreme Pharmaceutical Co., Inc., 354 Mercer Street, Jersey City, N.J. 07302.

16. Pentid-Sulfas Tablets; marketed by E. R. Squibb & Sons, Inc., Georges Road, New Brunswick, N.J. 08903.

17. Pentid-Sulfas for Syrup and Pentid "400" Sulfas for Syrup; marketed by E. R. Squibb & Sons, Inc.

18. Penicillin-Three Sulfonamide Tablets "100" and Penicillin-Three Sulfonamide Tablets "300"; marketed by Nysco Laboratories, Inc., 34-24 Vernon Boulevard, Long Island City, N.Y. 11106.

19. Buffered Potassium Penicillin G with 3 Sulfas Powder for Syrup; marketed by Nysco Laboratories, Inc.

C. Combination drugs containing potassium penicillin G, sulfadiazine, sulfamerazine, and sulfacetamide:

1. Flavored Penicillin G Powder with Triple Sulfonamides; by Vitamix Pharmaceuticals, Inc.

2. Penicillin with Sulfonamides Powder for Solution; marketed by Biocraft Laboratories, Inc.

D. Combination drugs containing phenoxymethyl penicillin (as the base or benzathine salt), sulfadiazine, and sulfamerazine:

1. Pen-Vee Sulfas, Tablets; marketed by Wyeth Laboratories, Inc., Philadelphia, Pa. 19101.

2. Pen-Vee Sulfas, Suspension; marketed by Wyeth Laboratories, Inc.

E. Combination drugs containing phenoxymethyl penicillin (as the base or potassium or benzathine salt), sulfadiazine, sulfamerazine, and sulfamethazine:

1. Compocillin VK with Sulfas Filmtab; marketed by Abbott Laboratories, North Chicago, Ill. 60064.

2. Compocillin-VK with Sulfas Granules for Oral Suspension; marketed by Abbott Laboratories.

3. V-Cillin Sulfa Tablets; marketed by Eli Lilly & Co.

4. V-Cillin Sulfa Pediatric for Oral Suspension; marketed by Eli Lilly & Co.

5. V-Cillin K Sulfa Tablets; marketed by Eli Lilly & Co.

6. V-Cillin K Sulfa Pediatric for Oral Suspension; marketed by Eli Lilly & Co.

F. Combination drugs containing benzathine penicillin G, sulfadiazine, sulfamerazine, and sulfamethazine:

1. Bicillin-Sulfas Suspension; marketed by Wyeth Laboratories, Inc.

2. Bicillin-Sulfas Tablets; marketed by Wyeth Laboratories, Inc.

The Academy has evaluated the above-listed products and found them ineffective as fixed combinations for those indications in the labeling that were specific enough to be evaluated. The Food and Drug Administration concurs with the views expressed by the Academy and concludes that there is a lack of substantial evidence that each of the above-listed drugs will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling.

Accordingly, the Commissioner of Food and Drugs intends to initiate proceedings to amend the antibiotic drug regulations (21 CFR Parts 141a et seq.) where necessary to delete from the list of drugs acceptable for certification those that contain the above-listed penicillin-sulfonamide combinations.

Prior to initiating such action, however, the Commissioner invites all interested persons who may be adversely affected by removal of these drugs from the market to submit pertinent data bearing on the proposal within 30 days following the date of publication of this notice in the FEDERAL REGISTER. Such data should be addressed to the Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

This announcement of the proposed action and implementation of the NAS-NRC reports for these drugs is made to give notice to persons who might be adversely affected by removal of these drugs from the market.

Firms listed above have been mailed a copy of the NAS-NRC report. Any interested person may obtain a copy of the reports on these drugs by writing to the Food and Drug Administration, Press Relations Office (CE-300), 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to the 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: March 25, 1969.

HERBERT L. LEY, Jr.,
Commissioner of Food and Drugs.

[F.R. Doc. 69-3817; Filed, Apr. 1, 1969; 8:48 a.m.]

COMBINATION DRUGS CONTAINING TETRACYCLINE HYDROCHLORIDE WITH VITAMINS AND OXYTETRACYCLINE WITH VITAMINS

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 preparations:

1. Achromycin SV Capsules; contain tetracycline hydrochloride, ascorbic acid, thiamine mononitrate, niacinamide, pyridoxine hydrochloride, folic acid, calcium pantothenate, menadione, cyanocobalamin, and riboflavin; by Lederle Laboratories Division, American Cyanamid Co., Pearl River, N.Y. 10965.

2. Terramycin S.F. Capsules; contain oxytetracycline, ascorbic acid, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, calcium pantothenate, cyanocobalamin, vitamin K, and folic acid; by Chas. Pfizer & Co. (International), 235 East 42d Street, New York, N.Y. 10017.

