(2) The labeling on or within the package from which the drug is to be dispensed bears adequate information for its use by practitioners in accord with the “full disclosure” labeling requirements of §201.100 of this chapter, including a recommendation that patients be directed to dissolve any such tablets in an appropriate amount of liquid and to dilute any such liquid preparations adequately to assure against gastrointestinal injury associated with the oral ingestion of concentrated potassium salt preparations.

(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 teaspoonfuls or 3 tablespoonfuls) 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 phosphate/monobasic sodium phosphate oral solution) as a single daily dose. “Do not take more than 20 mL (4 teaspoonfuls) 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 tea-
spoonfuls) in a 24-hour period.” Chil-

deren 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 ini-
tially 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, ini-
tially introduced, or initially delivered
for introduction into interstate com-
merce, that is not in compliance with
this section is subject to regulatory ac-
tion.
[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 prescrip-
tion 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 should be
used only under medical supervision in
the emergency treatment of poisonings is controver-
sial.
(b) In connection with its study of
this problem, the Food and Drug Ad-
ministration has obtained the views of
medical authorities. It is the unani-

mous 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 ip-
ecac syrup in 1 fluid ounce containers
be permitted to be sold without pre-
scription so that it will be readily
available in the household for emer-
gency treatment of poisonings, under
medical supervision, and that the drug
be appropriately packaged and labeled
for this purpose.
(c) In view of the above recommenda-
tions, 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 pack-
aged in a quantity of 1 fluid ounce (30
milliliters), and its label bears, in addi-
tion to other required label informa-
tion, 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 ad-
vice.”
(2) A warning to the effect: “Warn-
ing—Keep out of reach of children. Do
not use in unconscious persons. Ordin-
arily, 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 mil-

liliters) in persons over 1 year of age.
§ 201.309 Acetophenetidin (phen-
acetin)-containing preparations;
necessary warning statement.
(a) In 1961, the Food and Drug Ad-
ministration, pursuant to its statutory re-

sponsibility for the safety and effec-
tiveness of drugs shipped in interstate
commerce, began an active investiga-
tion 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 pro-
longed use of the drug were in fact re-
ponsible for kidney lesions and dis-

ease. 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