(301) 504–0800 or delivered to the Office of the Secretary, Room 501, 4330 East-West Highway, Bethesda, Maryland 20814. Copies should be submitted in five copies and captioned "Sleepwear Policy Statement." Comments may also be filed by telefacsimile to (301) 504–0127 or by e-mail to cpsc os@cpsc.gov.

FOR FURTHER INFORMATION CONTACT: Patricia Fairall, Program Manager, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0400, extension 1369.

SUPPLEMENTARY INFORMATION:

A. Background

The Consumer Product Safety Commission enforces two flammability standards for children's sleepwear. The flammability standard for children's sleepwear in sizes 0 through 6X is codified at 16 CFR Part 1615. The flammability standard for children's sleepwear in sizes 7 through 14 is codified at 16 CFR Part 1616.

On September 9, 1996, the Commission issued a final rule amending the flammability standards for children's sleepwear to exclude from the definition of "children's sleepwear," codified at 16 CFR 1615.1(a) and 1616.2(a), (1) garments sized for infants nine months of age or younger and (2) tight-fitting garments for children older than nine months. 61 FR 47634. The Commission found that such tight-fitting garments did not present an unreasonable risk of injury. Rather, the Commission's information showed that many severe incidents occurred with loose-fitting garments such as oversized t-shirts used inappropriately as sleepwear. The Commission concluded that garments fitting closely and that touch the body at key points should be exempt from the sleepwear standards because they do not present the same risk as loose-fitting garments. These amendments became effective on January 1, 1997. However, the Commission also issued a stay of enforcement for close-fitting garments which are labeled and promoted as underwear. That stay expires on June 9, 1998.

B. Clarification

The Commission has become aware that the garment industry is concerned about the policy statements in 16 CFR 1615.64(d) and 1616.65(d), which suggest segregation of items covered by the children's sleepwear standards from all fabrics and garments that are beyond the scope of the children's sleepwear standards. The purpose of the September 9, 1996 final rule was to allow garments sized for a child nine months and under and tight-fitting garments in sizes above nine months to be sold and used as sleepwear. Therefore, the Commission proposes to modify the policy statements at 1615.64(d) and 1616.65(d) to provide that infant garments (defined in the amended sleepwear standard at 16 CFR 1615.1(c)(1) as sized for a child nine months and under) and "tight-fitting" garments (defined in the amended sleepwear standard at 16 CFR 1615.1(o) and 1616.2(m)) can be marketed and promoted with other sleepwear.

For the reasons stated above and pursuant to the authority of Section 4 of the Flammable Fabrics Act (15 U.S.C. 1193), the Commission proposes to amend 16 CFR 1615.64 and 1616.65 to read as follows:

PART 1615—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 0 THROUGH 6X

1. The authority citation for part 1615 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–70; 15 U.S.C. 1193.

2. Section 1615.64 is amended by revising paragraph (d) introductory text to read as follows:

§ 1615.64 Policy to clarify scope of the standard.

* * * * *

(d) Retailers, distributors, and wholesalers, as well as manufacturers, importers, and other persons (such as converters) introducing a fabric or garment into commerce which does not meet the requirements of the flammability standards for children's sleepwear, have an obligation not to promote or sell such fabric or garment for use as an item of children's sleepwear. Also, retailers, distributors, and wholesalers are advised not to advertise, promote, or sell as an item of children's sleepwear any item which a manufacturer, importer, or other person (such as a converter) introducing the item into commerce has indicated by label, invoice, or, otherwise, does not meet the requirements of the children's sleepwear flammability standards and is not intended or suitable for use as sleepwear. "Infant garments" as defined by § 1615.1(c) and "tight-fitting" garments as defined by § 1615.1(o) are exempt from the standard which requires flame resistance. They may be marketed as sleepwear for purposes of this section. Additionally, retailers are advised:

* * * * *

PART 1616—STANDARD FOR THE FLAMMABILITY OF CHILDREN'S SLEEPWEAR: SIZES 7 THROUGH 14

1. The authority citation for part 1616 continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–70; 15 U.S.C. 1193.

2. Section 1616.65 is amended by revising paragraph (d) introductory text to read as follows:

§ 1616.65 Policy scope of the standard.

* * * * *

(d) Retailers, distributors, and wholesalers, as well as manufacturers, importers, and other persons (such as converters) introducing a fabric or garment into commerce which does not meet the requirements of the flammability standards for children's sleepwear, have an obligation not to promote or sell such fabric or garment for use as an item of children's sleepwear. Also, retailers, distributors, and wholesalers are advised not to advertise, promote, or sell as an item of children's sleepwear any item which a manufacturer, importer, or other person (such as a converter) introducing the item into commerce has indicated by label, invoice, or, otherwise, does not meet the requirements of the children's sleepwear flammability standards and is not intended or suitable for use as sleepwear. "Tight-fitting" garments as defined by § 1616.2(m) are exempt from the standard which requires flame resistance. They may be marketed as sleepwear for purposes of this section. Additionally, retailers are advised:

* * * * *

Dated: May 12, 1998.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 98–13028 Filed 5–20–98; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 334

[Docket No. 78N–036L]

RIN 0910–AA01

Laxative Drug Products for Over-the-Counter Human Use; Proposed Amendment to the Tentative Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is amending the tentative final monograph for over-the-counter (OTC) laxative drug products to include additional general and professional labeling for oral and rectal dibasic sodium phosphate/monobasic sodium phosphate (sodium phosphates) drug products. FDA is proposing new warnings and directions for these products and a new time to effect statement for rectal products based on new data submitted after publication of the tentative final monograph for OTC laxative drug products. This proposal is part of the ongoing review of OTC drug products conducted by FDA. Elsewhere in this issue of the **Federal Register** the agency is finalizing the package size limitation and warning prior to the completion of the final monograph for OTC laxative drug products.