The Academy has evaluated the above-listed products as ineffective as fixed combinations for their labeled indications. The Food and Drug Administration concludes that there is a lack of substantial evidence that each component of such combination drugs makes a contribution to the total effect the drug purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling. Accordingly, the Commissioner of Foods and Drugs intends to initiate proceedings to amend the antibiotic drug regulations (21 CFR Parts 141c, 146c) where necessary to delete from the list of drugs acceptable for certification those that contain the tetracycline hydrochloride-vitamin combination.

Prior to initiating such action, however, the Commissioner invites all interested persons who may be adversely affected by removal of this tetracycline hydrochloride-vitamin combination from the market to submit pertinent data bearing on the proposal within 30 days following the date of publication of this notice in the FEDERAL REGISTER. Such data should be addressed to the Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

This announcement of the proposed action and implementation of the NAS-NRC report for this drug is made to give notice to persons who might be adversely affected by removal of this drug from the market.

There is no monograph in the regulations under section 507 of the Federal Food, Drug, and Cosmetic Act which provides for certification of the oxytetracycline-vitamin combination. Samples of such drug will not be acceptable for certification.

The firms listed above have been mailed a copy of the NAS-NRC report. Any interested person may obtain a copy of the report on the above-named drugs by writing to the Food and Drug Administration, Press Relations Office (CE-300), 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to the 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 (21 CFR 2.120).

Dated: March 25, 1969.

HERBERT L. LEY, Jr.,
Commissioner of Food and Drugs.

[F.R. Doc. 69-3818; Filed, Apr. 1, 1969; 8:48 a.m.]

CERTAIN TETRACYCLINE-NYSTATIN, OXYTETRACYCLINE-NYSTATIN, AND DEMETHYL-CHLORTETRACYCLINE-NYSTATIN COMBINATION PREPARATIONS FOR ORAL USE

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 products:

A. Combination drugs containing tetracycline, tetracycline hydrochloride, or tetracycline phosphate complex with nystatin:

1. Mysteclin-V Capsules; E. R. Squibb & Sons, Inc., Georges Road, New Brunswick, N.J. 08903.

2. Tetrastatin for Oral Suspension; Chas. Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017.

3. Tetrastatin Capsules; Chas. Pfizer & Co., Inc.

4. Comycin Half-Strength Capsules; The Upjohn Co., 7171 Portage Road, Kalamazoo, Mich. 49002.

5. Comycin Capsules; The Upjohn Co.

6. Achrostatin V for Oral Suspension; Lederle Laboratories, Division of American Cyanamid Co., West Middletown Road, Pearl River, N.Y. 10965.

7. Achrostatin V Capsules; Lederle Laboratories, Division of American Cyanamid Co.

B. Combination drugs containing oxytetracycline and nystatin:

1. Terrastatin for Oral Suspension; Chas. Pfizer & Co., Inc.

2. Terrastatin Capsules; Chas. Pfizer & Co., Inc.

C. Combination Drugs containing demethyl chlortetracycline and nystatin:

1. Declostatin for Oral Suspension; Lederle Laboratories, Division of American Cyanamid Co.

2. Declostatin Capsules; Lederle Laboratories, Division of American Cyanamid Co.

The Academy has evaluated the above-listed drugs and found them ineffective as fixed combinations for simultaneous antimicrobial therapy and monilial prophylaxis. Adequate documented evidence that the fixed combinations are useful during therapy in preventing clinical disease due to monilial superinfection is lacking.

The Food and Drug Administration concurs with the Academy's evaluation and concludes that there is a lack of substantial evidence that each of the above-listed drugs will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling. Accordingly, the Commissioner of Food and Drugs intends to initiate proceedings to amend the antibiotic drug regulations (21 CFR Parts 141c, 146c, 148k, 148n), as necessary, to delete from the list of drugs acceptable for certification those that contain the above-listed antibiotic combinations.

Prior to initiating such action, however, the Commissioner invites all interested persons who may be adversely affected by removal of these drugs from the market to submit pertinent data bearing on the proposal within 30 days following publication of this notice in the FEDERAL REGISTER. Such data should be addressed to the Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

This announcement of the proposed action and implementation of the NAS-NRC reports for these drugs is made to give notice to persons who might be adversely affected by removal of these drugs from the market.

The firms listed above have been mailed a copy of the subject NAS-NRC reports, and any interested person may obtain a copy by writing to the Food and Drug Administration, Press Relations Office (CE-300), 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to the 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 (21 CFR 2.120).

Dated: March 25, 1969.

HERBERT L. LEY, JR.,
Commissioner of Food and Drugs.

[F.R. Doc. 69-3819; Filed, Apr. 1, 1969; 8:49 a.m.]

