

May 24, 1968

3,4-dichlorobenzyl methylcarbamate and 20 percent of 2,3-dichlorobenzyl methylcarbamate in or on garlic at 0.15 part per million and in or on potatoes and the succulent form, dry form, and hay of beans, peanuts, peas, and soybeans at 0.1 part per million were established at the request of the Union Carbide Corp., Post Office Box 8361, South Charleston, W. Va. 25303. These temporary tolerances expired October 14, 1967, and the company has requested an extension of these temporary tolerances to permit additional tests in accordance with the temporary permit issued by the U.S. Department of Agriculture.

The Commissioner of Food and Drugs has determined that extension of these temporary tolerances will protect the public health; therefore, an extension has been granted that will expire May 15, 1969.

This action is taken pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (sec. 408(j), 68 Stat. 516; 21 U.S.C. 346a (j)) and delegated by him to the Commissioner (21 CFR 2.120).

Dated: May 15, 1968.

J. K. KIRK,
Associate Commissioner
for Compliance.

[F.R. Doc. 68-6208; Filed, May 23, 1968;
8:47 a.m.]

DRUGS FOR HUMAN USE

Drug Efficacy Study Implementation Announcement Regarding Lututrin

The Food and Drug Administration has reviewed and evaluated a report received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on the following preparations:

1. Lutrexin tablets; 3,000 units of lututrin per tablet; manufactured by Hynson, Westcott & Dunning, Inc., Baltimore, Md. 21201.

2. Treximest tablets; 500 units of lututrin and 1.0 milligram of sodium estrone sulfate per tablet; manufactured by Hynson, Westcott & Dunning, Inc., Baltimore, Md. 21201.

The Academy report states that lututrin may possibly be effective; however, the Academy also states the claims made for the drug—treatment of functional dysmenorrhea, selected cases of premature labor, and threatened and habitual abortion—are inappropriate or unwarranted in the absence of sound documentation.

The Food and Drug Administration also concludes that the claims for lututrin are inappropriate and unwarranted in the absence of sound documentation. The holder of the new-drug applications for the drugs listed above is provided 60 days from the date of publication of this announcement in the FEDERAL REGISTER to submit adequate documentation, not previously submitted, in support of the representations made for the product.

The holder of the new-drug applications for these drugs has been mailed a

copy of the NAS-NRC report. Any other manufacturer, packer, or distributor of such drug or any other interested person may obtain a copy of the NAS-NRC report on lututrin by writing to the Food and Drug Administration, Press Relations Office, 200 "C" Street SW., Washington, D.C. 20204.

The Commissioner of Food and Drugs invites the holders of the new-drug applications for lututrin as well as any interested person and all persons who may be adversely affected by this announcement to meet informally with officials of the Administration to discuss any medical matters relating to the conclusions regarding this drug.

Persons desiring to attend such meeting should notify the Special Assistant for Drug Efficacy Study Implementation, Bureau of Medicine, Food and Drug Administration, 200 "C" Street SW., Washington, D.C. 20204, and suitable arrangements will be made.

Any written comments on this announcement may be addressed to the Special Assistant for Drug Efficacy Study Implementation at the address given above. Comments regarding medical matters and conclusions to be discussed at the meeting should be received no later than 20 days before any meeting is held.

This notice is issued pursuant to the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 701(a), 52 Stat. 1050-53, as amended, 1055; 21 U.S.C. 352, 355, 371(a)) and delegated to the Commissioner (21 CFR 2.120).

Dated: May 17, 1968.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 68-6213; Filed, May 23, 1968;
8:48 a.m.]

ATOMIC ENERGY COMMISSION

[Docket No. 50-301]

**WISCONSIN ELECTRIC POWER CO.
AND WISCONSIN MICHIGAN
POWER CO.**

**Notice of Hearing on Application for
Provisional Construction Permit**

In the matter of Wisconsin Electric Power Co. and Wisconsin Michigan Power Co. (Point Beach Nuclear Plant Unit No. 2), Docket No. 50-301.

Pursuant to the Atomic Energy Act of 1954, as amended (the Act) and the regulations in Title 10, Code of Federal Regulations, Part 50, "Licensing of Production and Utilization Facilities," and Part 2, rules of practice, notice is hereby given that a hearing will be held at 10 a.m., local time, on June 25, 1968, in the City Council Chambers, Manitowoc, Wis., to consider the application filed under section 104b of the Act by Wisconsin Electric Power Co. and Wisconsin Michigan Power Co. (the applicants) for a provisional construction permit for a pressurized water reactor designed to initially operate at 1,396 megawatts

(thermal) to be located at the applicants' site in the town of Two Creeks, Manitowoc County, Wis.

The hearing will be conducted by the Atomic Safety and Licensing Board designated by the Atomic Energy Commission consisting of Dr. John C. Geyer, Baltimore, Md.; Mr. Reuel C. Stratton, Hartford, Conn.; and J. D. Bond, Esq., Chairman, Washington, D.C., Dr. Milton C. Edlund, Ann Harbor, Mich., has been designated as a technically qualified alternate.

A prehearing conference will be held by the Board at 9:30 a.m., local time, on June 11, 1968, in Federal Office Building No. 7, Room No. 5102, 17th and H Streets NW., Washington, D.C. 20506 (entrance on 17th Street) to consider the matters provided for consideration by § 2.752 of 10 CFR Part 2 and section II of Appendix A to 10 CFR Part 2.

The Director of Regulation proposes to make affirmative findings on Item Nos. 1-3 and a negative finding on Item 4 specified below as the basis for the issuance of a provisional construction permit to the applicants substantially in the form proposed in Appendix A hereto.

1. Whether in accordance with the provisions of 10 CFR 50.35(a):

(a) The applicants have described the proposed design of the facility, including, but not limited to, the principal architectural and engineering criteria for the design, and have identified the major features or components incorporated therein for the protection of the health and safety of the public;

(b) Such further technical or design information as may be required to complete the safety analysis and which can reasonably be left for later consideration, will be supplied in the final safety analysis report;

(c) Safety features or components, if any, which require research and development have been described by the applicants and the applicants have identified, and there will be conducted, a research and development program reasonably designed to resolve any safety questions associated with such features or components; and

(d) On the basis of the foregoing, there is reasonable assurance that (i) such safety questions will be satisfactorily resolved at or before the latest date stated in the application for completion of construction of the proposed facility, and (ii) taking into consideration the site criteria contained in 10 CFR Part 100, the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety of the public;

2. Whether the applicants are technically qualified to design and construct the proposed facility;

3. Whether the applicants are financially qualified to design and construct the proposed facility; and

4. Whether the issuance of a permit for the construction of the facility will be inimical to the common defense and security or to the health and safety of the public.

In the event that this proceeding is not a contested proceeding, as defined by