DATES: Submit written comments or objections by August 19, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Turner, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 21, 1975 (40 FR 12902), FDA published, under 21 CFR 330.10(a)(6), an advance notice of proposed rulemaking to establish a monograph for OTC laxative, antidiarrheal, emetic, and antiemetic drug products, together with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these classes. The Panel recommended monograph status for phosphate salts, such as sodium biphosphate [1] and sodium phosphate [2] (40 FR 12902 at 12940).

The agency's proposed regulation, in the form of a tentative final monograph, for OTC laxative drug products was published in the **Federal Register** of January 15, 1985 (50 FR 2124). The agency also proposed monograph status for sodium phosphates oral solution [3]. (See proposed § 334.58(d)(5)(i), 50 FR 2124 at 2152 and 2155.) In addition to its use as an OTC laxative for the relief of occasional constipation, sodium phosphates oral solution is used as part of a bowel cleansing regimen in preparing a patient for surgery or for preparing the colon for x-ray or endoscopic examination. (See proposed § 334.80(a)(2), 50 FR 2124 at 2157.) Sodium phosphates oral solution and sodium phosphates enema [4], respectively, are the current United States Pharmacopeia (USP) names for the oral and rectal dosage forms of the combination of sodium phosphates ingredients.

In the **Federal Register** of March 31, 1994 (59 FR 15139), the agency proposed to amend the tentative final monograph for OTC laxative drug products to limit the OTC container size for sodium phosphates oral solution to not greater than 90 milliliters (mL). The agency noted that the major trade product containing sodium phosphates oral solution was marketed in 45-mL, 90-mL, and 240-mL bottles. The purgative dose or dose used for colonoscopy is 45 mL. Because the product was available in three sizes, the manufacturer's labeling advised physicians to prescribe by volume and not to prescribe by the bottle and not to exceed the recommended dosage, as serious side effects may occur. Despite this labeling, the multiple container sizes available in the marketplace have caused consumer confusion and appear to have been involved in several consumer deaths (59 FR 15139 at 15140).

Because of the reported cases of accidental overdosing and the confusion that has occurred between 240-mL and 90-mL container sizes, the agency proposed that the 240-mL size container of sodium phosphates oral solution should no longer remain in the OTC marketplace. In the interest of safety, the agency proposed to limit the maximum OTC container size for this product to 90 mL.

The agency proposed to include the package size limitation and a warning (informing consumers not to exceed the recommended dosage unless directed by a doctor) in the monograph for OTC laxative drug products. However, that monograph has not been finalized to date. Because of the potential serious safety risk involved, elsewhere in this issue of the **Federal Register** the agency is finalizing the package size limitation and warning prior to the completion of the final monograph for OTC laxative drug products. The agency is including this information in part 201 (21 CFR part 201) at this time and will incorporate it into the final monograph for OTC laxative drug products at a later date.

Based on new data submitted since the January 15, 1985, and the March 31, 1994, proposals were published, the agency is proposing in this document additional general and professional labeling for oral and rectal sodium phosphates products for OTC laxative use. In the **Federal Register** of February 27, 1997 (62 FR 9024), FDA proposed to establish a standardized format for the labeling of OTC drug products. When the agency finalizes that proposal, the agency will also amend the final version of the rule proposed herein, as needed, to conform to the final labeling rule. Copies of previous rulemakings discussed above and information that has come to the agency's attention since publication of the proposals are on public display in the Dockets Management Branch (address above).

II. The Agency's Labeling Proposals for Sodium Phosphates

A. Introduction

One comment informed the agency of modifications made in the labeling of its rectal enema sodium phosphates product. The comment had expanded the professional labeling to include additional warning statements regarding use in patients with a colostomy, congenital megacolon, imperforate anus, impaired renal function, heart disease, congestive heart failure, preexisting electrolyte disturbances (such as dehydration or those secondary to the use of diuretics), or in patients using calcium channel blockers, diuretics, or other medications that may affect electrolyte levels, as hypocalcemia, hyperphosphatemia, hypernatremia, and acidosis may occur. The comment cited several references (Refs. 1, 2, and 3) to support its warning statements. The professional labeling also included information on the treatment of electrolyte imbalances. The comment stated that the labeling no longer recommends the use of this enema product in children under 2 years of age. The comment mentioned that a summarized version of the professional

[1] The Panel designated this ingredient "sodium biphosphate." However, monobasic sodium phosphate is currently the official name for this ingredient in the *USP Dictionary of USAN and International Drug Names*, 1997.

[2] The Panel designated this ingredient "sodium phosphate." However, dibasic sodium phosphate is currently the official name for this ingredient in the *USP Dictionary of USAN and International Drug Names*, 1997.

[3] Sodium phosphates oral solution is the official name for a solution of dibasic sodium phosphate and monobasic sodium phosphate in the *U.S. Pharmacopeia 23/National Formulary 18*, 1995.

