

Memorandum in Response to Canadian Government Submissions Re: Environmental Impact of the Tanker System Related to the Trans-Alaska Pipeline, Alyeska Pipeline Service Co., October 1971.

Marine Transportation Systems of the Trans-Alaska Pipeline System, U.S. Coast Guard, February 1972.

These documents have been and will continue to be available for public examination in the Department of the Interior Library, 18th and C Streets NW., Washington, DC. In addition, the first three items listed above have been and will continue to be available for public inspection at the Office of the State Director, Bureau of Land Management, Anchorage, Alaska, and at the Office of the District Manager, Bureau of Land Management, Fairbanks, Alaska.

The environmental impact statement and the related economic and security analysis have been prepared to provide information to the Secretary of the Interior and other Federal officers regarding the decisions on applications for permits to construct, operate, and maintain the proposed trans-Alaska pipeline.

No action will be taken on these applications before May 4, 1972.

ROGERS C. B. MORTON,
Secretary of the Interior.

MARCH 20, 1972.

[FR Doc.72-4449 Filed 3-21-72;8:50 am]

DEPARTMENT OF COMMERCE

National Bureau of Standards VOLUNTARY PRODUCT STANDARDS

Notice of Action on Proposed Withdrawal

In accordance with the provisions of § 10.12 of the Department's published "Procedures for the Development of Voluntary Product Standards" (15 CFR Part 10, as amended; 35 F.R. 8349, dated May 28, 1970), notice is hereby given of the withdrawal of nine standards identified below. Each of these standards, Commercial Standard (CS) and Simplified Practice Recommendation (R), has been found to be obsolete, no longer technically adequate, no longer acceptable to and used by the industry, or otherwise not in the public interest.

- CS 116-54 Homogenous-wall, bituminized-fiber drain, and sewer pipe.
- CS 226-59 Laminated-wall, bituminized-fiber drain, and sewer pipe.
- CS 270-65 Acrylonitrile-butadiene-styrene (ABS), plastic drain, waste, vent pipe, and fittings.
- CS 272-65 Polyvinyl chloride (PVC), plastic drain, waste, vent pipe, and fittings.
- CS 228-61 Styrene rubber plastic drain, sewer pipe, and fittings.
- CS 188-66 Cast-iron soil pipe and fittings.
- CS 143-60 Perforated vitrified clay pipe (standard and extra strength).
- CS 224-60 Vitrified clay sewer pipe (standard and extra strength).
- R 241-45 Clay sewer pipe and fittings.

Public notice of the Department's intention to withdraw these standards was published in the FEDERAL REGISTER on January 25, 1972, (37 F.R. 1130), and a 45-day period was provided for the submission of comments or objections concerning the proposed withdrawal of any of these standards. No objections to the Department's intention of withdrawing any of these standards have been received by the National Bureau of Standards.

The effective date for the withdrawal of these standards will be 60 days after the publication of this notice. This withdrawal action terminates the authority to refer to these standards as Voluntary Product Standards developed under the Department of Commerce Procedures.

LEWIS M. BRANSCOMB,
Director.

MARCH 16, 1972.

[FR Doc.72-4332 Filed 3-21-72;8:46 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[DESI 9411]

PREPARATIONS CONTAINING MECLIZINE AND PYRIDOXINE HYDROCHLORIDE 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 drugs:

Bonadoxin Tablets and Drops, containing meclizine hydrochloride and pyridoxine hydrochloride; J. B. Roerig & Co. Division, Chas. Pfizer & Co., Inc., New York, N.Y. 10017 (NDA 9-411, NDA 10-095).

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. Meclizine hydrochloride combined with pyridoxine hydrochloride lacks substantial evidence of effectiveness for nausea and vomiting of pregnancy.

2. Meclizine hydrochloride combined with pyridoxine hydrochloride is possibly effective for treatment of motion sickness, radiation sickness, vertigo associated with Meniere's syndrome, labyrinthitis, dizziness associated with cerebral arteriosclerosis, relief of symptoms of pylorospasm and/or colic of infancy, and for control of nausea and vomiting in other conditions.

B. Marketing status. 1. Within 60 days of the date of publication of this an-

nouncement in the FEDERAL REGISTER, the holder of any approved new drug application for which a drug 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 the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 9411, 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.

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 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: March 10, 1972.

SAM D. FINE,
*Associate Commissioner
for Compliance.*

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