

In consideration of the foregoing the last sentence of SFAR-12 is hereby amended, effective immediately, by striking out the words "October 25, 1965" and by inserting in place thereof the words "May 1, 1966."

(Secs. 313(a), 601, 603, and 604 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, 1423, and 1424)

Issued in Washington, D.C., on October 21, 1965.

WILLIAM F. MCKEE,
Administrator.

[F.R. Doc. 65-11492; Filed, Oct. 26, 1965;
8:45 a.m.]

Title 5—ADMINISTRATIVE PERSONNEL

Chapter I—Civil Service Commission

PART 213—EXCEPTED SERVICE

Water Resources Council

Section 213.3380 is added to show that the position of Director, Water Resources Council Staff, is excepted under Schedule C. Effective on publication in the FEDERAL REGISTER § 213.3380 is added as set out below.

§ 213.3380 Water Resources Council.

(a) Director, Water Resources Council Staff.

(R.S. 1753, sec. 2, 22 Stat. 403, as amended; 5 U.S.C. 631, 633; E.O. 10577, 19 F.R. 7521, 3 CFR, 1954-1958 Comp., p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,

[SEAL] MARY V. WENZEL,
Executive Assistant to
the Commissioners.

[F.R. Doc. 65-11516; Filed, Oct. 26, 1965;
8:47 a.m.]

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

PART 131—INTERPRETATIVE STATEMENTS RE WARNING ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

Ipecac Syrup in One Fluid Ounce Containers; Required Warnings and Directions

Pursuant to the authority provided in the Federal Food, Drug, and Cosmetic Act (secs. 502(f), 701(a), 52 Stat. 1051, 1055; 21 U.S.C. 352(f), 371(a)) and delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90), Title 21 is amended in the following respects.

1. Part 3 is amended by adding thereto the following new section:

§ 3.30 Ipecac syrup; warnings and directions for use for over-the-counter sale.

(a) It is estimated that each year about 500,000 accidental poisonings occur in the United States and result in approximately 1,500 deaths, of which over 400 are children. In the emergency treatment of these poisonings, ipecac syrup is considered the emetic of choice. The immediate availability of this drug for use in such situations is critical, since rapid treatment may be the difference between life and death. The restriction of this drug to prescription sale limits its availability in emergencies. On the other hand, it is the consensus of informed medical opinion that ipecac syrup should be used only under medical supervision in the emergency treatment of poisonings. In view of these facts, the question of whether ipecac syrup labeled as an emergency treatment for use in poisonings should be available over the counter has been controversial.

(b) In connection with its study of this problem, the Food and Drug Administration has obtained the views of medical authorities. It is the unanimous recommendation of the American Academy of Pediatrics, the American Association of Poison Control Centers, the American Medical Association, and the Medical Advisory Board of the Food and Drug Administration that ipecac syrup in 1 fluid ounce containers be permitted to be sold without prescription so that it will be readily available in the household for emergency treatment of poisonings, under medical supervision, and that the drug be appropriately packaged and labeled for this purpose.

(c) In view of the above recommendations, the Commissioner of Food and Drugs has determined that it is in the interest of the public health for ipecac syrup to be available for sale without prescription, provided that it is packaged in a quantity of 1 fluid ounce (30 milliliters), and its label bears, in addition to other required label information, the following, in a prominent and conspicuous manner:

(1) A statement conspicuously boxed and in red letters, to the effect: "For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice."

(2) A warning to the effect: "Warning—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosine, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested."

(3) Usual dosage: 1 tablespoon (15 milliliters) in persons over 1 year of age.

2. Section 131.16 is amended by inserting therein in alphabetical order a new item reading as follows:

§ 131.16 Drugs for human use; warning and caution statements required by regulations.

IPECAC SYRUP IN ONE-FLUID OUNCE CONTAINERS FOR EMERGENCY TREATMENT OF POISONING, TO INDUCE VOMITING. (See § 3.30 of this chapter.)

Ipecac syrup packaged for over-the-counter sale must bear statements to the following effect, in a prominent and conspicuous manner:

The following statement (boxed and in red letters):

"For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice."