[4] Sodium phosphates enema is the official name for a solution of dibasic sodium phosphate and monobasic sodium phosphate in the *U.S. Pharmacopeia 23/National Formulary* 18, 1995.

labeling will appear on the product's retail carton.

The agency agrees with the comment that the professional labeling for these sodium phosphates products should be expanded to include more information for health professionals to ensure safe use. As a result of the comment's additional warnings, the agency has reevaluated all of the labeling for sodium phosphates products (oral and rectal). The agency notes that the comment included calcium channel blockers in its professional warning. However, the agency is not aware of any specific data to show that sodium phosphates products should not be used in patients taking calcium channel blockers. Therefore, calcium channel blockers will not be included in the professional warning for sodium phosphates products at this time.

B. Professional Labeling

In § 334.80(b)(2) of the tentative final monograph for OTC laxative drug products (50 FR 2124 at 2157), the agency proposed the following warnings in the professional labeling for products containing sodium phosphates: "Do not use in patients with megacolon, as hypernatremic dehydration may occur. Use with caution in patients with impaired renal function." The comment's labeling and information in the literature provide a basis to expand this warning. Individuals with impaired renal function (Refs. 4 through 8, including the elderly (Ref. 5)), heart disease (Refs. 8, 9, and 10), acute myocardial infarction (Refs. 11 and 12), unstable angina (Ref. 12), dehydration (Refs. 1 and 9), or who are on diuretics (Ref. 10) are at risk for an electrolyte imbalance to occur with use of oral and rectal sodium phosphates products. Sodium phosphates can cause alterations in serum levels of sodium, potassium, phosphate, chloride, and calcium and, in some people, such changes can be life threatening. The reduction of calcium levels reflects changes in ionized calcium (Ref. 13). Hypocalcemia with subsequent low levels of ionized calcium may result in neuromuscular irritability, heart block, and cardiovascular failure (Ref. 13). Therefore, the agency has determined that the warnings in the professional labeling for oral and rectal sodium phosphates products in proposed § 334.80(b)(2) (redesignated as § 334.80(b)(2)(i) in this proposal) should be expanded. The agency has made an effort to present the warning information in a new format using specific headings to make it clearer and more readable as follows:

"Do not use" (these three words in bold print) "in patients with congestive heart failure."

"Use with caution" (these three words in bold print) "in patients with impaired renal function, heart disease, acute myocardial infarction, unstable angina, preexisting electrolyte disturbances (such as dehydration or those secondary to the use of diuretics), the elderly, or people taking drugs that may affect electrolyte levels."

The agency is also including the following information regarding prevention and treatment of an electrolyte imbalance.

"Monitor electrolytes." (these two words in bold print) "Give sufficient fluid replacement with all oral and rectal sodium phosphates products to prevent dehydration." "What can occur:" (these three words in bold print) "Hypocalcemia, hyperphosphatemia, hypernatremia, hypokalemia, and acidosis. These conditions are more likely to occur when more than one dose of sodium phosphates is given in a 24-hour period."

"What you should do:" (these four words in bold print) "Advise people to follow recommended dose. Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement. (Some examples of references for treatment of this condition are Fonkalsrud, E., and J. Keen, Hypernatremic Dehydration Hypertonic Enemas in Congenital Megacolon, *The Journal of the American Medical Association*, 199:584586, 1967, and Edmondson, S., and T. D. Almquist, Iatrogenic Hypocalcemic Tetany, *Annals of Emergency Medicine*, 19:938–940, 1990.)"

The agency is including additional warnings for rectal sodium phosphates products because of reports of its misuse in certain individuals by health professionals. Fatal or life-threatening consequences have resulted from excess dosages of sodium phosphates enemas in adults (Refs. 4, 6, and 14) and in young children (Refs. 10, 15, and 16). The agency notes that many of these adverse effects occurred when sodium phosphates enemas were used in children under 2 years of age. Sodium phosphates enemas have also been misused in individuals with colon abnormalities (Refs. 1, 4, 10, 17, and 18) and rectal abnormalities (Refs. 5, 19, and 20). Individuals with a functional abnormality of the colon, e.g., a colostomy (Refs. 10, 21, and 22), imperforate anus (Refs. 4 and 21), atonic colon (Ref. 4), or congenital megacolon (Refs. 1, 4, 10, and 21) are at risk for hyperosmotic dehydration and hyperphosphatemia with the use of sodium phosphates enemas. Such individuals have a tendency to retain the enema for a prolonged period of time, and considerable absorption of the phosphate ion occurs. Several cases of rectal gangrene have occurred after an enema nozzle injury in individuals with hemorrhoids (Refs. 19, 20, and 23). The authors believed that the rectal injury was compounded due to the necrotizing effect of the sodium phosphates on the rectal tissue. Other reports (Refs. 19, 20, and 23 through 26) indicate that following an enema tip injury to the rectum, the presence of sodium phosphates causes a pronounced inflammatory response and tissue damage which, if untreated, can produce serious consequences. Based on the above, the agency is proposing to add the following warnings in the professional labeling in proposed § 334.80(b)(2)(ii) for sodium phosphates enemas to inform health professionals to carefully monitor use in certain individuals or not to use at all. This information is also presented in the new format using specific headings:

"Do not use" (these three words in bold print) "sodium phosphates enema in children under 2 years of age or in patients with congenital megacolon or imperforate anus because of the risk of hyperosmotic dehydration and hyperphosphatemia."

