Subpart E—Drug Products for the Treatment and/or Prevention of Nocturnal Leg Muscle Cramps

§ 343.100 Scope.

(a) An over-the-counter drug product for the treatment and/or prevention of nocturnal leg muscle cramps in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 343.103 Definitions.

As used in this part:

Nocturnal leg muscle cramps. A condition of localized pain in the lower extremeties occurring in middle life and beyond with no regular pattern concerning time or severity and variously attributed to:

(1) Arterial insufficiency with resulting anoxic muscle spasm;

(2) Excessive venous dilation secondary to sudden emptying of small venules into larger vessels during recumbency; and

(3) Accumulation of products of muscle metabolism with local pH changes due to lactic acid accumulation.

§ 343.110 Active ingredients for the treatment and/or prevention of nocturnal leg muscle cramps. [Reserved]

§ 343.150 Labeling of products for the treatment and/or prevention of nocturnal leg muscle cramps.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "nocturnal leg muscle cramps treatment," or "nocturnal leg muscle cramps treatment and prevention."

(b) *Indications.* The labeling of the product states, under the heading "Indications", the following: "For the treatment and/or prevention of nocturnal leg muscle cramps." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the prohibitions in section 502(a) of the act against misbranding by the use of false or misleading labeling and the prohibition in section 301(d) of the act against the introduction into interstate commerce of unapproved new drugs.

(c) *Warnings.* For products containing quinine: "Discontinue use if ringing in the ears, deafness, skin rash, or visual disturbances occur. Do not take if pregnant, sensitive to quinine, or under 12 years of age."

(d) *Directions.* [Reserved]

Frank E. Young,

Commissioner of Food and Drugs.

Dated: September 10, 1985.

Margaret M. Heckler,

Secretary of Health and Human Services.

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21 CFR Part 357

[Docket No. 79N-0379]

Exocrine Pancreatic Insufficiency Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) exocrine pancreatic insufficiency drug products (drug products used to treat pancreatic enzyme deficiency) are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by January 7, 1986. New data by November 10, 1986. Comments on the new data by January 8, 1987. These dates are consistent with the time periods specified in the agency's revised procedural regulations for reviewing and classifying OTC drugs (21 CFR 330.10). Written comments on the agency's economic impact determination March 10, 1986.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 21, 1979 (44 FR 75666) FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC exocrine pancreatic insufficiency drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by April 21, 1980. Reply comments in response to comments filed in the initial comment period could be submitted by May 21, 1980.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, two manufacturers, one foundation, and two physicians submitted comments. Copies of the comments received are also on public display in the Dockets Management Branch.

The advance notice of proposed rulemaking, which was published in the **Federal Register** on December 21, 1979 (44 FR 75666), was designated as a "proposed monograph" in order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10). Similarly, the present document is designated in the OTC drug review regulations as a "tentative final monograph." Its legal status, however, is that of a proposed rule. In this tentative final monograph (proposed rule) to establish Subpart E of Part 357, FDA states for the first time its position on the establishment of a monograph for OTC exocrine pancreatic insufficiency drug products. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC exocrine pancreatic insufficiency drug products.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC exocrine pancreatic insufficiency drug products as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. Modifications have been

made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them.

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking for OTC exocrine pancreatic insufficiency drug products (published in the **Federal Register** of December 21, 1979; 44 FR 75666), the agency suggested that the conditions included in the monograph (Category I) be effective 30 days after the date of publication of the final monograph in the **Federal Register** and that the conditions excluded from the monograph (Category II) be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph, regardless of whether further testing was undertaken to justify their future use. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that it is impractical to expect new labeling to be in effect 30 days after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products may have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be a further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register**. The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes, cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31696) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Tentative Conclusions on the Comments

All comments objected for varying reasons to the Panel's recommendation that pancreatic extracts (pancreatin and pancrelipase) for treating exocrine pancreatic insufficiency be available OTC.

1. Several comments stated that pancreatic extracts should not be available OTC because the disease states that lead to exocrine pancreatic insufficiency, e.g., cystic fibrosis, chronic pancreatitis, post-pancreatectomy, and pancreatic ductal obstruction, require physician diagnosis and treatment. The comments argued that, generally, OTC drug products should be used to treat self-diagnosable conditions and that the public should be able to determine the safe and effective dosage levels from the labeling. The comments contended that none of these criteria are satisfied with respect to pancreatic extracts.

The agency agrees that, in general, the criteria stated by the comments are important in deciding whether a drug should be prescription or OTC. However, these criteria are not the sole determining factors. Section 503(b)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)(1)(B)) sets out the principal statutory requirements with respect to the marketing status of a drug. Specifically, it states that a drug shall be dispensed only upon prescription when "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [it] is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." In the case of pancreatic extracts, the agency does not believe the statutory requirements for prescription restriction are met.

Although the condition of exocrine pancreatic insufficiency requires diagnosis by a physician and the disease states that give rise to exocrine pancreatic insufficiency require close monitoring by a physician, the agency believes that once the insufficiency is diagnosed, a consumer can safely and effectively self-treat the condition with pancreatic extracts.

The recommended OTC dose of pancreatic extracts is virtually free of toxicity. Although doses in considerable excess of the recommended dose have been associated with hyperuricosuria (increased amounts of uric acid in the urine) and hyperuricemia (increased amounts of uric acid in the blood), these problems have not been observed at the recommended OTC dose nor have the increased levels of uric acid been associated with any clinical manifestations. (See comment 2 below.) Also, as discussed in comments 2, 3, and 4 below, other adverse effects that have been associated with these products may be adequately handled through labeling. The agency does not believe that these effects are significant enough to warrant restricting the pancreatic extracts to prescription status.

The agency recognizes that the dose of pancreatic extracts is highly individualized, but believes that the patient is able to self-monitor the presenting symptom (stools with a high fat content) and make any necessary adjustments within the OTC recommended dose. For example, if a person snacks between meals, additional doses of the pancreatic extracts may need to be taken to keep the fatty stools under control. However, the need to adjust dosage is dependent on the amount and content of the diet and will vary from individual to individual. Even if the pancreatic extracts were limited to prescription status, the patient would need to make these same adjustments.

Because the condition of exocrine pancreatic insufficiency can be self-monitored and because pancreatic extracts are not toxic at the recommended OTC dose, the agency sees no need to restrict these drugs to prescription status.

The agency is also aware that a number of pancreatic extract products have been available OTC for many years, whereas others have been available only on prescription. The agency is unaware of any safety problems associated with those products which have been available OTC. There is no reason for perpetuating the dual marketing of these products. Therefore, the agency is proposing that pancreatin and pancrelipase, at the dosages recommended by the Panel, be available OTC.

2. Two comments objected to the OTC availability of pancreatic extracts because hyperuricosuria and hyperuricemia have been associated with their use. The comments supplied several references to support their position (Refs. 1, 2, and 3). One comment also noted that the use of pancreatic extracts may results in obstipation (intractable constipation) or intestinal obstruction (Refs. 4, 5, and 6).

The maximum daily dose recommended by the Panel for pancreatin was 42 grams (g) and 3.5 g for pancrelipase. In each of the references cited by the comments, hyperuricosuria or hyperuricemia was reported to result from daily doses of pancreatic extracts in considerable excess of those recommended by the Panel. However, even when hyperuricosuria or hyperuricemia occurred, the increased uric acid levels are not associated with any clinical manifestations. The agency is unaware of any reports of hyperuricosuria or hyperuricemia when pancreatic extracts are given within the dosage range recommended by the Panel. Likewise, obstipation and intestinal obstruction have been associated with excessive doses of pancreatic extracts, but have not been reported at the recommended OTC dose.

The agency believes that the symptoms of exocrine pancreatic insufficiency can be controlled in most patients within the dosage limits recommended by the Panel. Although recognizing that some patients may require medication in excess of the labeled dose, the agency does not believe the dose should be exceeded without a doctor's knowledge. For this reason, the agency is proposing a warning (§ 357.450(c)(2)) in this tentative final monograph to state clearly that the dose should not be exceeded unless directed by a doctor.

The agency does not believe that the concerns regarding hyperuricosuria, hyperuricemia, obstipation, or intestinal obstruction from the use of pancreatic extracts warrant restricting these drugs to prescription status.

References

(1) Stapleton, F.B., et al., "Hyperuricosuria Due to High-Dose Pancreatic Extract Therapy in Cystic Fibrosis," *New England Journal of Medicine*, 295:246–248, 1976.

(2) Nousia-Arvanitakis, S., et al., "Therapeutic Approach to Pancreatic Extract-Induced Hyperuricosuria in Cystic Fibrosis," *Journal of Pediatrics*, 90:302–305, 1977.

(3) Davidson, G. P., et al., "Iatrogenic Hyperuricemia in Children with Cystic Fibrosis," *Journal of Pediatrics*, 93:976–978, 1978.

(4) Wood, R. E., T. F. Boat, and C. F. Doershuk, "State of the Art—Cystic Fibrosis," *American Review of Respiratory Diseases*, 113:833–875, 1976.

(5) Letter from C. Denning, St. Vincent's Hospital to R. Vodra, Cystic Fibrosis Foundation, included in Comment No. C00005, Docket No. 79N–0379, Dockets Management Branch.

(6) Letter from H. Shwachman, The Children's Hospital Medical Center to R. J. Beall, Cystic Fibrosis Foundation, included in Comment No. C00005, Docket No. 79N–0379, Dockets Management Branch.

3. One commenter, citing personal experiences in treating patients with pancreatic extracts, reported that serious ulcerations of the mouth, lips, and tongue can occur from chewing tablets of pancreatic extracts. The commenter pointed out that this problem is of particular concern in cystic fibrosis patients because the ulceration provides an ideal portal of entry for the pathogenic bacteria constantly harbored by these patients. The commenter questioned whether pancreatic extracts should be available OTC in light of these adverse effects.

The agency is aware that if the pancreatic extracts are retained in the mouth, the enzymes will begin to digest the mucous membranes and cause ulcerations. However, the agency believes that the labeling of these products can adequately guard against this problem by including the following warning: "Swallow quickly to lessen potential for mouth irritation." In addition, the agency is proposing that tablet dosage forms contain the warning "Do not chew."

4. One comment cited reports of hypersensitivity reactions, including life-threatening asthmatic attacks (anaphylaxis), occurring in parents who administer powdered dosage forms of pancreatic extracts to children (Refs. 1, 2, and 3). The comment stated that these adverse reactions should be considered in deciding whether these drugs are safe for OTC use.

The agency is aware of a number of case reports in the literature of allergic reactions occurring after repeated inhalation of pancreatic extract powder in persons administering the drug (Refs. 3 through 11). The incidence of these reactions is estimated to be between 5 to 11 percent of the population exposed to pancreatic extracts (Ref. 3). For the most part, the reactions are limited to rhinitis, conjunctivitis, and mild asthma symptoms. Although more severe reactions have been reported, they do not appear to be widespread, and restricting the drugs to prescription status would not have prevented them from occurring. However, the agency believes the problems could be minimized by including a warning on these products advising persons not to inhale the powder and is proposing the following warning for pancreatic extracts marketed as powders: "Avoid inhalation of powder. Sensitive individuals may experience allergic

reactions." Also, because parents often open the capsule dosage form and sprinkle the contents on their child's food, the following warning is proposed for capsule dosage forms: "If capsules are opened, avoid inhalation of powder. Sensitive individuals may experience allergic reactions."

References

(1) Letter from C. Denning, St. Vincent's Hospital to R. Vodra, Cystic Fibrosis Foundation, included in Comment No. C00005, Docket No. 79N–0379, Dockets Management Branch.