The following warning: Warning—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosine, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested.

(Secs. 502(f), 701(a), 52 Stat. 1051, 1055; 21 U.S.C. 352(f), 371(a))

Dated: October 19, 1965.

WINTON B. RANKIN,
Assistant Commissioner
for Planning.

[F.R. Doc. 65-11386; Filed, Oct. 26, 1965;
8:45 a.m.]

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

PART 130—NEW DRUGS

PART 131—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE

Chlorcyclizine, Cyclizine, Meclizine; Statement of Policy re Warning etc.

Pursuant to the authority provided in the Federal Food, Drug, and Cosmetic Act (secs. 503(b)(1)(C), 505, 701, 52 Stat. 1052, 1055, as amended 65 Stat. 648, 649, 76 Stat. 781 et seq.; 21 U.S.C. 353(b)(1)(C), 355, 371) and delegated to the Commissioner of Food and Drugs by the Secretary of Health, Education, and Welfare (21 CFR 2.90), Title 21 is amended as set forth below:

1. Part 3 is amended by adding thereto the following new section:

§ 3.29 Chlorcyclizine, cyclizine, meclizine; warnings; labeling requirements.

(a) The Food and Drug Administration, pursuant to its responsibility for the safety and effectiveness of drugs, has conducted active investigations of reports of available animal data which reveal that chlorcyclizine hydrochloride, cyclizine hydrochloride and lactate, and meclizine hydrochloride exert a terato-

of the serious health risks associated with the ingestion of larger than intended doses of this product. Further, because an overdose of either oral or rectal enema sodium phosphates can cause an electrolyte imbalance, additional warning and direction statements are required for the safe use of any OTC laxative drug product containing sodium phosphates.

(b) Any OTC drug product for laxative or bowel cleansing use containing sodium phosphates as an active ingredient when marketed as described in paragraph (a) of this section is misbranded within the meaning of section 502 of the Federal Food, Drug, and Cosmetic Act unless packaged and labeled as follows:

(1) Package size limitation for sodium phosphates oral solution: Container shall not contain more than 90 mL (3 oz).

(2) Warnings. The following sentences shall appear in boldface type as the first statement under the heading "Warnings."

(i) Oral dosage forms. "Taking more than the recommended dose in 24 hours can be harmful."

(ii) Rectal enema dosage forms. "Using more than one enema in 24 hours can be harmful."

(3) Directions—(i) The labeling of all orally or rectally administered OTC drug products containing sodium phosphates shall contain the following directions in boldface type immediately preceding the dosage information: "Do not" ("take" or "use") "more unless directed by a doctor. See Warnings."

(ii) For products containing dibasic sodium phosphate/monobasic sodium phosphate identified in §334.16(d) marketed as a solution. Adults and children 12 years of age and over: Oral dosage is dibasic sodium phosphate 3.42 to 7.56 grams (g) and monobasic sodium phosphate 9.1 to 20.2 g (20 to 45 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 45 mL (9 teaspoons) or 3 tablespoons (15 mL) in a 24-hour period." Children 10 and 11 years of age: Oral dosage is dibasic sodium phosphate 1.71 to 3.78 g and monobasic sodium phosphate 4.5 to 10.1 g (10 to 20 mL dibasic sodium phos-

phate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 20 mL (4 teaspoons) in a 24-hour period." Children 5 to 9 years of age: Oral dosage is dibasic sodium phosphate 0.86 to 1.89 g and monobasic sodium phosphate 2.2 to 5.05 g (5 to 10 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 10 mL (2 teaspoons) in a 24-hour period." Children under 5 years of age: ask a doctor.

(c) After June 22, 1998, for package size limitation and September 18, 1998, for labeling in accord with paragraph (b) of this section, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce, or any such drug product that is repackaged or relabeled after these dates regardless of the date the product was manufactured, initially introduced, or initially delivered for introduction into interstate commerce, that is not in compliance with this section is subject to regulatory action.