"Stop using" (these two words in bold print) "if there is resistance to the enema tip. Forcing the tip into the rectum can result in a serious injury that requires immediate medical attention."

"Use sodium phosphates enema with extreme caution" (these seven words in bold print) "in patients with a colostomy or atonic colon (because of the risk of hyperosmotic dehydration and hyperphosphatemia) or with a rectal abnormality, such as hemorrhoids (because sodium phosphates can cause serious damage to the rectal mucosa if an enema tip injury occurs). Using more than one sodium phosphates enema in a 24-hour period can cause serious electrolyte problems."

The "Do not use" warning for sodium phosphates enemas in § 334.80(b)(2)(ii)(A) may be combined with the "Do not use" warning for all sodium phosphates products in § 334.80(b)(2)(i)(A). The warning proposed for sodium phosphates products in § 334.80(b)(2) of the tentative final monograph, which stated "Do not use in patients with megacolon, as hypernatremic dehydration may occur. Use with caution in patients with impaired renal function," is superseded by the warnings in this amendment.

The agency notes that the comment stated that a summarized version of the professional labeling will appear on the product's retail package. Professional labeling is labeling provided to health professionals but not to the general public. Therefore, a summarized version of this professional labeling should not appear on the retail package. As discussed in section II.C of this document, the agency has developed labeling for sodium phosphates products that it believes adequately

informs consumers of the proper use of these products.

C. OTC Labeling

In § 334.58(c)(2)(i) of the tentative final monograph (50 FR 2124 at 2155), the agency proposed the following warning for products containing sodium phosphates: "Do not use this product if you have kidney disease, unless directed by a doctor." The agency is proposing to expand the warning for oral and rectal products that contain sodium phosphates because consumers who have kidney disease (Refs. 4 through 7), heart problems (Refs. 8 through 12), or are dehydrated (Refs. 1 and 9) should not use sodium phosphates products, unless directed by a doctor.

The agency has also determined that a new warning is needed to restrict the number of days that all oral and rectal sodium phosphates products can be used, unless directed by a doctor. The Panel in its report (40 FR 12902 at 12941) and the agency in the tentative final monograph (50 FR 2124 at 2153) recommended that the use of sodium phosphates be restricted to 1 week (7 days). However, the agency has reviewed new data indicating that sodium phosphates can cause electrolyte imbalances within 24 hours after the initial dose is taken (Refs. 4, 11, and 12) (also see the final rule for oral and rectal OTC sodium phosphates drug products published elsewhere in this issue of the **Federal Register**). These blood level changes have occurred in individuals with no underlying renal failure or active heart disease (Refs. 11, 12, and 27). The agency is concerned that daily use of sodium phosphates products for 7 days may cause significant changes in the sodium, potassium, phosphate, chloride, and/or calcium blood levels. In the interest of consumer safety and to help reduce the risk of adverse effects that can occur from sequential doses of sodium phosphates, the agency believes that use of sodium phosphates should be limited to 3 days instead of 7 days. The revised warning for oral and rectal sodium phosphates, which appears in proposed § 334.58(c)(2)(i), states: "Do not use if" (these four words in bold print) "you have kidney disease, heart problems, or are dehydrated, or for more than 3 days, without asking a doctor."

In § 334.58(c)(2)(ii) of the tentative final monograph (50 FR 2124 at 2155), the agency proposed the following warning for oral dosage forms of sodium phosphates identified in § 334.16(d), (e), or (f): "Do not give to children under 5 years of age unless directed by a doctor." However, the agency is proposing to revise the directions for oral sodium phosphates products in new § 201.307(b)(3)(ii) (21 CFR 201.307(b)(3)(ii)) (designated as § 334.58(d)(5)(i) in this proposal) and in proposed § 334.58(d)(6) and (d)(7) to be consistent with other oral OTC laxative drug products. (See section II.D of this document.) Therefore, for consistency, the proposed warning in § 334.58(c)(2)(ii) for oral sodium phosphates is revised to state: "Do not give to children under 6 years of age, without asking a doctor."

In § 334.58(c)(2)(iii) of the tentative final monograph (50 FR 2124 at 2155), the agency proposed the following warning for sodium phosphates enemas: "Do not give to children under 2 years of age unless directed by a doctor." The agency also proposed the following direction for sodium phosphates enemas in § 334.58(d)(5)(ii) (50 FR 2124 at 2155): "* * * Children under 2 years of age: consult a doctor." However, because of adverse effects that have occurred when sodium phosphates enemas were used in children under 2 years of age, the agency is revising the warning and direction statements. Therefore, in § 334.58(c)(2)(iii) of this proposal, the revised warning for sodium phosphates rectal products states: "Do not use in children under 2 years of age." The corresponding direction, which appears in § 334.58(d)(5)(ii)(A) in this proposal, is revised to state: "* * * Do not use in children under 2 years of age." The agency believes it is necessary to have this information in both the warning and direction sections of the labeling because of the adverse effects that can occur when sodium phosphates enemas are used in children under 2 years of age.

D. Directions

Effectiveness is not increased when a sodium phosphates enema is retained more than 5 minutes (Refs. 28, 29, and 30). Data indicate that a sodium phosphates enema is usually expelled from the rectum within 20 minutes (Refs. 28, 29, and 30) and that increased blood levels of phosphorus and sodium and decreased levels of calcium can occur within several hours (Refs. 13, 17, and 30) if the enema is retained. Therefore, the agency is proposing a new direction for sodium phosphates rectal products in § 334.58(d)(5)(ii)(B) in this proposal, which states: "If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur."