COMBINATION DRUGS CONTAINING TETRACYCLINE WITH OLEANDOMYCIN OR TRIACETYLOLEANDOMYCIN

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 oral preparations marketed by Chas. Pfizer & Co. (International) or by J. B. Roerig & Co., Division of Chas. Pfizer & Co., Inc., 235 East 42d Street, New York, N.Y. 10017:

1. Signemycin Syrup containing tetracycline and triacetyloleandomycin.

2. Sigmamycin Syrup containing tetracycline and triacetyloleandomycin.

3. Signemycin Pediatric Drops containing tetracycline and triacetyloleandomycin.

4. Sigmamycin Pediatric Drops containing tetracycline and triacetyloleandomycin.

5. Signemycin Capsules containing tetracycline hydrochloride and triacetyloleandomycin.

6. Sigmamycin Capsules containing tetracycline and oleandomycin phosphate.

The Academy has evaluated these products and found them ineffective as a fixed combination for all specific indications appearing in their labeling. The Food and Drug Administration concurs with the views expressed by the Academy and concludes that there is no available evidence that the clinical efficacy of the combination is greater than that of either ingredient used alone.

On the basis of the lack of substantial evidence that each ingredient in the combination drugs listed above contributes to the total effects which the drugs are purported or represented to have under the conditions of use prescribed, recommended, or suggested in their labeling, the Commissioner of Food and Drugs intends to initiate proceedings to amend the antibiotic drug regulations (21 CFR Part 141c et al.) where necessary to discontinue certification of those products that contain the above-listed antibiotic combinations.

Prior to initiating such action, however, the Commissioner invites all interested persons who may be adversely affected by the removal of these drugs from the market to submit pertinent data relative to this proposal within 30 days following the date of publication of this notice in the FEDERAL REGISTER. Such data should be addressed to the Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

The purpose of this announcement of the proposed action and implementation of the NAS-NRC reports for these drugs is to notify all persons who might be adversely affected by the removal of these drugs from the market.

The firms listed above have been mailed a copy of the NAS-NRC reports. Any interested person may obtain a copy of these reports by writing to the Food and Drug Administration, Press Relation Office (CE-300), 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to the 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 (21 CFR 2.120).

Dated: March 25, 1969.

HERBERT L. LEY, JR.,
Commissioner of Food and Drugs.

[F.R. Doc. 69-3820; Filed, Apr. 1, 1969; 8:48 a.m.]

CERTAIN TETRACYCLINE-SULFONAMIDE COMBINATION PREPARATIONS (WITH AND WITHOUT ANALGESIC) FOR ORAL USE

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 products of Bristol Laboratories, Inc., Post Office Box 657, Syracuse, N.Y. 13201:

1. Tetrex Syrup with Triple Sulfonamides; contains tetracycline, sulfadiazine, sulfamerazine, and sulfamethazine.

2. Azotrex Syrup; contains tetracycline and sulfamethizole.

3. Polycycline Suspension with Triple Sulfonamides; contains calcium tetracycline, sulfadiazine, sulfamerazine, and sulfamethazine.

4. Azotrex Capsules; contains tetracycline phosphate complex, sulfamethizole, and phenazopyridine hydrochloride.

The Academy concludes that the above-listed products are ineffective or

ineffective as a fixed combination for labeled indications and that adequate clinical documentation of efficacy is lacking.

The Food and Drug Administration concurs with the Academy's evaluation and concludes that there is a lack of substantial evidence that each of the drugs listed above will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its labeling. Accordingly, the Commissioner of Food and Drugs intends to initiate proceedings to amend the antibiotic drug regulations (21 CFR Parts 141c, 146c) where necessary to delete from the list of drugs acceptable for certification those that contain the above-listed antibiotic combinations.

Prior to initiating such action, however, the Commissioner invites all interested persons who may be adversely affected by removal of these drugs from the market to submit pertinent data bearing on the proposal within 30 days following date of publication of this notice in the FEDERAL REGISTER. Such data should be addressed to the Special Assistant for Drug Efficacy Study Implementation (MD-16), Bureau of Medicine, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

This announcement of the proposed action and implementation of the NAS-NRC reports for these drugs is made to give notice to persons who might be adversely affected by removal of these drugs from the market.

The firm listed above has been mailed a copy of the reports. Any interested person may also obtain a copy by writing to the Food and Drug Administration, Press Relations Office (CE-300), 200 C Street SW., Washington, D.C. 20204.

This notice is issued pursuant to the 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 (21 CFR 2.120).

Dated: March 25, 1969.

HERBERT L. LEY, Jr.,
Commissioner of Food and Drugs.

[F.R. Doc. 69-3821; Filed, Apr. 1, 1969; 8:49 a.m.]

ATOMIC ENERGY COMMISSION

[Docket Nos. 50-315, 50-316]

INDIANA & MICHIGAN ELECTRIC CO.