(2) Letter from H. Shwachman, The Children's Hospital Medical Center to R. J. Beall, Cystic Fibrosis Foundation, included in Comment No. C00005, Docket No. 79N–0379, Dockets Management Branch.

(3) Ganier, M., and P. Lieberman, "IgE Mediated Hypersensitivity to Pancreatic Extract (PE) In Parents of Cystic Fibrosis (CF) Children," *Clinical Allergy*, 9:125–132, 1979.

(4) Nakamura, S., "On Occupational Allergic Asthma of Different Kinds Newly Found in Our Allergy Clinic," *Journal of Asthma Research*, 10:37–47, 1972.

(5) Dolan, T. F., and A. Meyers, "Bronchial Asthma and Allergic Rhinitis Associated With Inhalation of Pancreatic Extracts," *American Review of Respiratory Disease*, 110:812–813, 1974.

(6) Hill, D., "Pancreatic Extract Lung Sensitivity," *Medical Journal of Australia*, 2:553, 1975.

(7) Sakula, A., "Bronchial Asthma Due to Allergy to Pancreatic Extract: A Hazard in the Treatment of Cystic Fibrosis," *British Journal of Diseases of the Chest*, 71:295–299, 1977.

(8) Chignell, R., "External Influences On Nose and Throat," *Proceedings of the Royal Society of Medicine*, 65:679–681, 1972.

(9) Abernathy, R. S., "Why Wasn't Mother Skin Tested?", *Pediatrics*, 56:141, 1975.

(10) Bergner, A., and R. K. Bergner, "Pulmonary Hypersensitivity Associated With Pancreatin Powder Exposure," *Pediatrics*, 55:814–817, 1975.

(11) Twarog, F. G., "Hypersensitivity to Pancreatic Extract In Parents of Patients, With Cystic Fibrosis," *Journal of Allergy and Clinical Immunology*, 59:35, 1977.

5. Several comments stated that it is not feasible or possible to describe, in lay terms, the clinical, dietary, and other considerations necessary for consumers to select pancreatic extracts and to determine the dosage levels and modes of administration of these products. The comment contended that although the Panel recommended maximum daily doses for pancreatin and pancrelipase, these levels may be excessive for some individuals and inadequate for others. In addition, because of the wide variation in enzyme activities among products, and, in some cases, variations in enzyme levels between different forms of the same product, a consumer cannot readily make comparisons between products.

As discussed in comment 1 above, the agency recognizes that the dose of pancreatic extracts is highly individualized, but believes that patients are able to self-monitor their condition and make the necessary dosage adjustments as needed. Also, because these drug products would be used only after a diagnosis of exocrine pancreatic insufficiency has been made by a physician, the physician will have the opportunity to give advice on other clinical and dietary considerations.

The agency recognizes that because of the varying amounts of enzyme activities in pancreatic extract products it is important that the labeling of these products state the level of lipase, amylase, and protease activity per dosage unit. Therefore, the agency is proposing in this tentative final monograph that the enzyme activity levels per dosage unit be stated on the labeling of pancreatic extract products.

6. Several comments objected to the OTC availability of pancreatic extracts because persons not suffering from exocrine pancreatic insufficiency would have unlimited access to these drugs. The comments argued that there is no scientific evidence that people who do not have pancreatic insufficiency would benefit by consuming these drugs. In addition, the comment argued that long-term safety of these drugs in persons without pancreatic insufficiency has not been adequately assessed.

Pancreatic extracts have been available on the OTC market for many years in various digestive aid products. The Advisory Review Panel on OTC Miscellaneous Internal Drug Products also reviewed pancreatin and pancrelipase for the use in digestive aid drug products. In its report published in the **Federal Register** of January 5, 1982 (47 FR 454), the Panel concluded that these drugs are safe, but that additional data are needed to determine their effectiveness for testing symptoms of intestinal distress. The agency's position of the use of pancreatic extracts in digestive aid drug products will be stated in a future issue of the **Federal Register.** In addition, the label of pancreatic extracts intended for use in treating exocrine pancreatic insufficiency will carry a warning telling people not to take the product unless directed by a doctor. Nevertheless, these products should cause no harm in individuals who do not have exocrine pancreatic insufficiency if taken according to the labeled directions and other warnings.

7. Several comments contended that if pancreatic extract preparations were available OTC, cystic fibrosis patients would avoid checkups with their physician, thus allowing other complications (e.g., pulmonary infection or deterioration of pulmonary function) to go untreated.

The agency shares the comments' concern, but disagrees that the OTC availability of pancreatic extracts will cause cystic fibrosis patients to avoid checkups with their physician. Exocrine pancreatic insufficiency is only one component of the cystic fibrosis syndrome. Chronic obstructive pulmonary disease occurs in almost all cases of cystic fibrosis and is the major cause of morbidity and mortality in these patients. The pulmonary involvement tends to be progressive and to become severe enough that physician intervention is necessary. The pancreatic extracts have no effect on the progression of the lung involvement. In addition, the agency believes that patients with cystic fibrosis recognize the seriousness of their condition and will make frequent physician visits whether or not the pancreatic extracts are available OTC.

8. Several comments objected to the OTC availability of pancreatic extracts because many third-party reimbursers do not reimburse for OTC medications. The comments argued that making the pancreatic extracts available OTC would impose an insurmountable financial burden on patients who require these drugs.

In comment 1 above, the agency discusses the statutory provisions regarding prescription or OTC status of a drug. Financial considerations are not among the statutory criteria and, therefore, cannot be used in deciding whether pancreatic extracts should be available OTC. FDA is aware of variability in third-party reimbursements for OTC drugs. Because pancreatic extracts, for the most part, are also maintenance drugs, third-party reimbursers might wish to consider the need for any changes in current reimbursement policies for these drugs.

II. The Agency's Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

The agency has reviewed the claimed active ingredients submitted to the Panel as well as other data and information available at this time and concurs with the Panel's categorization of pancreatin and pancrelipase in Category I and hemicellulase in Category II for use in exocrine pancreatic insufficiency.

2. Testing of Category II and Category III Conditions

Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any exocrine pancreatic insufficiency ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the **Federal Register** of September 29, 1981 (46 FR 47740) and clarified in the **Federal Register** of April 1, 1983 (48 FR 14050). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made in the Panel's conclusions and recommendations follows.

1. The Panel did not recomend a specific statement of identity. The agency is proposing "pancreatic enzyme replacement" as the statement of identity for OTC pancreatic extract drug products.

2. The agency is proposing a warning to guard against the potential for mouth irritation. (See comment 3 above.)

3. The agency is proposing a warning advising against inhalation of pancreatic extract powder. (See comment 4 above.)

4. The agency is proposing that the enzyme activity levels per dosage unit be stated on the labeling of pancreatic extract products. (See comment 5 above.)

5. In an effort to further clarify the labeling of pancreatic extract products, the agency is proposing that the indications be limited to the following: "For the treatment of exocrine pancreatic insufficiency." In addition, the following warning is being proposed: "Do not take this product unless directed by a doctor." The agency believes that these two statements will be more meaningful and less confusing to consumers than the indication statement recommended by the Panel in § 357.450(b).

b. Because pancreatin is available from beef or pork (Ref. 1), the agency is proposing in this tentative final monograph that the pork-allergenicity warning recommended by the Panel in § 357.450(c) be included only on the labeling of pork-derived pancreatic extract products. For consistency in style between this and other similar warnings in other OTC drug monographs, the agency is proposing that the warning read as follows: "Do not take this product if you are allergic to pork."

7. Although the Panel recommended that the dose of pancreatic extracts be "as recommended by a physician," the agency does not believe that these directions are adequate for OTC labeling. The Panel did not specify whether the recommended maximum daily dose of pancreatic extracts was for adults or children, but the agency has determined that the dose applies to children as well as to adults. The agency is also aware that there is little difference in effectiveness between giving pancreatic extracts in divided doses with meals or giving them in evenly spaced intervals (1 to 2 hours) throughout the day (Ref. 2). Therefore, the agency is proposing that the labeling indicate that the maxium daily recommended dose of pancreatic extracts be administered to adults or children either in divided doses with meals (with an extra dose taken with food eaten between meals) *or* at 1- to 2-hour intervals throughout the day *or* as directed by a doctor.

8. The agency is aware that the United States Pharmaceopeia (U.S.P.) monographs for pancreatin and pancrelipase specify only the minimum amounts of enzyme activity per milligram (mg) and do not specify any upper limit of enzyme activity (Ref. 1). In addition, marketed products contain varying levels of enzyme activity per mg. The agency believes it would be confusing to specify the maximum daily recommended dose only in terms of a gram amount because there is no standard correlation between that amount and enzyme activity.

Also, it is not clear from the U.S.P. monographs whether the ratios of activity level (2 U.S.P. units lipase:25 U.S.P. units protease:25 U.S.P. units amylase for pancreatin; and 24 U.S.P. units lipase:100 U.S.P. units protease:100 U.S.P. units amylase for pancrelipase) are to be maintained in all products. The U.S.P. is also aware of these problems and presently has a revision committee looking into them (Ref. 3).

For these reasons, the agency is proposing in this tentative final monograph to include the maximum daily recommended enzyme activity levels based on the minimum levels established in the U.S.P. in addition to the gram amounts as follows: For pancreatin the maximum daily recommended dose is 42 g, equivalent to 84,000 U.S.P. units lipase activity, 1,050,000 U.S.P. units protease activity and 1,050,000 U.S.P. units amylase activity. For pancrelipase the maximum daily recommended dose is 3.5 g, equivalent to 84,000 U.S.P. units lipase activity, 350,000 U.S.P. units protease activity, and 350,000 U.S.P. units amylase activity. The agency invites specific comment on these proposed dosage limits.

References

(1) "United States Pharmacopeia XXI—National Formulary XVI," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 777–781, 1985.

(2) DiMagno, E. P., et al., "Fate of Orally Ingested Enzymes in Pancreatic Insufficiency—Comparison of Two Dosage Schedules," *New England Journal of Medicine*, 296:1318–1322, 1977.

(3) Memorandum of telephone conversation between J. Short, FDA, and E. Theimer, U.S.P., concerning interpretation of the U.S.P. Pancreatin and Pancrelipase monographs, August 22, 1983, copy included in OTC Volume 17BTFM.

9. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and any applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor". This tentative final monograph proposes that option.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC exocrine pancreatic insufficiency drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a

substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96-354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC exocrine pancreatic insufficiency drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC exocrine pancreatic insufficiency drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC exocrine pancreatic insufficiency drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on exocrine pancreatic insufficiency drug products, a period of 120 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. 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.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact, and the evidence supporting that finding may be seen in the Dockets Management Branch, Food and Drug Administration (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636). Under the new rule, an action of this type would require an environmental assessment under 21 CFR 25.31a(a).

Sections 357.450(d) (1) and (2) of this proposed rule contain collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these collection of information requirements. Other organizations and individuals desiring to submit comments on these collections of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Bruce Artim.

Exclusivity of Labeling. In the **Federal Register** of April 22, 1985 (50 FR 15810) the agency proposed to change its "exclusivity" policy for the labeling of OTC drug products that has existed during the course of the OTC drug review. Under this policy, the agency has maintained that the terms that may be used in an OTC drug product's labeling are limited to those terms included in a final OTC drug monograph.