The agency is proposing a new direction in § 334.58(d)(5)(ii)(C) for sodium phosphates rectal products. A sodium phosphates enema can cause serious damage to the rectal mucosa if the enema tip causes a rectal injury (Refs. 19, 20, and 23). If the enema tip perforates the rectum, antibiotic treatment or a temporary colostomy may be needed to prevent sepsis (Refs. 23 through 26, and 31). All rectal bleeding resulting from an enema tip injury should be medically evaluated because rectal perforations can be painless (Refs. 20, 25, and 31). Therefore, the new direction states: "Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care."

The agency is aware that labeling that was submitted to the Panel (Ref. 32) and currently marketed labeling (Ref. 33) for oral sodium phosphates products contain dosages for children 5 to 9 years of age, and for children 10 and 11 years of age. The Panel in its report (40 FR 12902 at 12940) and the agency in the tentative final monograph (50 FR 2124 at 2155) recommended dosages of oral sodium phosphates products for these age groups. Elsewhere, in this issue of the **Federal Register**, the agency included the above age ranges in the directions in new § 201.307(b)(3)(ii). The agency notes that the directions for sodium phosphates oral solution contain separate dosages for children 10 and 11 years of age, and for children 5 to 9 years of age. These age ranges are not consistent with age ranges used for the majority of OTC laxative drug products, which recommend dosages for children 6 to 11 years of age.

Therefore, the agency is proposing to revise the directions for oral sodium phosphates products in new § 201.307(b)(3)(ii) (designated as § 334.58(d)(5)(i) in this proposal), and in proposed § 334.58(d)(6) and (d)(7) to be consistent with other oral OTC laxative drug products. The proposed directions in § 334.58(d)(5)(i) state:

> * * * Children 6 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 teaspoonfuls) in a 24-hour period.' Children under 6 years of age: ask a doctor.

The proposed directions in § 334.58(d)(6) for products containing dibasic sodium phosphate identified in § 334.16(e) state: "* * * Children 6 to 9 years of age: Oral dosage is 0.86 to 1.89 g in a single daily dose. Children under 6 years of age: ask a doctor." The

proposed directions in § 334.58(d)(7) for products containing monobasic sodium phosphate identified in § 334.16(f) state: "* * * Children 6 to 9 years of age: Oral dosage is 1.12 to 5.05 g in a single daily dose. Children under 6 years of age: ask a doctor."

E. Time to Effect

The agency is proposing to revise the time to effect statement in proposed § 334.58(b)(2) for sodium phosphates rectal products from 2 to 15 minutes to 1 to 5 minutes. In three studies (Refs. 28, 29, and 30), 98 subjects (280 observations) were evaluated to determine the time to effect following use of sodium phosphates enema. In 98 percent of the observations (33 subjects accounted for 261/280 observations), the reported time to effect was within 10 minutes. In 83 percent of the observations, the time to effect was between 1 and 5 minutes. The average time to effect was 4 to 5 minutes and the mode was 3 to 5 minutes. The data do not indicate that sodium phosphates is more effective if the solution is retained more than 5 minutes (Refs. 28, 29, and 30). Therefore, the agency is proposing to revise § 334.58(b)(2) to state: "This product generally produces bowel movement in 1 to 5 minutes."

The agency invites specific comments on these proposed labeling statements. The agency will discuss its decision on these labeling proposals in a future issue of the **Federal Register**. Until the agency makes a final determination on these labeling statements, the agency encourages all manufacturers of sodium phosphates products voluntarily to label their products to include the proposed labeling statements. Because FDA is encouraging that the proposed labeling statements be used on a voluntary basis at this time, the agency will give manufacturers ample time after publication of a final rule to use up any labeling implemented in conformance with this document.

III. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Fonkalsrud, E., and J. Keen, "Hypernatremic Dehydration Hypertonic Enemas in Congenital Megacolon," *The Journal of the American Medical Association*, 199:584–586, 1967.
2. Goodman, L., and A. Gilman, *The Pharmacological Basis of Thearpeutics*, 6th ed., McGraw Hill, New York, p. 1005, 1980.
3. McConnell, T. H., "Fatal Hypocalcemia from Phosphate Absorption from Laxative Preparation," *The Journal of the American Medical Association*, 216:147–148, 1971.
4. Korzets, A. et al., "Life-Threatening Hyperphosphatemia and Hypocalcemic Tetany Following the Use of Fleet Enemas," *Journal of the American Geriatric Society*, 40:620–621, 1992.
5. Grosskopf, I. et al., "Hyperphosphataemia and Hypocalcaemia Induced by Hypertonic Phosphate Enema—An Experimental Study and Review of the Literature," *Human and Experimental Toxicology*, 10:351–355, 1991.
6. Biberstein, M., and B. A. Parker, "Enema-Induced Hyperphosphatemia," *The American Journal of Medicine*, 79:645–646, 1985.
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11. Vanner, S. J. et al., "A Randomized Prospective Trial Comparing Oral Sodium Phosphate with Standard Polyethylene Glycol-Based Lavage Solution (GoLytely) in the Preparation of Patients for Colonoscopy," *The American Journal of Gastroenterology*, 85:422–427, 1990.
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14. Rohack, J. J., B. R. Mehta, and K. Subramanyam, "Hyperphosphatemia and Hypocalcemic Coma Associated with Phosphate Enema," *Southern Medical Journal*, 78:1241–1242, 1985.
15. Edmondson, S., and T. D. Almquist, "Iatrogenic Hypocalcemic Tetany," *Annals of Emergency Medicine*, 19:938–940, 1990.
16. Sotos, J. F. et al., "Hypocalcemic Coma Following Two Pediatric Phosphate Enemas," *Pediatrics*, 60:305–307, 1977.
17. Spinrad, S. et al., "Treating Constipation with Phosphate Enema: An Unnecessary Risk," *Israel Journal of Medical Sciences*, 25:237–238, 1989.
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IV. Summary of the Agency's Proposal for OTC Laxative Drug Products Containing Sodium Phosphates

