



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

DEC 4 1979

MEMORANDUM FOR: Joseph M. Felton, Director
Division of Rules and Records

FROM: Robert G. Ryan, Director
Office of State Programs

SUBJECT: PROPOSED FEDERAL REGISTER NOTICE

Enclosed is a proposed Federal Register Notice. By this notice the U.S. Nuclear Regulatory Commission notes for the record that the Food and Drug Administration (FDA) has approved a New Drug Application (NDA) for the Carter-Wallace firm for producing potassium iodide (KI) as a thyroid blocking agent for use in a radiological accident. When published we intend to distribute copies of the notice to all appropriate public agencies for any action they deem necessary. Federal policy and guidance on the use of KI in a radiological emergency has not yet been developed and published by HHS (HEW). For your information, this draft of the notice was cleared with Edward Nida, FDA Public Information Specialist. Mr. Nida also stated that he cleared the draft with Dr. Jerome A. Halperin, Deputy Director, Bureau of Drugs, FDA. Mr. Nida may be reached at 301/443-3285.

A handwritten signature in black ink, appearing to read "Robert G. Ryan".

Robert G. Ryan, Director
Office of State Programs

Enclosure:
As stated.

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FDA APPROVES NDA FOR CARTER - WALLACE, INC.

FOR KI AS THYROID BLOCKING AGENT FOR USE IN A RADIOLOGICAL EMERGENCY

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Drug Availability Announcement

SUMMARY: The Food and Drug Administration (FDA) has approved a New Drug Application (NDA) for Carter-Wallace of Cranberry, New Jersey for potassium iodide (KI) as a thyroid blocking agent for use in a radiological emergency. The drug will be manufactured in both tablet and solution form. The use of this drug for this purpose was the subject of a study by the National Council on Radiation Protection and Measurement (NCRP); and a report (No. 55) by the NCRP published in August 1, 1977 entitled "Protection of the Thyroid Gland in the Event of Release of Radioiodine." The report recommended the consideration of the drug for the stated purpose. Federal policy and guidance concerning the circumstances under which this drug would be used have not yet been published.

An invitation to drug manufacturers to submit a NDA to provide and market KI to support a radiological emergency preparedness program for possible accidents at a fixed nuclear facility was published in the Federal Register in Volume 43, No. 242, p. 58798 and dated Friday, December 15, 1978.

To obtain information on the form and availability of potassium iodide for the purpose of thyroid blocking in a radiation emergency, contact Carter-Wallace, Inc., Cranberry, New Jersey, 609/655-6000. This number can be used for all emergencies in the day or night. An additional "backup" emergency number is 609/799-1167. The name of the drug is "Thyro-Block."

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EFFECTIVE DATE: Immediately

FOR FURTHER INFORMATION
CONTACT:

Carter-Wallace, Inc., Cranberry, New Jersey
(Phone: 609/655-6000 or 609/799-1167).

Dated at Washington, D.C. this _____ day of _____ 1979.

FOR THE NUCLEAR REGULATORY COMMISSION

Samuel J. Chilk
Secretary of the Commission

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