The proposed rule would establish three alternatives for stating the indications for use in OTC drug labeling while all other aspects of OTC drug labeling (i.e., statement of identity, warnings, and directions for use) would continue to be subject to the existing exclusivity policy. The proposed rule for OTC exocrine pancreatic insufficiency drug products included in this document incorporates the exclusivity proposal by providing for the use of other truthful or nonmisleading statements in the product's labeling to describe the indications for use. After considering all comments submitted on the proposed revision to the exclusivity rule, the agency will announce its final decision on this matter in a future issue of the **Federal Register**. The final rule for OTC exocrine pancreatic insufficiency drug products will incorporate the final decision on exclusivity of labeling.

Interested persons may, on or before January 7, 1986 submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-64, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before March 10, 1986. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to 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. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register**.

Interested persons, on or before November 10, 1986, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before January 8, 1987. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on January 8, 1987. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 357

OTC drugs; anthelmintic drug products, cholecystokinetic drug products, deodorant drug products for internal use, exocrine pancreatic insufficiency drug products, orally administered drug products for fever blisters, poison treatment drug products, and smoking deterrent drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 357 by adding new Subpart E as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart E—Exocrine Pancreatic Insufficiency Drug Products

Sec.
357.401 Scope.
357.403 Definition.
357.410 Exocrine pancreatic insufficiency active ingredients.
357.450 Labeling of exocrine pancreatic insufficiency drug products.

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

Subpart E—Exocrine Pancreatic Insufficiency Drug Products

§ 357.401 Scope.

(a) An over-the-counter exocrine pancreatic insufficiency drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart in addition to each of the general conditions established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.403 Definition.

As used in this subpart:

Exocrine pancreatic insufficiency. A condition in which the symptoms are due to inadequate exocrine pancreatic secretion as diagnosed by a physician.

§ 357.410 Exocrine pancreatic insufficiency active ingredients.

The active ingredient of the product consists of either one of the following when used within the dosage limits established for each ingredient:

(a) Pancreatin.

(b) Pancrelipase.

§ 357.450 Labeling of exocrine pancreatic insufficiency drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "pancreatic enzyme replacement."

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For the treatment of exocrine pancreatic insufficiency." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the prohibitions in section 502(a) of the act against misbranding by the use of false or misleading labeling and the prohibition in section 301(d) of the act against the introduction into interstate commerce of unapproved new drugs.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "Do not take this product unless directed by a doctor."

(2) "Do not exceed the labeled dose unless directed by a doctor."

(3) "Swallow quickly to lessen potential for mouth irritation."

(4) *For tablet dosage forms.* "Do not chew."

(5) *For powder dosage forms.* "Avoid inhalation of powder. Sensitive individuals may experience allergic reactions."

(6) *For capsule dosage forms.* "If capsules are opened, avoid inhalation of powder. Sensitive individuals may experience allergic reactions."

(7) *For pork-derived pancreatic products.* "Do not take this product if you are allergic to pork."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing pancreatin.* The daily dose of pancreatin is up to 42 grams (equivalent to 84,000 U.S.P. units lipase activity, 1,050,000 U.S.P. units protease activity, and 1,050,000 U.S.P. units amylase activity) either in divided doses at 1- or 2-hour interval *or* with meals and an extra dose taken with food eaten between meals *or* as directed by a doctor. The label must state the amount of enzyme activity per dosage unit in terms of U.S.P. units of lipase, amylase, and proteases activity.

(2) *For products containing pancrelipase.* The daily dose of pancrelipase is up to 3.5 grams (equivalent to 84,000 U.S.P. units lipase activity, 350,000 U.S.P. units protease activity, and 350,000 U.S.P. units amylase activity) either in divided doses at 1- or 2-hour intervals *or* with meals and an extra dose taken with food eaten between meals *or* as directed by a doctor. The label must state the amount of enzyme activity per dosage unit in terms of U.S.P. units of lipase, amylase, and protease activity.

(e) The word "physican" may be substituted for the word "doctor" in any of the labeling statements in this section.

Dated: October 8, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

[FR Doc. 85–26687 Filed 11–7–85; 8:45 am]

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federal register

Friday
November 8, 1985

Part VI

Environmental Protection Agency

40 CFR Part 280

Notification Requirements for Owners of Underground Storage Tanks; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 280

[OSW-FRL 2911-6]

Notification Requirements for Owners of Underground Storage Tanks

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Today the Environmental Protection Agency (EPA) is publishing a notification form to be used by owners of underground storage tanks that store or have stored petroleum or hazardous substances. Under section 9002 of the Resource Conservation and Recovery Act (RCRA), as amended, these owners are required to notify designated State or local agencies of the existence of their tanks. In publishing this form, EPA is fulfilling its obligation under section 9002(b) to prescribe the form of notice and the information it must contain. On May 28, 1985, EPA proposed two notification forms in the **Federal Register** (50 FR 21772–21781). In addition, the Agency noticed the availability of a revised form on August 30, 1985 in the **Federal Register** (50 FR 35261). Today's rulemaking reflects several modifications made to the proposed forms as well as the revised form in response to comments received. The form published today must be used by all owners subject to the section 9002 notification provisions unless the State in which the tank is located requires use of its own form or forms and such form(s) meet the requirements of section 9002.

DATE: Final rule effective November 8, 1985.

ADDRESS: The public docket for this final rule [Docket No. 9002] is located in Room S–212, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, and is available for viewing from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays. This docket contains, among other material, the economic analyses, background documents, and comments discussed in this preamble.

FOR FURTHER INFORMATION CONTACT: The RCRA/Superfund Hotline at (800) 424–9346 (toll free) or (202) 382–3000 in Washington, D.C.; or Virginia Cummings, Office of Solid Waste (WH–565A), U.S. Environmental Protection Agency, Washington, D.C. 20460, (202) 382–7925.

For information on implementation of this rulemaking, contact the EPA regional office below:

Region I

William Torrey, Waste Management Division, 150 Causeway Street, Room 701–709, Boston, Massachusetts 02223, (617) 223–6883

Region II

Tom Taccone, Program Support Section, Solid Waste Branch, 26 Federal Plaza, New York, New York 10278, (212) 264–0504

Region III

Dennis Carney, Hazardous Waste Management Division, 841 Chestnut Street, Philadelphia, Pennsylvania 19107, (215) 597–3182

Region IV

Mike Williams, Waste Management Division, 345 Courtland Street, N.E., Atlanta, Georgia 30365, (404) 881–3633

Region V

Gerald Phillips, Waste Management Division, 230 South Dearborn Street, Chicago, Illinois 60604, (312) 335–6159

Region VI

Faye Sandberg, Hazardous Materials Branch, 1201 Elm Street, Dallas, Texas 75270, (214) 767–2941

Region VII

Chest McLaughlin, RCRA Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101, (913) 236–2852

Region VIII

C. Jay Silvernale, LUST Coordinator, 999 18th Street, Suite 1300, Denver, Colorado 80202, (303) 293–1503

Region IX

Eve Levin, RCRA Program Section, 215 Fremont Street, San Francisco, California 94105, (415) 974–8169

Region X

Joan Cabreza, Waste Management Branch, RCRA Program Development Section, 1200 6th Avenue, Seattle, Washington 98101, (206) 442–0344

SUPPLEMENTARY INFORMATION:

I. Authority

These regulations are issued under the authority of sections 9001, 9002, and 9006 of the Resource Conservation and Recovery Act (RCRA) of 1976, as amended (42 U.S.C. 6991, 6992, and 6996).

II. Background

A. The Statutory Framework

On November 8, 1984, President Reagan signed the Hazardous and Solid Waste Amendments of 1984. These Amendments extend and strengthen the provisions of the Resources Conservation and Recovery Act (RCRA) of 1976, the Federal law protection human health and the environment from improper waste management practices. One of the new RCRA provisions, Subtitle I, initiates a program to control hazards created by underground storage tanks. The Subtitle I program regulates underground tanks that store petroleum and substances defined as hazardous under section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (except substances regulated as hazardous wastes under Subtitle C of RCRA).

Underground storage tank is defined in section 9001(1) of Subtitle I as "any one or combination of tanks (including underground pipes connected thereto) which is used to contain an accumulation of regulated substances, and the volume of which (including the volume of the underground pipes connected thereto) is 10 percent or more beneath the surface of the ground."

Section 9001(1) excludes the following from the definition of underground storage tank:[1]

(1) Farm or residential tanks of 1,100 gallons or less capacity used for storing motor fuel for noncommercial purposes;

(2) Tanks used for storing heating oil for comsumptive use on the premises where stored;

(3) Septic tanks;

(4) Pipeline facilities (including gathering lines) regulated under (a) the Natural Gas Pipeline Safety Act of 1968, (b) the Hazardous Liquid Pipeline Safety Act of 1979, or (c) which is an intrastate pipeline facility regulated under State laws comparable to the provisions of law referred to in (a) and (b) above;

(5) Surface impoundments, pits, ponds, or lagoons;

(6) Storm water or wastewater collection systems;

(7) Flow-through process tanks;

(8) Liquid traps or associated gathering lines directly related to oil or gas production and gathering operations; or

(9) Storage tanks situated in an underground area (such as a basement, cellar, mineworking, drift, shaft, or tunnel) if the tank is situated upon or above the surface of the floor.

Subtitle I was developed by Congress in response to a growing number of groundwater contamination incidents caused by substances leaking from underground storage tanks. To assist States in locating and evaluating such tanks, Congress required in section 9002 of Subtitle I that owners of underground storage tanks notify designated State or local agencies of the existence of their tanks. As a means of enforcing the

[1] The term underground storage tank does not include any pipes connected to any of the tanks described in the exclusions.

notification requirements for owners of such tanks. Congress authorized the assessment of civil penalties against any owner who knowingly fails to notify or who submits false information regarding any tank for which notification is required.

B. The Notification Requirements

Section 9002 requires owners of underground storage tanks used to store or dispense regulated substances on or after November 8, 1984, to notify by May 8, 1986, and provide information on the age, size, type, location, and use of each tank.[2] Owners who bring underground storage tanks into use after May 8, 1986, must notify within 30 days of bringing the tank into use and provide information on the age, size, type, location, and use of such tanks.

Section 9002 also imposes requirements on owners of underground storage tanks which were taken out of operation after January 1, 1974, but remain in the ground. Owners of these tanks must notify by May 8, 1986, and provide information to the extent known on the date the tank was taken out of operation; the size, type, and location of the tank; and the type and quantity of substances left stored in the tank on the date it was taken out of operation.

With respect to tanks in use on or after November 8, 1984, the term "owner" is defined in the statute as "any person who owns an underground storage tank." Thus, for any tank used to store or dispense regulated substances after November 8, 1984, the "owner" is the current owner.

With respect to tanks permanently taken out of operation before November 8, 1984, the statute defines "owner" as any person who owned the tank "immediately before discontinuation of its use." Thus for tanks taken out of operation between January 1, 1974 and November 8, 1984, the person obligated to provide notification concerning the tank is the person who last owned the tank before it was taken out of use.

To ensure that owners of underground storage tanks are informed of their responsibility to notify, Congress also imposed certain obligations on persons who deposit regulated substances in tanks and on tank sellers. From December 9, 1985 through May 9, 1987 anyone depositing regulated substances in an underground storage tank must notify the owner or operator of such tanks of the owner's notification responsibilities. Beginning 30 days after EPA issues new tank performance standards under section 9003(e), any person who sells a tank intended to be used as an underground storage tank must inform the purchaser of the tank of the owner's notification requirements.

Section 9002 requires EPA, in consultation with State and local officials and after notice and opportunity for public comment, to prescribe the form of the notice and the information it must contain. Section 9002 requires that designated State or local agencies, not EPA, receive the notification. EPA has provided in Appendix II a list of these Agencies. Owners of underground storage tanks are advised to consult this list to determine: (1) To whom notice must be sent; and (2) whether the State in which the underground tank is located requires the use of the EPA form or an alternate State form for notification purposes. The State forms noted in Appendix II have been reviewed by EPA and are consistent with Federal requirements. Owners may thus use these forms to fulfill their Federal notice obligation. The listing, however, does not represent an EPA finding that State requirements, such as those concerning who must notify and when notification must be received, are consistent with section 9002.