Based on new information, the agency is proposing changes in the labeling for oral and rectal sodium phosphates drug products. A summary of the changes proposed in this document follows.

1. The agency is revising proposed § 334.16(d), (e), and (f) of the monograph to use the current USP names for dibasic sodium phosphate/monobasic sodium phosphate (sodium phosphates) drug products. (See section I of this document.)

2. The agency is revising the warning proposed in § 334.58(c)(2)(ii) for

products containing oral sodium phosphates identified in § 334.16(d), (e), and (f) to state: "Do not give to children under 6 years of age, without asking a doctor."(See section II.C of this document.)

3. The agency is revising the directions for oral sodium phosphates in new § 201.307(b)(3)(ii) (designated as § 334.58(d)(5)(i) in this proposal) and in proposed § 334.58(d)(6) and (d)(7) to be consistent with other oral OTC laxative drug products. The directions will include oral dosages for children 6 years of age and older and state to ask a doctor for children under 6 years of age. (See section II.D of this document.)

4. The agency is changing the "time to effect" statement proposed in § 334.58(b)(2) for rectal dosage forms of sodium phosphates from 2 to 15 minutes to 1 to 5 minutes. (See section II.E of this document.)

5. The agency is expanding the warning for oral and rectal sodium phosphates proposed in § 334.58(c)(2)(i) to state: "Do not use if" (these four words in bold print) "you have kidney disease, heart problems, or are dehydrated, or for more than 3 days, without asking a doctor." (See section II.C of this document.)

6. The agency is revising the warning proposed for rectal dosage forms of sodium phosphates in § 334.58(c)(2)(iii) which stated, "Do not give to children under 2 years of age unless directed by a doctor," to read: "Do not use in children under 2 years of age." The agency is also revising the direction proposed for rectal sodium phosphates in § 334.58(d)(5)(ii) which stated, "Children under 2 years of age: consult a doctor," with a new direction in § 334.58(d)(5)(ii)(A) that states: "Do not use in children under 2 years of age." (See section II.C of this document.)

7. The agency is proposing new directions for rectal dosage forms of sodium phosphates in § 334.58(d)(5)(ii)(B) that state: "If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur." (See section II.D of this document.)

8. The agency is proposing new directions in § 334.58(d)(5)(ii)(C) for rectal dosage forms of sodium phosphates that state: "Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care." (See section II.D of this document.)

9. The agency is revising the professional labeling for oral and rectal sodium phosphates proposed in § 334.80(b)(2) to include additional "Do not use" and "Use with caution" warnings. The agency is also including new information about monitoring electrolytes and treating electrolyte imbalances. The new warnings and other information appear in § 334.80(b)(2)(i) and (b)(2)(ii). (See section II.B of this document.)

10. The agency has made an effort to shorten and simplify some of the labeling, e.g., by using the phrase "without asking a doctor" instead of "unless directed by a doctor." The agency has also proposed a new format for professional labeling. The agency believes that these changes will provide a clear and readable format for these labeling statements. FDA is inviting specific comments on this labeling format and on the wording of these statements.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities.

Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) requires that agencies prepare a written statement and economic analysis before proposing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency believes that this proposed rule is consistent with the principles set out in the Executive Order and in these two statutes. The purpose of this proposed rule is to add warning and direction statements to the general OTC and health professional (for health professionals only) labeling of oral and rectal OTC sodium phosphates drug products. These warning and direction statements concern product toxicity and are intended to help ensure the safe and effective use of all OTC sodium phosphates drug products. Potential benefits include reduced toxicity when consumers use, and health professionals recommend, these products.

The agency has been informed that relabeling costs of the type required by this proposed rule (changes to both consumer and professional labeling) generally average about $3,000 to $4,000 per stock keeping unit (SKU) (individual products, packages, and sizes). The agency is aware of 3 manufacturers that together produce 4 SKU's of oral sodium phosphates drug products and approximately 125 SKU's of rectal sodium phosphates drug products. There may be a few additional small manufacturers or a few additional products in the marketplace that are not identified in the sources FDA reviewed. Assuming that there are about 130 affected OTC SKU's in the marketplace, total one-time costs of relabeling would be $390,000 to $520,000.

The agency also believes that actual costs could be lower for several reasons. First, most of the label changes will be made by private label manufacturers that tend to use simpler and less expensive labeling. Second, labeling changes would not be required until the final monograph for OTC laxative drug products is issued and becomes effective. The agency is proposing a 12-month implementation period that would allow the manufacturers to coordinate these changes with routinely scheduled label printing and/or other revisions required by the final monograph for OTC laxative drug products. Thus, relabeling costs for these products would be mitigated or reduced by the cost of other labeling changes that the final monograph will also require.