[63 FR 27843, May 21, 1998]

§ 201.308 Ipecac syrup: warnings and directions for use for over-the-counter sale.

(a) It is estimated that each year about 500,000 accidental poisonings occur in the United States and result in approximately 1,500 deaths, of which over 400 are children. In the emergency treatment of these poisonings, ipecac syrup is considered the emetic of choice. The immediate availability of this drug for use in such situations is critical, since rapid treatment may be the difference between life and death. The restriction of this drug to prescription sale limits its availability in emergencies. On the other hand, it is the consensus of informed medical opinion that ipecac syrup should be used only under medical supervision in the emergency treatment of poisonings. In view of these facts, the question of whether ipecac syrup labeled as an emergency treatment for use in poisonings should be available over the counter has been controversial.

(b) In connection with its study of this problem, the Food and Drug Administration has obtained the views of medical authorities. It is the unanimous recommendation of the American Academy of Pediatrics, the American Association of Poison Control Centers, the American Medical Association, and the Medical Advisory Board of the Food and Drug Administration that ipecac syrup in 1 fluid ounce containers be permitted to be sold without prescription so that it will be readily available in the household for emergency treatment of poisonings, under medical supervision, and that the drug be appropriately packaged and labeled for this purpose.

(c) In view of the above recommendations, the Commissioner of Food and Drugs has determined that it is in the interest of the public health for ipecac syrup to be available for sale without prescription, provided that it is packaged in a quantity of 1 fluid ounce (30 milliliters), and its label bears, in addition to other required label information, the following in a prominent and conspicuous manner:

(1) A statement conspicuously boxed and in red letters, to the effect: "For emergency use to cause vomiting in poisoning. Before using, call physician, the Poison Control Center, or hospital emergency room immediately for advice."

(2) A warning to the effect: "Warning—Keep out of reach of children. Do not use in unconscious persons. Ordinarily, this drug should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates such as kerosene, gasoline, coal oil, fuel oil, paint thinner, or cleaning fluid have been ingested."

(3) Usual dosage: 1 tablespoon (15 milliliters) in persons over 1 year of age.

§ 201.309 Acetophenetidin (phenacetin)-containing preparations: necessary warning statement.

(a) In 1961, the Food and Drug Administration, pursuant to its statutory responsibility for the safety and effectiveness of drugs shipped in interstate commerce, began an active investigation of reports of possible toxic effects and renal damage due to misuse of the drug acetophenetidin. This study led to

the decision that there was probable cause to conclude that misuse and prolonged use of the drug were in fact responsible for kidney lesions and disease. The Commissioner of Food and Drugs, in December 1963, appointed an ad hoc Advisory Committee of Inquiry on Possible Nephrotoxicity Associated With the Abuse of Acetophenetidin (Phenacetin)-Containing Preparations. This committee, composed of scientists in the fields of pharmacology and medicine, on April 23, 1964, submitted its findings and conclusions in the matter and recommended that all acetophenetidin (phenacetin)-containing preparations bear a warning as provided in section 502(f)(2) of the Federal Food, Drug, and Cosmetic Act.

(b) On the basis of the studies made by the Food and Drug Administration and the report of the Advisory Committee, the Commissioner of Food and Drugs has concluded that it is necessary for the protection of users that the label and labeling of all acetophenetidin (phenacetin)-containing preparations bear a warning statement to the following effect: "Warning—This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician."

§ 201.310 Phenindione; labeling of drug preparations intended for use by man.

(a) Reports in the medical literature and data accumulated by the Food and Drug Administration indicate that phenindione, a synthetic anticoagulant drug, has caused a number of cases of agranulocytosis (with two fatalities). There are also reports implicating the drug in cases of hepatitis and hypersensitivity reactions. In view of the potentially serious effects found to be associated with preparations of this drug intended for use by man, the Commissioner of Food and Drugs will regard such preparations as misbranded within the meaning of section 502(f) (1) and (2) of the Federal Food, Drug, and Cosmetic Act, unless the label and labeling on or within the package from which the drug is to be dispensed, and