III. Response to Comments on the Proposed Notification Requirements

A. Introduction

The majority of the commenters supported the proposed rulemaking with minor modifications. Five major issues, however, were raised in the comment letters received by the Agency on the May 28, 1985, proposal. These issues concerned:

1. Mandatory use of the Federal notification form by all tank owners;
2. Additional information to be provided by tank owners;
3. Clarification of certain definitions;
4. Notification responsibilities for sellers of tanks and depositors of regulated substances;
5. Implementation of the notification requirements.

1. Mandatory use of the Federal notification form.

In the preamble to the proposed rule, EPA suggested that States could modify the Federal notification forms to obtain additional information, or develop a separate notification form specifically suited to State needs. The issue most frequently mentioned by commenters was whether EPA should require States to use EPA's form or to use their own forms. Many industry commenters felt that EPA should encourage States to adopt EPA's form in the interest of maintaining uniformity and simplicity in the underground storage tank program. For companies with underground storage tanks in two or more States, they noted, compliance with the notification provisions of EPA's underground storage tank regulations would be considerably simplified if a uniform Federal notification form were required. They argued that, should a State insist upon having additional information, the State could provide an addendum to the Federal form or carry out a follow-up data request on only those facilities of interest.

In addition, several commenters expressed the belief that section 9002 requires EPA to prescribe a form to be used nationwide and that there is no statutory authority for EPA to approve alternative State forms.

In response to these comments, the Agency points out that section 9002 does not require EPA to mandate nationwide use of the Federal form. It merely requires EPA to "prescribe the form of notice and the information to be included in the notifications." Using a standard dictionary definition, the word "prescribe" can be interpreted several ways. It could mean "to lay down as a guide, direction, or rule of action; to specify with authority; or to designate or order the use as a remedy." Accordingly, EPA believes that section 9002 provides EPA the flexibility to prescribe its form as a guide for States but does not necessarily mandate use of EPA's form by States that opt to use their own forms.

In light of the specific language used in this provision, the Agency believes that the phrase "to prescribe the form of the notice" does not require the use of one standardized notice form. Rather, the Agency believes that the statute requires it to set out the type of notice that will comply with section 9002 information requirements.

The EPA form is to be used as the notice form in States where no State notification forms have been developed (that conform to the minimum statutory requirements) and as a guide for States that develop their own forms. This interpretation accords with EPA's view of the principal purpose of section 9002, which is to aid States in developing basic information concerning the tank universe within their borders.

Furthermore, EPA believes that it would be unreasonable to require States with notification programs already underway that satisfy the requirements of section 9002 to adopt the Federal forms. For them to make major changes in their programs and to require a second notification would be a needless

[2] No notification is required for tanks taken out of the ground prior to May 8, 1986 or for tanks taken out of operation on or before January 1, 1974.

and expensive duplication of effort for both the State and the tank owner subject to its reporting requirements. In those States where data collection that accords with the requirements of section 9002 has already taken place, therefore, EPA believes that notification under these State registration programs should be accepted as compliance with section 9002. Thus, EPA is not requiring States to use the Federal form if the State provides a form that meets the statutory requirements of section 9002.

In response to the argument made by commenters for mandating use of the Federal form with a State addendum, EPA does not believe that this action would significantly reduce the burden to tank owners. The regulated community may need to provide as much information in an addendum as would be required by a State form.

In light of the burden on owners subject to reporting in more than one State, the Agency is encouraging States to use the EPA form. EPA has tried to produce a form that States will want to use, one that is simple and straightforward, yet meets the requirements of section 9002. We have worked closely with many States in developing the form and have communicated to them that the objective of the present notification program is to obtain basic and accurate information quicky while avoiding imposition of excessive burdens or unproductive requirements on the regulated community. In addition, we notified the public of the availability of a new form in the **Federal Register** on August 30 (50 FR 35261) and invited comments on it. The present form reflects those comments on both the May and August proposals.

2. Additional information to be provided by tank owners.

In the preamble to the proposed rule (50 FR 21774, May 28, 1985), the Agency indicated that it had rejected the option of requiring more information from tank owners than is expressly required under section 9002. EPA expressed its belief that inclusion of additional information requirements across the board, in all States, would involve increased time and costs to the regulated community and to the State or local agency processing the information. EPA noted that if a State prefers to request more information, it can provide an addendum to the EPA form to suit its needs or develop its own form.

The Agency solicited comment from the States in the proposal on the applicability of the proposed forms to their needs. At that time, EPA also requested comment from the members of the public who would be required to use the form.

Commenters representing six States believed EPA should require additional information. Many State commenters stated that EPA should require a description of any leaks or spills that have occurred at the facility. Other commenters said the notification forms should contain information on the installation status (i.e., whether the tank was installed under industry approved methods) and on methods or equipment used for leak detection or prevention.

Nearly all of the commenters who opposed additional information requirements were members of the regulated community. Many of these commenters recommended that EPA resist all attempts to expand and further complicate the notification form to include additional information not specifically required by section 9002. They argued that additional information requirements would increase the cost and complexity of implementation.

In response to EPA's suggestion that States could "piggy back" additional State information requirements to the Federal form, only one industry representative expressly disapproved. That commenter felt that EPA should discourage States from providing an addendum to the Federal form on the grounds that the initial notification should not attempt to address all the questions that may arise concerning underground storage tanks. Several other commenters said that States that perceive gaps in the section 9002 notification program or that require additional information for their particular tank programs should use section 9004 ("Approval of State programs") rather than 9002 to obtain that data.

The Agency believes that the latter commenter's reference to section 9004 in this matter is inappropriate. Section 9004 provides for the approval by EPA of State underground storage tank programs that meet minimum Federal requirements. It requires that States seeking approval have a notification program that accords with the requirements of section 9002, but it does not provide States authority apart from section 9002 to collect information for notification purposes.

After careful consideration of the other comments and concerns described above, EPA has decided to promulgate a form that will limit the information required in the notification form to those matters specifically mentioned, in section 9002. The Agency based this decision on a number of factors. First, the Agency believes that the purpose of the notification program is to collect information that could be used to develop a preliminary tank inventory. To add more detailed reporting requirements would convert the relatively modest notification obligation contemplated by Congress into a major undertaking. The Agency believes there will be ample opportunity later for the States and tank owners to consider what additional information might be necessary for the administration of ongoing State programs.

Second, the Agency also recognizes that requiring additional information will escalate costs because such additional information may often be difficult to obtain. Even if one assumes that additional information can be obtained, the Agency questions the value of such information for this notification program. For example, leak detection systems and methods of tank gauging are frequently changed. Thus, such information could soon be outdated or be in need of continuous revision.

In some areas, however, the Agency found it necessary to request additional information. The first area is piping. Although piping is included in the legal definition of underground storage tank contained in section 9001(1), EPA did not differentiate the parts of the tank system in the proposed forms. Several State commenters expressed concern that the proposed form appears to exclude piping, a significant oversight because piping is part of the tank definition and leaks from piping have been identified as a significant source of release incidents. We now include information requirements on the piping portion of the tank separately on the notification form.

The second area for which additional information is required on the final form is closure. For purposes of clarification, a box was added for owners to indicate if the tank was filled with an inert solid material. EPA believes this information can be useful to agencies in determining which of the tanks no longer will require follow-up action.

The third area concerns the addition of a box under "type of notification" where owners can indicate whether the notification is an original submission or an amendment to a previous submission. It should be noted, however, that the submission of this information will be optional on the form and that owners are not required to amend or update their registrations under the Federal law. Nevertheless, owners may be required to update the forms under State law. Thus, the addition of these boxes will be useful in those States.

3. Clarification of certain definitions.

EPA received many comments requesting clarification of several statutory definitions that were found in the proposed rule.

(a) *Owner.* One definition several commenters found unclear was the term "owners." Under the statute an owner is defined as: "(a) in the case of an underground storage tank in use on the date of enactment of the Hazardous and Solid Waste Amendments of 1984, or brought into use after that date, any person who owns an underground storage tank used for the storage, use, or dispensing of regulated substances; and (b) in the case of any underground storage tank in use before the date of enactment of the Act, but no longer in use on the date of enactment, owner means any person who owned such tank immediately before the discontinuation of its use."

A number of commenters found this definition confusing. With respect to tanks taken out of operation by former owners, one commenter stated that, because the term "owner" may include former owners, if the tanks were taken out of service between January 1, 1974 and November 8, 1984, it may be extremely difficult for such owners to know or determine whether their tanks will be placed back into use by subsequent owners. Another commenter stated that, unless a former owner of a nonoperational tank is aware of the requirements, he will probably assume that the current tank owner or landowner where the tank is located is the owner for purposes of notification. One commenter recommended that the definition of tank owner be reworded to make the current owner of the facility responsible for notification.

With respect to tanks of current owners, several comenters pointed out that ownership questions may be difficult to resolve because tanks have been purchased, installed, and transferred under many kinds of arrangements, including partnerships, executory interests, and trusts. In some instances tanks may have been installed under sale and lease-back arrangements, or a bank may have taken title as a security interest for a purchase money loan. One commenter said that because tank owners were often not required to keep documentation concerning the sale or transfer of their tanks, such documentation in many cases had been lost or destroyed.

Several other commenters suggested that with respect to current owners the following approaches be considered, only where ownership may be disputed or is uncertain: (1) presume that the person in direct control of the real property and facilities is the owner of the tank unless he ascertains that another entity accepts ownership and will file the notification form; (2) presume that a person is *not* an owner of the tank if he cannot, through reasonable efforts, confirm the sale or transfer of such tanks, and is not the owner of the real estate where the tank is located, and has not received notice pursuant to the depositor notice requirement.

Another commenter suggested that with respect to all tanks, EPA could indicate that any person with an interest in a tank could submit the required notification without admitting ownership.

EPA has carefully considered these suggestions of the commenters. While EPA cannot revise the definition contained in the statute, the Agency will attempt to clarify its meaning by providing the Agency's interpretation of what tanks EPA considers to be "no longer in use" prior to November 8, 1984, for which notice must be provided by former owners discontinuing their use, and what tanks it considers to be "in use" on or after November 8, 1984, for which notification must be provided by current owners.

With regard to a tank no longer in use on November 8, 1984, for which notification must be provided by the owner who discontinued its use, EPA believes that such an owner should notify if the owner knows or has reason to believe the tank was *permanently* taken out of use for storing regulated substances. Indications that a tank is permanently out of use are: (a) If it is filled with inert solid material or otherwise rendered unusable, or (b) if there is reason to believe that it will not be used in the future (e.g., the owner abandoned the tank, intakes and vents are paved over, access piping is disconnected or removed, or the tank was sold to a person who had no use for the tank, such as a residential real estate developer).

With regard to tanks in use on or after November 8, 1984, notification must be provided by the tank's current owner. If the tank was in operation on November 8, 1984, the current owner is responsible to provide notification under the statute even if the tank was permanently taken out of use after November 8, 1984, and even if the current owner was not the person who took the tank out of use. For example, if a tank was in use on November 8, 1984, but was taken out of use before it was sold to a new owner the following month, the new owner has the responsibility to notify even though the new owner had never used the tank to store regulated substances.