The proposed rule would not require any new reporting and recordkeeping activities. Therefore, no additional professional skills are needed. There are no other Federal rules that duplicate, overlap, or conflict with the proposed rule.

The agency considered but rejected several labeling alternatives: (1) Voluntary relabeling, (2) publication of the labeling information in the *FDA Drug Bulletin* or professional journals, and (3) an exemption from coverage for small entities. The agency does not consider the first or third alternative acceptable because they do not assure that consumers or health professionals will have the most recent needed information for safe and effective use of these sodium phosphates drug products. The agency considers the second alternative useful and may proceed with such publications. However, such publications do not provide a permanent labeling requirement, which

the agency considers necessary for these products.

This proposed rule may have a significant economic impact on the manufacturers of these products, all of which are considered to be small entities, using the U.S. Small Business Administration designations for this industry (750 employees). The agency believes that any other unidentified manufacturer of these products is also likely to be a small entity. These manufacturers will need to change the information panel of each affected sodium phosphates SKU and print new professional labeling. Among the steps the agency is taking to minimize the impact on these small entities are: (1) To provide 1 year for implementation to enable entities to use up existing labeling stock, and (2) to allow these labeling changes to be coordinated with other labeling changes required by the final monograph. The agency believes that these actions should help reduce the relabeling cost for small entities.

The agency considered but rejected both a shorter and a longer implementation period. While the agency would like to have this new labeling in place as soon as possible, it considers a period less than 1 year difficult for manufacturers to implement all of the labeling required by the final monograph. The agency considered a longer effective date but finds it unacceptable because it would not assure that consumers have the most recent needed information for safe and effective use of OTC sodium phosphates drug products at the earliest possible time. Manufacturers are encouraged to implement the new labeling as soon as possible after the final monograph is published.

The analysis shows that this proposed rule is not economically significant under Executive Order 12866 and that the agency has undertaken important steps to reduce the burden to small entities. Nevertheless, some entities, especially those private label manufacturers that provide labeling for a number of the affected products, may incur significant impacts. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act. Finally, this analysis shows that the Unfunded Mandates Act does not apply to the proposed rule because it would not result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC laxative drug products containing sodium phosphates. Comments regarding the impact of this rulemaking on OTC laxative drug products containing sodium phosphates should be accompanied by appropriate documentation. The agency is providing a period of 90 days from the date of publication of this proposed rulemaking in the **Federal Register** for development and submission of comments on this subject. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VII. Environmental Impact

The agency has determined under 21 CFR 25.31(c) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Request for Comments

Interested persons may, on or before August 19, 1998, submit written comments or objections on the proposed regulation to the Dockets Management Branch (address above). Three copies of all comments or objections are to be submitted, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments and objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA is proposing that any final rule based on this proposal be effective 12 months after the date of its publication in the **Federal Register**.

List of Subjects in 21 CFR Part 334

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 334 (proposed in the **Federal Register** of January 15, 1985, 50 FR 2124) be amended as follows:

PART 334—LAXATIVE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 334 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 334.16 is amended by revising paragraphs (d), (e), and (f) to read as follows:

§ 334.16 Saline laxative active ingredients.

* * * * *

(d) Dibasic sodium phosphate/ monobasic sodium phosphatemarketed as a solution.

(e) Dibasic sodium phosphate.

(f) Monobasic sodium phosphate.

3. Section 334.58 is amended by revising paragraph (b)(2), by revising paragraph (c)(2), by revising the heading of paragraph (d)(5) and text of paragraph (d)(5)(i), by redesignating paragraph (d)(5)(ii) as (d)(5)(ii)(A) and revising new (d)(5)(ii)(A), by adding new paragraphs (d)(5)(ii)(B) and (d)(5)(ii)(C), and by revising the headings and text of paragraphs (d)(6) and (d)(7) to read as follows:

§ 334.58 Labeling of saline laxative drug products.

* * * * *

(b) * * *

(2) *Rectal dosage forms.* "This product generally produces bowel movement in 1 to 5 minutes."

(c) * * *

(2) *For products containing dibasic sodium phosphate or monobasic sodium phosphate identified in § 334.16(d), (e), or (f)*—(i) "Do not use if" (these four words in bold print) "you have kidney disease, heart problems, or are dehydrated, or for more than 3 days, without asking a doctor."

(ii) *Oral dosage forms.* "Do not give to children 5 years of age and under, without asking a doctor."

(iii) *Rectal dosage forms.* "Do not use in children under 2 years of age."

(d) * * *

(5) *For products containing dibasic sodium phosphate/ monobasic sodium phosphate identified in § 334.16(d) and marketed as a solution*—(i) Oral dosage. Adults and children 12 years of age and over: Oral dosage is dibasic sodium phosphate 3.42 to 7.56 grams and monobasic sodium phosphate 9.1 to 20.2 grams (20 to 45 milliliters (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 grams and monobasic sodium phosphate 4.5 to 10.1 grams (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 6 to 9 years of age: Oral dosage is dibasic sodium phosphate 0.86 to 1.89 gram and monobasic sodium phosphate 2.2 to 5.05 grams (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 teaspoonfuls) in a 24-hour period." Children under 6 years of age: ask a doctor.