Notice of Issuance of Provisional Construction Permits

Notice is hereby given that, pursuant to the initial decision of the Atomic Safety and Licensing Board, dated March 21, 1969, the Director of the Division of Reactor Licensing has issued Provisional Construction Permits Nos. CPPR-60 and CPPR-61 to the Indiana & Michigan Electric Co. for the construction of two pressurized water nuclear reactors, designated as Donald C. Cook Nuclear Plant Units 1 and 2, on the applicants site on the eastern shore of Lake Michigan in Lake Township, Berrien County, Mich., about 11 miles south-southwest of Benton Harbor, Mich. The reactors are each designed for initial operation at approximately 3,250 megawatts (thermal).

A copy of the initial decision is on file in the Commission's Public Document Room, 1717 H Street NW., Washington, D.C.

Dated at Bethesda, Md., this 25th day of March 1969.

For the Atomic Energy Commission.

F. SCHROEDER,
Acting Director,
Division of Reactor Licensing.

[F.R. Doc. 69-3778; Filed, Apr. 1, 1969; 8:45 a.m.]

[Docket No. 50-294]

MICHIGAN STATE UNIVERSITY

Notice of Issuance of Facility License

No request for a hearing having been filed following publication of the notice of proposed action in the FEDERAL REGISTER, the Atomic Energy Commission has issued, effective as of the date of issuance, Facility License No. R-114 to Michigan State University ("MSU"). The license authorizes MSU to operate a TRIGA Mark I nuclear reactor on its campus in East Lansing, Mich.

The facility license was issued in the form published in the Notice of Proposed Issuance of Facility License in the FEDERAL REGISTER on February 18, 1969, 34 F.R. 2334. The Technical Specifications issued with the license contain an additional reporting requirement that was not in the proposed Technical Specifications.

Dated at Bethesda, Md., this 21st day of March 1969.

For the Atomic Energy Commission.

DONALD J. SKOVHOLT,
Assistant Director for Reactor Operations, Division of Reactor Licensing.

[F.R. Doc. 69-3884; Filed, Apr. 1, 1969; 8:50 a.m.]

[Docket No. 50-124]

VIRGINIA POLYTECHNIC INSTITUTE

Notice of Issuance of Amended Facility License

The Atomic Energy Commission ("the Commission") has issued, effective as of the date of issuance, Amendment No. 2, as set forth below, to Facility License No. R-62. The license authorizes the Virginia Polytechnic Institute to possess and operate the Argonaut-type nuclear research reactor facility located on its campus in Blacksburg, Va. The amendment, which revises the license in its entirety, incorporates revised Technical Specifications for operation of the facility and extends to November 16, 1979, the expiration date of the license in accordance with applications for license amendment dated February 18, and March 11, 1969, respectively. The amended license more precisely sets forth the reporting requirements and expands the record keeping section to include records on maintenance operations, and tests and measurements performed.

Within fifteen (15) days from the date of publication of this notice in the FEDERAL REGISTER, the applicant may file a request for a hearing, and any person whose interest may be affected by the issuance of this amended license may file a petition for leave to intervene. Requests for a hearing and petitions to intervene shall be filed in accordance with the provisions of the Commission's rules of practice, 10 CFR Part 2. If a request for a hearing or a petition for leave to intervene is filed within the time prescribed in this notice, the Commission will issue a notice of hearing or an appropriate order.

For further details with respect to this amendment, see (1) the licensee's applications for license amendment dated February 18, and March 11, 1969, (2) a related Safety Evaluation prepared by the Division of Reactor Licensing, and (3) the Technical Specifications, all of which are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. A copy of item (2) above may be obtained at the Commission's Public Document Room or upon request addressed to the U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Director, Division of Reactor Licensing.

Dated at Bethesda, Md., this 20th day of March 1969.

For the Atomic Energy Commission.

DONALD J. SKOVHOLT,
Assistant Director for Reactor Operations, Division of Reactor Licensing.

[License R-62; Amdt. 2]

1. The Atomic Energy Commission ("the Commission") has found that:

A. The applications for license, as amended, dated February 18, 1969, and March 11, 1969, comply with the requirements of the Atomic Energy Act of 1954, as amended (hereinafter, "the Act"), and the Commission's regulations set forth in Title 10, CFR, Chapter 1;

B. There is reasonable assurance that (i) the activities authorized by the license, as amended, can be conducted at the designated location without endangering the health and safety of the public, and (ii) such activities will be conducted in compliance with the application and rules and regulations of the Commission;

C. The Institute is technically and financially qualified to engage in the activities authorized by this license, as amended, in accordance with the Commission's regulations;

D. The Institute is a nonprofit educational institution and will operate the reactor for the conduct of educational activities, and is therefore exempt from the financial protection requirement of subsection 170a of the Act. The licensee has executed an indemnity agreement pursuant to 10 CFR Part 140;