The Agency has presented these interpretations in an effort to minimize confusion concerning the notification requirements for tanks taken out of operation. With respect to tanks for which ownership is unclear because of uncertain title, however, EPA has determined not to adopt presumptions suggested by commenters. The Agency believes these presumptions may define ownership in a manner that is not consistent with the statutory definition of owner. The Agency recognizes the need for further guidance with respect to the definition of "owner," but believes that such guidance cannot be given until the Agency has had an opportunity to consider its implications. EPA will address these issues in a later rulemaking or guidance.

Recognizing that there may be confusion concerning ownership interests and wishing to encourage notification for all tanks, the Agency has decided to modify the notification form to allow persons other than the "owner" to notify. By permitting persons other than the owner to notify, however, the Agency realizes that some double reporting may occur, but such reporting would likely provide States with a more complete inventory of underground storage tanks. Because of this modification to the form, EPA believes it is unnecessary to adopt commenters' suggestions for establishing ownership by using presumptions.

(b) *Depositors.* The Agency also received comments requesting clarification of who is a "person who deposits regulated substances" into a tank for purposes of Section 9002(a)(4)." In the proposed rule, EPA indicated that depositors could include operators, distributors, and transporters. Several commenters recommended that a "person who deposits" should be defined as an entity whose employees or agents physically transfer regulated substances into an underground storage tank. Under this definition, the transporter would be the most likely person to give notice. Commenters did not clarify to whom notice should be given (e.g., hourly worker at facility, supplier, facility office).

Another commenter suggested that the refiner or marketer, not the common carrier or trucker, should be responsible for giving notice to the tank owner. The commenter argued that the refiner or marketer has already been given that responsibility under the FTC octane rules as well as the Department of Energy's price rules.

EPA believes that the purpose of this provision is to provide a source of information via normal commercial relationships for tank owners concerning their responsibility to notify. Thus, EPA has concluded that the burden for informing owners should be

on the party last selling the regulated substances (i.e., the person who conveys title in the substances to the owner) prior to its being placed in the tank, and not necessarily the entity who physically deposits the substance in the tank. The Agency believes that enforceability of the requirements for depositors would be otherwise difficult. For these reasons, the Agency encourages those who sell regulated substances to outline the notification requirements on the shipping papers or on the invoice that accompanies the sale. EPA also acknowledges, however, that there are other acceptable methods for depositors of regulated substances to fulfill their statutory duty to provide reasonable notification to owners or operators. These methods are addressed in more detail elsewhere in this Section.

(c) *Seller.* Several commenters requested that EPA clarify who is "a person who sells a tank intended to be used as an underground storage tank." The Agency believes that the tank seller, in the context of the notification requirements, is the last person in the marketing distribution chain. It should be noted that the notification requirements apply to sellers of second-hand tanks as well as new tanks.

(d) *Underground storage tank.* The Agency received many comments requesting clarification on the statutory definition of underground storage tank. Several commenters suggested that the Agency provide guidance on what is a "tank" and what is "connected piping." Other commenters requested EPA to clarify its intent regarding the following exclusions for tanks: tanks situated in an underground area; liquid traps; flow-through process tanks; pits; and tanks used for storing heating oil for consumptive use on the premises where stored. Several commenters suggested EPA consider a de minimus exemption for small storage tanks.

The Agency recognizes the need for guidance on the terms discussed above. The inclusion of such definitions in the final rulemaking would require proposal, solicitation of comments, and in-depth consideration of the implications of each definition with regard to future rulemakings under Subtitle I. Because the Agency needs time to study the exclusions before it defines these terms, however, EPA has chosen to define such terms when it promulgates technical standards in 1987. The Agency is aware that some tanks may eventually not qualify as underground storage tanks regulated under Subtitle I when the definitions are refined. In the meantime, owners are advised that, until these issues are clarified, the failure to notify will be at their own risk. EPA does not regard the submission of this notification as an admission of ownership for the purpose of this program or for any future regulatory program under Subtitle I. Likewise, failure to notify does not relieve an owner of obligations that are imposed under the statute or under future rulemakings.

4. Notification responsibilities for sellers of tanks and depositors of regulated substances.

In the preamble to the proposed rule, EPA suggested several methods by which a tank seller or depositor of regulated substances could inform the owner, operator, or purchaser of an underground storage tank of the owner's notification responsibilities. These methods included leaving a copy of the EPA notification form with the owner or operator, printing the notification requirements on the shipping papers, or providing a description of the notification requirements on the invoice. The Agency solicited comment from persons who deposit regulated substances into tanks and tank sellers on the kind of guidance that would be helpful to them in communicating the notification requirements to the appropriate persons.

Many commenters agreed with the methods recommended by the Agency and felt that it is essential that persons who deposit regulated substances and tank sellers be given the flexibility to decide how their responsibilities might best be carried out. One commenter also suggested that notification could be in the form of mailing certified letters to the owners or operators advising them of the notification requirements. Other commenters requested that EPA provide standardized wording for use with delivery tickets or invoices and recommended this language be included in an appendix to the final rule.

Several commenters requested clarification on whether a depositor must inform an owner or operator each time product is deliverd during the 18-month notification period or whether a one-time notification complies with the requirements of Section 9002. Other commenters pointed out that there is no guarantee that operators who receive notices from depositors will pass that information on to the owner. They suggested that EPA require an operator who is served notice by the supplier or tank seller to submit such notice to the owner within a specified amount of time.

The Agency would like to reiterate its belief that there are a number of acceptable methods that depositors could use to notify the tank owner or operator of the owner's notification responsibility, including mailing of a certified letter to owners or operators.

EPA also believes there should be a number of acceptable methods available to a tank seller to fulfill his responsibility to inform the tank purchaser of the owner's notification obligations. Thus, EPA does not intend to use this rule to prescribe, restrict, or prohibit any particular method.

In response to the comment that standard language be used by depositors and sellers in notifying owners, EPA agrees that unless EPA recommends such language, there may be inaccuracies or deficiencies in the notice provided. Accordingly, Appendix III sets forth suggested language to be used for a one-time notification letter and for a statement on shipping tickets and invoices.

In response to the comment requesting clarification on the adequacy of a one-time notice by depositors, EPA believes that notifying an owner or operator once during the 18-month period is sufficient.

The Agency has considered the issue of forwarding the advisory notice from the operator to the owner. EPA has determined, however, that it does not have the authority under section 9002 to impose such a requirement on operators.

5. Implementation of the notification requirements.

The Agency received many comments on EPA's intended use of the existing toll-free RCRA/Superfund Hotline to assist tank owners in completing the notification form. Several commenters were concerned that, in view of the large number of newly regulated small businesses, the Agency would receive many questions. This additional burden could overload the existing hotline, rendering it ineffective. To rectify this situation, a number of commenters suggested a separate hotline for the UST program. They stated that if a toll free telephone number were used, it should be a number separate from the existing RCRA/Superfund Hotline.

The Agency has evaluated the need for a separate hotline and has determined that it will augment the resources for the existing hotline rather than create a separate service. EPA believes that this decision is appropriate given that State agencies will be the primary points of contact concerning the notification requirements and form for owners of underground storage tanks.

C. The Notification Form

The majority of commenters endorsed EPA's decision to adopt a simple notification form that is limited to the

information required by the 1984 RCRA Amendments. Many commenters stated that the form is straightforward and can be easily completed. Others recommended that EPA adopt the proposed forms but with minor modifications and additions.

The following paragraphs discuss the comments EPA received on the proposed forms and the Agency's response to these comments.

1. General Instructions.

EPA received a number of comments concerning the general instructions for the proposed forms. Many of these comments were editorial. Others concerned the definitions of "underground storage tank" and "owner." One commenter believed that the statutory language to define these terms may be too technical for small entities to understand. The Agency has already responded to comments concerning definitions in Section III(A)(3) of this preamble.

Several commenters recommended that the instructions on the forms should indicate that owners are not expected to expend extensive time and resources to retrieve the necessary data.

Congress provided in Section 9002 that owners of tanks taken out of service submit information "to the extent known" rather than require owners of tanks taken out of service to expend extensive time and resources to retrieve the necessary data (e.g., going beyond available documents and contacting previous owners to determine the age of tanks, construction materials, etc.). Congress made no such provision, however, for current owners of tanks. Thus, current owners of underground storage tanks in use or that will be brought into use in the future are expected to take any available steps to provide the necessary information about their tanks. In recognition, however, that there may be situations where it is impossible for current owners to obtain all the necessary data to complete the form, the Agency has provided owners the option of indicating "unknown" as an answer. In a situation where no actual record exists, an owner may provide a response based on reasonable estimates, rather than indicate the answer is unknown.

One commenter stated that the instructions for the out-of-service tanks are not acceptable. The commenter suggested that the Agency clarify whether all the information requested is to be accurate as of the time the tank was taken out of service, or whether some of the information is to be current as of the date of notification. For example, is the name of the facility to be what it was at the time the tank was taken out of service (Jones Service Station) or what it is now (perhaps a parking lot)?

Because the primary purpose of the notification program is to assist States in determining where underground storage tanks are located and what regulated substances they contain, EPA believes that informaton on both the previous and current owners should be noted in this situation. Providing only the name of the owner at the time the tank was taken out of service could be misleading as the above example suggests. Requiring information on both previous and current owners provides a greater degree of certainty of knowing what the tanks contained (or may still contain) and where they are located. In an effort to help States distinguish between current and former owners, EPA has provided boxes on the form to indicate whether the respondent is a "current" or "former" owner.

Several commenters recommended that EPA reword the penalty statement in the instructions. Evidence of deliberate failure to notify or knowing submission of false information is the statutory standard, they stated, and the sentence should be modified to comply with the statute. EPA has adopted the language of the penalty statement as it appears in the statute. The additions suggested by the commenters would significantly change the meaning of the statute, and such alterations are not within the Agency's authority.

2. Format.

Many commenters suggested that EPA combine the two forms into one form. This would result in less paperwork for tank owners and serve to minimize confusion. It would also reduce the printing costs and simplify administrative handling by the State agencies processing the information. The Agency agrees with the commenters and has combined the information requirements of the two proposed forms into a single, two-sided form.

Other format changes suggested by commenters have been adopted and include: (1) Eliminating all Federal agency logos, names, and mailing addresses so that State or local logos and addresses can be inserted; (2) adding a space for total number of tanks being reported; and (3) reducing the number of lines for specific tanks. EPA also removed the preprinted tank numbers from the form in response to a comment that photocopies of the form must be altered for facilities with more than eight tanks, and in response to the desire expressed by some commenters to use existing company tank identification numbers in lieu of preassigned, sequential numbers.

Several commenters requested that EPA provide coding lists for materials of construction, external protection, and substance stored to make the form more amenable to a computerized data-processing system. EPA has consulted statisticians concerning this suggestion and on the basis of their analyses, has decided that the probability for error is greater with coded responses than with direct indication of choice.

3. Specific Line Items.

Name and Address of the Facility. One State commenter requested that EPA change the heading on the form from "name and address of the facility" to "location of tanks." Accordingly, the Agency has made this requested modification for clarity. The Agency has also modified the location address block so that the owner may now provide the name of the company site identifier as an alternative to the facility name. The owner is also required to provide the street address (or, in rural areas, the name or route number of the State road) as well as the city where the tanks are located. A number of commenters requested that the Agency include a space for county name and zip code so that batch reports of tank facilities may be printed. In response to this comment, the Agency has included such requirements on the final form.

Several State commenters suggested that tank location should be specified by some universal locater system such as township, range and section number, universal transverse meridians, or latitude and longitude. They suggested that this requirement would be particularly useful outside of metropolitan areas. Another State commenter suggested that facility locations, particularly in rural areas, should reference municipal tax maps. They pointed out that the location of a facility is often difficult to describe because of the lack of street numbers and names.