(ii) *Rectal enema dosage.* (A) Adults and children 12 years of age and over: Enema dosage is dibasic sodium phosphate 6.84 to 7.56 grams and monobasic sodium phosphate 18.24 to 20.16 grams in a single daily dose. Children 2 to 11 years of age: Enema dosage is dibasic sodium phosphate 3.42 to 3.78 grams and monobasic sodium phosphate 9.12 to 10.08 grams in a single daily dose. "Do not use in children under 2 years of age." (Manufacturers should convert these dosages to the amount of solution to be used.)

(B) "If no urge is felt after 5 minutes of using, try to empty bowel. Call a doctor promptly if no liquid comes out of the rectum after 30 minutes because dehydration could occur."

(C) "Stop using if tip is hard to insert. Forcing the tip into the rectum can cause injury (especially if you have hemorrhoids). If enema tip causes rectal bleeding or pain, get immediate medical care."

(6) *For products containing dibasic sodium phosphate identified in § 334.16(e).* Adults and children 12 years of age and over: Oral dosage is 3.42 to 7.56 grams in a single daily dose. Children 10 to 11 years of age: Oral dosage is 1.71 to 3.78 grams in a single daily dose. Children 6 to 9 years of age: Oral dosage is 0.86 to 1.89 gram in a single daily dose. Children under 6 years of age: ask a doctor.

(7) *For products containing monobasic sodium phosphate identified in § 334.16(f).* Adults and children 12 years of age and over: Oral dosage is 4.5 to 20.2 grams in a single daily dose. Children 10 to 11 years of ages: Oral dosage is 2.25 to 10.1 grams in a single daily dose. Children 6 to 9 years of age: Oral dosage is 1.12 to 5.05 grams in a single daily dose. Children under 6 years of age: ask a doctor.

4. Section 334.80 is amended by redesignating paragraph (b)(2) as paragraph (b)(2)(i) and revising it, and by adding paragraph (b)(2)(ii), to read as follows.

§ 334.80 Professional labeling.

* * * * *

(b) * * *

(2) *For products containing dibasic sodium phosphate or monobasic sodium phosphate identified in § 334.16(d), (e), or (f)*—(i) *Oral and rectal dosage forms*—(A) "Do not use" (these three words in bold print) "in patients with congestive heart failure."

(B) "Use with caution" (these three words in bold print) "in patients with impaired renal function, heart disease, acute myocardial infarction, unstable angina, preexisting electrolyte disturbances (such as dehydration or those secondary to the use of diuretics), the elderly, or people taking drugs that may affect electrolyte levels."

(C) "Monitor electrolytes." (these two words in bold print) "Give sufficient fluid replacement with all oral and rectal sodium phosphates products to prevent dehydration."

(D) "What can occur:" (these three words in bold print) "Hypocalcemia, hyperphosphatemia, hypernatremia, hypokalemia, and acidosis. These conditions are more likely to occur when more than one dose of sodium phosphates is given in a 24-hour period."

(E) "What you should do:" (these four words in bold print) "Advise people to follow recommended dose. Treatment of electrolyte imbalance may require immediate medical intervention with appropriate electrolyte and fluid replacement. (Some examples of references for treatment of this condition are Fonkalsrud, E., and J. Keen, 'Hypernatremic Dehydration Hypertonic Enemas in Congenital Megacolon,' *The Journal of the American Medical Association*, 199:584–586, 1967, and Edmondson, S., and T. D. Almquist, 'Iatrogenic Hypocalcemic Tetany,' *Annals of Emergency Medicine*, 19:938–940, 1990.)"

(ii) *Rectal dosage forms.* (A) "Do not use" (these three words in bold print) "sodium phosphates enema in children under 2 years of age or in patients with congenital megacolon or imperforate anus because of the risk of hyperosmotic dehydration and hyperphosphatemia."

(B) "Stop using" (these two words in bold print) "if there is resistance to the enema tip. Forcing the tip into the rectum can result in a serious injury that requires immediate medical attention."

(C) "Use sodium phosphates enema with extreme caution" (these seven words in bold print) "in patients with a colostomy or atonic colon (because of the risk of hyperosmotic dehydration and hyperphosphatemia) or with a rectal abnormality, such as hemorrhoids (because sodium phosphates can cause serious damage to the rectal mucosa if an enema tip injury occurs). Using more than one sodium phosphates enema in a 24-hour period can cause serious electrolyte problems."

* * * * *

Dated: April 27, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12054 Filed 5–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGDO1–98–002]

RIN 2121–AA97

Safety Zone; New York Super Boat Race, New York

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone in the lower Hudson River, for the New York Super Boat Race. The temporary safety zone would be in effect on Sunday, September 13, 1998, from 11:30 a.m. until 4:00 p.m. unless extended or terminated sooner by the Captain of the Port, New York. The proposed safety zone would restrict vessel traffic in the Lower Hudson River between Battery Park and Pier 76 in Manhattan. The proposed safety zone is needed to protect racing participants and spectator craft from the hazards associated with high speed powerboat racing.

DATES: Comments must be received on or before August 19, 1998.

ADDRESSES: Comments should be mailed to Lieutenant Junior Grade Alma Kenneally, Waterways Oversight Branch, Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, New York 10305.

FOR FURTHER INFORMATION CONTACT: Lieutenant Junior Grade Alma Kenneally, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4195.