EPA recognizes that sometimes street addresses alone are not sufficient and that inclusion of the information suggested above could add considerable precision to determining the location of tanks. The Agency has decided not to require such information, however, because it would complicate the form and would require owners to undertake additional effort by researching tax records, deeds and mortgages. EPA believes this additional effort is not warranted.

Owner of Tank. Elsewhere in this preamble tank ownership is discussed. EPA recognizes that because of the varied nature of ownership interests in real property (particularly for gasoline-

marketing operations) there are many cases where tank ownership is uncertain. One commenter recommended that EPA change the heading in Item 3 on the proposed form to read "owner of tank and owner of property." The commenter pointed out that the property owner may not own the tank and may not be aware that the lessee has installed an underground storage tank on his property. These comments have prompted EPA to add a box that can be checked in cases where ownership of the tank is uncertain.

Contact Person. In response to comments, EPA would like to clarify that the contact person for the facility is the person responsible for the day-to-day monitoring of the tank. The contact person may be the owner or the owner's authorized representative. In recognition that employees are more subject to change than are their job titles, EPA has modified the form to include a space for the job title of the contact persons. By so doing, inquiries can be directed to a particular position, even if the position is no longer held by the same individual.

Type of Owner. EPA has revised Item 5 ("Type of Owner") to provide for identification of State or local government-owned tanks, federally-owned tanks, and privately-owned tanks. The form requires the owner to provide a federal facility General Services Administration (GSA) identification number for Federal tanks, to assist Federal agencies that may want to ascertain the status of their tanks. In an effort to simplify the form, information concerning the "type of owner" is now included in Section 1, "Ownership of the Tanks."

For State Use Only. One State commenter requested that EPA provide space on the notification form so that States may attach a form serial or accounting number identification. The Agency agrees and has changed the form accordingly to facilitate the identification of those owners who may file subsequent notifications and to facilitate automated data processing.

Information on Tanks.—(a) *Age.* A number of commenters remarked that many owners do not know the age of their tanks. Accurate information on the age of tanks or when the tanks were last used may be even more difficult or impossible to obtain. In consideration of these comments, the Agency now requests owners to provide an estimate of the age of their tanks rather than specifying the exact age of their tanks.

(b) *Material of Construction.* In the proposal, EPA listed only steel and fiberglass reinforced plastic tanks for specific identification in the notification form. EPA has since determined that there may be tanks that are partially in-ground or above-ground that satisfy the underground storage tank definition. In addition, review of the comments indicates that some devices, such as sumps, which typically may not be considered tanks by the owner, may also meet the definition of underground tank contained in section 9001(1). Many of these devices are constructed of concrete. Thus, in the final notification form, EPA has added "concrete" to the list of tank construction materials. This addition does not necessarily mean that all sumps or concrete tanks are underground storage tanks. It will still be up to the owner to determine if he owns a tank that satisfies the statutory definition of "underground storage tank."

(c) *Corrosion Protection.* EPA received many comments concerning types of internal and external corrosion protection systems. On the proposed forms, owners are required to specify whether the tank is internally protected with a lining or whether it is unlined. One commenter requested that the Agency define the kinds of tank linings considered to be internal protection.

Other commenters directed their remarks toward external protection systems. For example, several commenters requested that the term "coating" be clarified and defined. One commenter recommended that the Agency revise the instruction concerning this to indicate that *all* appropriate boxes should be checked. The commenter stated that it is common for a tank to be both coated and wrapped or have some form of cathodic protection plus a coating.

EPA defines internal lining as any material that is applied over the inside surface of the tank. Many types of materials are used for this purpose, such as polyesters, epoxies, and ceramics. On the notification form, the Agency asks only that the owner indicate whether or not the tank is internally lined. The owner is not required to specify the type of lining.

In regard to external protection systems, the term "coating" means any material that is applied over the outside surface of the tank. Types of coatings commonly used include asphalt, coal tar epoxy, and fiberglass reinforced plastic (FRP). On today's form, EPA requires the owner to indicate the kind of external protection system used on the tank. The Agency has listed fiberglass reinforced plastic coating to the list of types of external corrosion protection because it is one of the more common methods of corrosion protection. Other coatings are generally supplemented with cathodic protection. EPA has also modified the instruction concerning external protection so that the owner can now indicate whether the tank is equipped with more than one protection system.

(d) *Type of Substance Stored.* On the proposed forms, owners are asked to identify which of two categories of substances the tank contains: CERCLA hazardous substances or petroleum. If the tank is storing petroleum, the owner is asked to indicate which type (i.e., gasoline, diesel, or kerosene). If the tank is storing a CERCLA hazardous substance, the owner had to provide the name of the hazardous substance or the Chemical Abstracts Service (CAS) registry number.

Several commenters questioned the Agency's classification of petroleum substances. One commenter did not believe there is any need to distinguish between diesel and kerosene petroleum substances and suggested grouping these along with heating oil into a single category of distillates. Several commenters believed that the Agency should distinguish the types of gasoline stored in a tank (i.e., regular, unleaded, premium) because the type of gasoline is related to the issue of product compatibility with tanks. One commenter also suggested that the Agency expand the choices beyond those discussed above to include used oil, aviation gas, jet fuel, and gasohol.

EPA has considered these comments and has decided not to combine petroleum substances into a single category of distillates because EPA believes the substances are sufficiently different to warrant obtaining information about them individually. On the other hand, the Agency has determined that it is not necessary to distinguish the types of gasoline stored. Listing gasoline by type does not provide useful information concerning substance compatibility with tanks because different brands of the same type of gasoline can vary in formulation. Likewise, the Agency has allowed for the reporting of alcohol blends with gasoline under the "gasoline" category. In an effort to keep the form simple, the Agency has restricted its list of type of petroleum substance stored to generic classes.

EPA has added "used oil" to the list of choices because it is one of the most commonly stored regulated substances. The Agency has determined that if used oil is eventually listed as a hazardous waste under Subtitle C of RCRA, the Agency would have jurisdiction under both Subtitle C and Subtitle I to regulate used oil. This position is based on the fact that the exclusion for hazardous

wastes under Subtitle I applies to CERCLA substances (Section 9001(2)(A)). It does not apply to petroleum substances that are identified in section 9001(2)(B). The technical standards that will apply to used oil tanks will be promulgated in the future. In the meantime, notification under Subtitle I is required for used oil and for any petroleum hazardous waste that is not currently regulated as a hazardous waste under Subtitle C of RCRA.

Several commenters addressed the identification of CERCLA hazardous substances. In the preamble to the proposed rule, EPA suggested that owners contact the RCRA/Superfund Hotline at (800) 424-9346 if they were unsure whether the chemicals stored in their tanks were CERCLA hazardous substances. EPA also stated that the Agency could provide interested persons with a list of such substances upon request.[3]

One commenter stated that in situations where a commercially available product (which contains CERCLA hazardous substances) is being stored in an underground storage tank, readily available chemical identification information should suffice for identifying the "substance type" on the notification, such as information from material safety data sheets required by the Occupational Safety and Health Administration. The Agency believes that the "regulatory synonyms" identified in Table 302.4 of the Reportable Quantity regulation (50 FR 13475, April 4, 1985) may be used in the notification form. The use of trade names, however, may not be used since the exact chemical constituents of any particular product generally are not readily available to the State or local agencies.

A commenter who referred to the list of CERCLA hazardous substances noted that it contains both commercial chemicals and discarded commercial chemical products. The commenter requested that EPA clarify which of these substances would be subject to the notification requirements. Every substance on the CERCLA list is a regulated substance unless it is a hazardous waste regulated under Subtitle C. This means some waste streams on the CERCLA list are not regulated substances for the purposes of Subtitle I. On the other hand, commercial products that become Subtitle C hazardous wastes when discarded or when they are intended to be discarded, are regulated substances under Subtitle I until they are discarded or intended to be discarded as wastes.

In the preamble to the proposed rule, EPA solicited comment regarding what is the most appropriate indication of stored CERCLA hazardous substance when there is a mixture of chemicals in one tank. The Agency proposed that the owner indicate the substance of greatest quantity in the mixture.

The majority of commenters stated that it is sufficient to report only the major component present in the mixture. They also stated that, because many industry products are complex mixtures containing potentially large numbers of hazardous substances, it would be difficult and very expensive to list all products stored. One State commenter stated that his agency's ADP system would not have the capability to include information on more than one substance per tank.

Several commenters argued that all substances should be identified so that the potential environmental threat from a tank could be determined. Other commenters stated that, although listing all the substances in the mixture would be an unnecessary burden, EPA's proposal to list the substance of greatest quantity would not accurately reflect the tank's contents. One commenter recommended that all major substances present in volumes of 10 percent or greater be identified. Another commenter stated that EPA should provide a space for a product description, the CERCLA substance of greatest quantity, and the concentration of the substance.

Other commenters stated that using toxicity as one basis for notification is inappropriate because the degree of toxicity of a substance is unrelated to its potential to leak from an underground storage tank. One commenter stated that the Agency should not require tank owners to list the substance that is the most toxic because few owners possess the technical or scientific expertise to evaluate the relative toxicities of materials in the mixture.

The Agency has carefully considered these comments and recognizes that, while more detailed information may be needed to respond to an actual tank leak, this greater level of detail is unnecessary for development of a general tank inventory, which is the primary objective of this notification effort. The data supplied under this initial notification effort should not be viewed as the sole source of information to be used for emergency responses. Therefore, the notification form continues to require the owner to indicate only the CERCLA hazardous substance of greatest quantity in a mixture. Where a tank is used to store more than one substance during a year, the Agency requires that only the most typical use or use of greatest quantity during the year be identified on the notification form.

Certification. In the instructions for the proposed notification form, EPA stated that the form must be signed and certified by the owner or authorized representative of the facility. The Agency defined authorized representative as "a person responsible for the overall operation of the facility, as for example, a plant manager or superintendent, or a person of equivalent responsibility." A number of commenters disagreed with this definition, arguing that the certification should be restricted to an officer or other official representative of the owner, and not permit the signature by a mere employee.

In response to these comments, EPA would like to clarify its definition of authorized representative: it is a person who is authorized by the owner to sign the notice.

One commenter requested that, for companies with many tanks or multiple locations, certification be allowed in a cover letter rather than on the notification form itself so that the owner would not have to sign hundreds of certifications. In response to this comment, the Agency has modified the form to take into account locations with many tanks. Thus, the certification statement and the signature line have been moved to the first page of the form. Owners are permitted to sign one form, if it is part of a series of notification forms for several tanks at one location. We have rejected the commenter's suggestion, however, to permit certification by cover letter for owners of tanks at more than one location. To permit such certification could result in separation of the certifications from the forms and present a problem in data management and storage of the forms.

There may be instances when the notifier is not an owner or his authorized representative but some other interested party. In such cases, the notifier should indicate this on the form by crossing out the word "owner" under the certification and substituting the word "notifier."

4. Additional data requests.

Elsewhere in this preamble, the Agency discussed its rationale for limiting the information required in the notification form to the in items specified in Section 9002. As we have explained earlier, in response to comments EPA has added information

[3] The list of CERCLA hazardous substances was published in the Federal Register on April 4, 1985 (50 FR 13546).

requirements concerning tank closure and piping.

A number of commenters also requested that EPA provide space for the owner's identification of tanks (e.g., number, code name, location). In particular, one commenter stated that for large facilities having several buildings, such identifiers may be critical as tanks containing the same material may be located at more than one building. As its response to these comments, EPA has eliminated the prenumbering found on the proposed forms and has designated that space for such identifiers.

EPA received many comments, including six from States, requesting that the Agency provide for updating of information whenever significant changes occur at the site. These changes could include the installation or replacement of tanks or piping, permanent removal of a tank from operation, and changes in the chemical substance(s) being stored. Several commenters stated the notification form would be a much more effective management and enforcement tool if the owner were required to update a tank's status as it changes.

Other commenters believed that tank notifications should be made on a one-time-only basis because a continual notification system could be resource intensive and yield little additional useful information.

EPA recognizes that the accuracy of the underground storage tank data compiled from the notifications submitted under Section 9002 will not remain current unless updated to incorporate future changes, but believes that Section 9002 does not provide EPA authority to require owners to update their notices in the future. To compensate for this limitation, however, EPA provided a place on the form to indicate whether the notification is an initial or an amended report, so that States that may opt to require updates of the information received in the original notification can do so using EPA's form. The addition of this block imposes no additional Federal information requirements on the tank owner.

D. Other Comments

The Agency also received a number of comments concerning the following subjects: (1) Jurisdiction for the Subtitle I program on Indian lands; and (2) EPA's role in communicating the notification requirements to the regulated community.

Several commenters requested clarification as to how EPA would handle notification of tanks located on Indian lands. The Agency believes that Subtitle I does not provide States the authority to assert jurisdiction over underground storage tanks on Indian reservations or other lands held in trust for Indian peoples. Some States may have such authority by treaty or an act of Congress other than Subtitle I. Nevertheless, Section 9002 imposes a Federal requirement on all underground storage tank owners to provide notification to the State or local agencies designated under Section 9002(b). This is an obligation under Federal law, not State law, and applies to Indians in the same way it applies to any other "person" who is an owner of an underground storage tank. Accordingly, Indian tank owners must provide notification to the appropriate agencies listed in Appendix II. In States that do not have jurisdiction to assert State laws over Indian tribes or individual Indians, however, Indians cannot be required by such States to use State forms. In such States, Indians will be deemed to have complied with Section 9002 if they use the Federal form, but such form must be sent to the appropriate State or local agencies listed in Appendix II. The notification form has been amended to include a box that should be checked if a tank is located on Indian reservations or other trust lands.

Other commenters requested clarification of EPA's role in the implementation of State notification programs. Two State commenters recommended that EPA conduct a national or regional advertising campaign to inform tank owners of their requirements to notify. One of these States also said that EPA should assist States with regional mailings of general underground storage tank information to all permit holders.

EPA plans to provide a notification handbook to the States to aid in implementing and informing tank owners of their notification programs.

IV. The Final Notification Form

As was stated earlier in this preamble, Section 9002 was included in Subtitle I to provide States with some basic information about underground storage tanks within their jurisdictions. This information could be used to establish State programs aimed at preventing, detecting, and correcting leaks from these tanks. Owners are encouraged by EPA to maintain records of the data they submit to the designated State agencies.

EPA attempted to produce a notification form that is easy to complete and that fulfills the requirements of Section 9002. The format is designed to simplify the completion of the form (i.e., in most cases, answers may be provided by checking a box). The Agency has thus attempted to minimize the burden upon all tank owners, the majority of whom own small businesses.

A. Information Included in the Form

Appendix I sets forth the form to be used by owners of underground storage tanks. The following paragraphs provide details concerning the information requirements of this form.

The owner of an underground storage tank must give his name, address, and phone number. The owner must also provide information concerning a contact person; i.e., an individual who is responsible to him for monitoring the day-to-day operation of the tank. This information should include such persons name, title, address, and phone number. In addition, the owner is required to provide information on the location of his tank and the status of the tank, (whether it is currently in use, temporarily out of use, or permanently out of use).

For underground storage tanks in use or that are brought into use after May 8, 1986, EPA requires owners to estimate the age of the tank and to indicate its capacity in gallons. With respect to the type of tank, EPA has characterized type to mean materials of construction and internal and external corrosion protection, if any. The owner is required to indicate whether the tank is constructed of steel, fiberglass reinforced plastic, or concrete. If the tank is not constructed of these materials, the owner is asked to specify the material. Listed in the form are several types of corrosion protection systems. The owner must specify the kind of internal and external protection system with which the tank is equipped. The owner is also required to provide information on piping.

Concerning the use of the tank, the owner must identify which of two categories of substances the tank contains: CERCLA hazardous substances or petroleum. If the tank is storing a hazardous substance, the owner must provide the name of the CERCLA chemical or the Chemical Abstracts Service (CAS) registry number. When a mixture of several hazardous substances is stored in one tank, the owner must specify the name of the substance of greatest quantity. If the tank is used to store different hazardous substances at different times, the owner must specify the name of the substance typically stored or stored in greatest quantity during the year immediately preceding the submission

of the notice. If a tank is storing petroleum, the owner is required to indicate the type of petroleum that is stored.

For underground storage tanks taken out of use permanently after January 1, 1974 (but still in the ground), the owner is required to provide the same information as discussed above. In addition, the owner must estimate the date of last use and the quantity of substance remaining in the tank. The owner must also indicate whether the tank was filled with inert material, such as sand or concrete. If the tank is taken out of the ground prior to May 8, 1986, notification is not required.

B. Copies of the Form

EPA is providing States with a camera-ready copy of the notification form. Owners of underground storage tanks should contact the appropriate designated State agency that is implementing the notification program to determine if the State has copies of the form or is using its own State form. (Appendix II provides a list of the designated State agencies.)

V. Confidentiality Provisions

EPA received several comments concerning the confidentiality provisions that were discussed in the preamble to the proposed regulation. Commenters were concerned that confidentiality may not be adequately protected in States that do not effectively implement the underground storage tank regulations. Several commenters recommended that EPA strengthen the confidentialty provisions to provide assurance to the regulated community that legitimate proprietary information will be adequately safeguarded.

Because the information reported in the notification forms will be sent to a designated State or local agency, not to EPA, the information will not be subject to Federal public disclosure laws. The Agency cannot, of course, interfere with State confidentiality provisions. Owners of underground storage tanks who seek protection from disclosure should, therefore, contact the appropriate State office for information on applicable confidentiality provisions.

National Costs for the Notification Requirements

EPA received a number of comments on the Agency's estimated costs to tank owners to meet the notification requirements.

Some commenters disagreed with the Agency's assumption that an average facility was comprised of three tanks. One representative of the chemical industry stated that a more typical facility would have ten to several hundred tanks; another commenter estimated that a utility company may have as many as 600 tanks at one facility. Commenters argued that because the Agency has underestimated the number of tanks at a facility, it has significantly understated the costs of the notification requirements. One commenter stated that as a result of underestimating the number of tanks at large facilities, the costs to a large facility could be underestimated by a factor of ten to twenty. Should this be the case, the commenter argued that the regulations would be classified as a major rule.

Although the Agency agrees that some facilities do have more than three tanks per facility (e.g., large chemical companies), the majority of facilities with tanks used for petroleum (e.g., gas stations) and specialty chemical products are unlikely to have more than three tanks. The Agency believes that a typical facility has three tanks. EPA recognizes, of course, that for facilities with a significantly larger number of tanks, the costs could be underestimated; the number of these facilities is not great, however, and, therefore, the total national costs of the regulation will not increase significantly. In addition, large facilities that have computer capabilities for monitoring the contents of their tanks may be able, through negotiations with States, to substitute computer printouts for the EPA or State notification forms. This will reduce the cost to these facilities both in data retrieval and in notification costs.

A number of commenters stated that the Agency underestimated the average time required per facility to complete the notification from. Because tanks may be used for mixtures of products or for more than one product over a year, identifying all the products included in the tank would take more than 30 minutes per facility. Commenters stated that for facilities with tanks taken out of service since 1974, it would take much longer than 30 minutes to obtain the necessary information, especially for facilities that have been sold. If the Agency required detailed information on the internal lining of the tank and external corrosion protection (information similar to that required on the California notification form), it could take significantly longer than 30 minutes to complete the from. Commenters' estimates of the time required ranged from 30 minutes to 2 hours per tank and form several hours to 8 hours per facility.

In response to these comments, the Agency points out that the final notification form, as modified in response to comments, should take less time to fill out than the forms previously proposed. First, the Agency is specifying that the notification form include only information on the most predominant chemical constituent stored in the tank over the past year. For tanks containing mixtures, the form now includes a box indicating that the tank contains a mixture of regulated substances. Owners, will not, therefore, be required to identify all the different constituents in the tank. Second, EPA is not requiring extensive information on the internal and external characteristics of the tank that could increase the amount of time required to complete the form.

EPA is requiring owners of tanks taken out of service to provide the information requested on the form only "to the extent known." Thus, these owners need not contact all previous owners to obtain the notification information. This is consistent with the assumptions EPA used to estimate the time required to complete the form and that the Agency presented in the proposed rule.

The Agency has assumed that an owner of a facility that has three tanks will require 30 minutes to complete the notification form. This includes the time necessary to read the instructions, delegate responsibility for completing the form, retrieve information, complete the form, submit it for management review, and to do the necessary clerical work. It should be possible for an owner of a large facility to supply the information in about eight hours, especially if the facility has computer capabilities for data retrieval.

The Agency also received comments challenging EPA's estimated hourly salary rate. The commenters argued that a person with considerable expertise would be needed to complete the notification form, especially if detailed information on the tank's liner and external materials were required. The Agency disagrees with this comment because detailed technical information is not requested on the form. Only information that is readily available is expected. Thus, the Agency continues to maintain that the average estimate of $15 per hour is a reasonable estimate.

Finally, one commenter challenged the Agency's assumption that notification costs for product distributors would range from $50 to $100. This commenter argued that it would be significantly more expensive to account for the costs of collecting State forms, printing, and driver training, especially if a distributor

has clients in many different States with different State forms.

The preamble to the proposed rule stated that a depositor must "reasonably notify" the tank owner or operator of his notification obligations. Approaches that the Agency considers appropriate for notifying the tank owner or operator include providing the tank owner with a copy of the notification form (or the required State form) *or* printing the notification requirements on the shipping papers that accompany the shipment or on the invoice itself or writing a one-time letter to the owners.

The Agency estimated the notification costs of $50 for depositors and tank sellers. This assumes that the tank owner will need about two hours of managerial and clerical time to comply with the notification requirements. This translates into a combined hourly rate of $25, including benefits and overhead. This cost is for preparing a cover letter and obtaining notification forms, or for preparing a standard notice that would be distributed at the time of transactions. The $100 estimate includes a follow-up letter after the initial notification.

In developing the costs for depositors, the Agency assumed that the distributor would choose the least-cost option. Therefore, a large distributor with clients in many different States would most likely choose to include the notification requirements on the shipping papers or invoices rather than collect and distribute notification forms for each of the applicable States. Thus, the costs to the distributor would involve only the costs of printing the notice on the invoice.

Although EPA continues to consider its per facility notification cost to be reasonable estimates, EPA has revised the population estimate in light of new information. The Agency has undertaken more thorough research of the facilities subject to the Subtitle I requirements in support of the technical standards that the Agency will be proposing. This research indicates that there is a maximum of 500,000 facilities that have petroleum tanks. The Agency expects chemical product tank facilities to compose no more than 20 percent of the total underground storage tank facility population. Therefore, the Agency is revising the underground storage tank population estimate from 1.2 million facilities to about 600,000 facilities. The Agency still assumes that 90 percent of these facilities have three tanks apiece. The remaining 10 percent are large facilities with 10 tanks apiece.

EPA has concluded that the notification requirements do not impose a significant economic burden on members of the affected population. (See Sections VII and IX for additional information on the economic impact of this rule.)

VII. Compliance With Executive Order 12291

Executive Order 12291 [46 FR 13193, February 9, 1981] requires that a regulatory agency determine whether a new regulation will be "major" and, if so, that a Regulatory Impact Analysis be conducted. A major rule is defined as a regulation that is likely to result in:

(1) An annual effect of the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, and local Government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Since today's rulemaking does not result in any of the above effects, it does not meet the definition of a major regulation. Accordingly, the Agency is not conducting a Regulatory Impact Analysis.

This rulemaking has been submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

VIII. Paperwork Reduction Act

Pursuant to section 3504(h) of the Paperwork Reduction Act of 1980, the reporting and recordkeeping provisions of today's final rule have been approved by OMB and the approval number is 2050–0049. to comments by OMB and the public regarding the reporting and recordkeeping provisions of the rule.

IX. Regulatory Flexibility Act

The Regulatory Flexibility Act requires that Federal agencies prepare regulatory flexibility analyses assessing the impacts of proposed rules on entities such as small businesses, small organizations, and small governmental jurisdictions. Such an analysis is not required, however, when the head of an agency certifies that a proposed rule will not have a significant economic impact on a substantial number of small entities.

EPA considers the information required by these rules to be the minimum necessary to administer the notification program effectively. Since most of the requested information is readily accessible, little time should be needed to prepare the notification response. Any additional economic impact on the public resulting from implementation of this regulation is expected to be negligible since notification is required only once, and is primarily an administrative procedure. Accordingly, I certify that these proposed rules, if promulgated, would not have a significant impact on a substantial number of small entities.

X. List of Subjects in 40 CFR Part 280

Administrative practice and procedure, Underground storage tanks, Hazardous materials, Hazardous waste, Water pollution control, Confidential business information.

Dated: November 5, 1985.

Lee M. Thomas,

Administrator.

For the reasons set out in the preamble, Title 40 of the Code of Federal Regulations, Part 280 is amended as follows:

PART 280—UNDERGROUND STORAGE TANK REGULATIONS

(1) The authority cite for Part 280 continues to read as follows:

Authority: 42 U.S.C. §§ 6991, 6992, and 6996.

(2) Section 280.1 is amended by adding the following definitions in alphabetical order:

§ 280.1 Definitions and Exemptions.

"Operator" means any person in control of, or having responsibility for, the daily operation of the underground storage tank.

"Owner" means (a) in the case of an underground storage tank in use on November 8, 1984, or brought into use after that date, any person who owns an underground storage tank used for the storage, use, or dispensing of regulated substances, and (b) in the case of any underground storage tank in use before November 8, 1984, but no longer in use on that date, any person who owned such tank immediately before discontinuation of its use.

* * * * *

(3) Section 280.3 is added to read as follows:

§ 280.3 Notification requirements.

(a) On or before May 8, 1986, each owner of an underground storage tank currently in use must submit, in the form prescribed in Appendix I of this section, a notice of the existence of such tank to the State or local agency or department designated in Appendix II of this section to receive such notice.

(b) On or before May 8, 1986, each owner of an underground storage tank taken out of operation after January 1, 1974 (unless the owner knows that such

tank has been removed from the ground) must submit, in the form prescribed in Appendix I of this section, a notice of the existence of such tank to the State or local agency or department designated in Appendix II of this section to receive such notice.

(c) Any owner who brings an underground storage tank into use after May 8, 1986, must, within 30 days of bringing such tank into use, submit, in the form prescribed in Appendix I of this section, a notice of the existence of such tank to the State or local agency or department designated in Appendix II of this section to receive such notice.

(d) In States where State law, regulations, or procedures require owners to use forms that differ from those set forth in Appendix I of this section to fulfill the requirements of this section, the State forms may be submitted in lieu of the forms set forth in Appendix I of this section. If a State requires that its form be used in lieu of the form presented in this regulation, such form must meet the requirements of Section 9002.

(e) Owners required to submit notices under paragraphs (a) through (c) of this section must provide notices to the appropriate agencies or departments identified in Appendix II of this section for each tank they own. Owners may provide notice for several tanks using one notification form, but owners who own tanks located at more than one place of operation must file a separate notification form for each separate place of operation.

(f) Notices required to be submitted under paragraphs (a) through (c) of this section must provide all of the information indicated on the prescribed form (or appropriate State form) for each tank for which notice must be given.

(g) Beginning on December 9, 1985 through May 9, 1987 any person who deposits regulated substances in an underground storage tank must make reasonable efforts to notify the owner or operator of such tank of the owner's obligations under paragraphs (a) through (c) of this section.

(h) Beginning 30 days after the Administrator issues new tank performance standards pursuant to RCRA section 9003(e), any person who sells a tank intended to be used as an underground storage tank must notify the purchaser of such tank of the owner's notification obligations under paragraphs (a) through (c) of this section.

(i) Paragraphs (a) through (c) of this section do not apply to tanks for which notice was given pursuant to section 103(c) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980.

BILLING CODE 6560-50-M

APPENDIX I to §280.3

Notification for Underground Storage Tanks

FORM APPROVED
OMB NO. 2050-0068
APPROVAL EXPIRES 6-30-88

STATE USE ONLY

I.D. Number

Date Received

GENERAL INFORMATION

Notification is required by Federal law for all underground tanks that have been used to store regulated substances since January 1, 1974, that are in the ground as of May 8, 1986, or that are brought into use after May 8, 1986. The information requested is required by Section 9002 of the Resource Conservation and Recovery Act, (RCRA), as amended.

The primary purpose of this notification program is to locate and evaluate underground tanks that store or have stored petroleum or hazardous substances. It is expected that the information you provide will be based on reasonably available records, or, in the absence of such records, your knowledge, belief, or recollection.

Who Must Notify? Section 9002 of RCRA, as amended, requires that, unless exempted, owners of underground tanks that store regulated substances must notify designated State or local agencies of the existence of their tanks. Owner means

(a) in the case of an underground storage tank in use on November 8, 1984, or brought into use after that date, any person who owns an underground storage tank used for the storage, use, or dispensing of regulated substances, and

(b) in the case of any underground storage tank in use before November 8, 1984, but no longer in use on that date, any person who owned such tank immediately before the discontinuation of its use.

What Tanks Are Included? Underground storage tank is defined as any one or combination of tanks that (1) is used to contain an accumulation of "regulated substances," and (2) whose volume (including connected underground piping) is 10% or more beneath the ground. Some examples are underground tanks storing: **1.** gasoline, used oil, or diesel fuel; and **2.** industrial solvents, pesticides, herbicides or fumigants.

What Tanks Are Excluded? Tanks removed from the ground are not subject to notification. Other tanks excluded from notification are:

1. farm or residential tanks of 1,100 gallons or less capacity used for storing motor fuel for noncommercial purposes;

2. tanks used for storing heating oil for consumptive use on the premises where stored;

3. septic tanks;

4. pipeline facilities (including gathering lines) regulated under the Natural Gas Pipeline Safety Act of 1968, or the Hazardous Liquid Pipeline Safety Act of 1979, or which is an intrastate pipeline facility regulated under State laws;

5. surface impoundments, pits, ponds, or lagoons;

6. storm water or waste water collection systems;

7. flow-through process tanks;

8. liquid traps or associated gathering lines directly related to oil or gas production and gathering operations;

9. storage tanks situated in an underground area (such as a basement, cellar, mineworking, drift, shaft, or tunnel) if the storage tank is situated upon or above the surface of the floor.

What Substances Are Covered? The notification requirements apply to underground storage tanks that contain regulated substances. This includes any substance defined as hazardous in section 101 (14) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), with the exception of those substances regulated as hazardous waste under Subtitle C of RCRA. It also includes petroleum, e.g., crude oil or any fraction thereof which is liquid at standard conditions of temperature and pressure (60 degrees Fahrenheit and 14.7 pounds per square inch absolute).

Where To Notify? Completed notification forms should be sent to the address given at the top of this page.

When To Notify? 1. Owners of underground storage tanks in use or that have been taken out of operation after January 1, 1974, but still in the ground, must notify by May 8, 1986. **2.** Owners who bring underground storage tanks into use after May 8, 1986, must notify within 30 days of bringing the tanks into use.

Penalties: Any owner who knowingly fails to notify or submits false information shall be subject to a civil penalty not to exceed $10,000 for each tank for which notification is not given or for which false information is submitted.

INSTRUCTIONS

Please type or print in ink all items except "signature" in Section V. **This form must by completed for each location containing underground storage tanks.** If more than 5 tanks are owned at this location, photocopy the reverse side, and staple continuation sheets to this form.

Indicate number of continuation sheets attached ☐

I. OWNERSHIP OF TANK(S)

Owner Name (Corporation, Individual, Public Agency, or Other Entity)

Street Address

County

City State ZIP Code

Area Code Phone Number

Type of Owner *(Mark all that apply ☒)*

☐ Current ☐ State or Local Gov't ☐ Private or Corporate

☐ Former ☐ Federal Gov't (GSA facility I.D. no. _____) ☐ Ownership uncertain

II. LOCATION OF TANK(S)

(If same as Section 1, mark box here ☐)

Facility Name or Company Site Identifier, as applicable

Street Address or State Road, as applicable

County

City (nearest) State ZIP Code

Indicate number of tanks at this location ☐

Mark box here if tank(s) are located on land within an Indian reservation or on other Indian trust lands ☐

III. CONTACT PERSON AT TANK LOCATION

Name (If same as Section I, mark box here ☐) Job Title Area Code Phone Number

IV. TYPE OF NOTIFICATION

☐ Mark box here only if this is an amended or subsequent notification for this location.

V. CERTIFICATION (Read and sign after completing Section VI.)

I certify under penalty of law that I have personally examined and am familiar with the information submitted in this and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete.

Name and official title of owner or owner's authorized representative	Signature	Date Signed

CONTINUE ON REVERSE SIDE

EPA Form 7530-1(11-85)

Owner Name (from Section I) _____ Location (from Section II) _____ Page No. ____ of ____ Pages

VI. DESCRIPTION OF UNDERGROUND STORAGE TANKS *(Complete for each tank at this location.)*

Tank Identification No. (e.g., ABC-123), or Arbitrarily Assigned Sequential Number (e.g., 1,2,3...)	Tank No.	Tank No.	Tank No.	Tank No.	Tank No.
1. Status of Tank *(Mark all that apply ☒)*					
Currently in Use	☐	☐	☐	☐	☐
Temporarily Out of Use	☐	☐	☐	☐	☐
Permanently Out of Use	☐	☐	☐	☐	☐
Brought into Use after 5/8/86	☐	☐	☐	☐	☐
2. Estimated Age (Years)					
3. Estimated Total Capacity (Gallons)					
4. Material of Construction *(Mark one ☒)*					
Steel	☐	☐	☐	☐	☐
Concrete	☐	☐	☐	☐	☐
Fiberglass Reinforced Plastic	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Please Specify	_____	_____	_____	_____	_____
5. Internal Protection *(Mark all that apply ☒)*					
Cathodic Protection	☐	☐	☐	☐	☐
Interior Lining (e.g., epoxy resins)	☐	☐	☐	☐	☐
None	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Please Specify	_____	_____	_____	_____	_____
6. External Protection *(Mark all that apply ☒)*					
Cathodic Protection	☐	☐	☐	☐	☐
Painted (e.g., asphaltic)	☐	☐	☐	☐	☐
Fiberglass Reinforced Plastic Coated	☐	☐	☐	☐	☐
None	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Please Specify	_____	_____	_____	_____	_____
7. Piping *(Mark all that apply ☒)*					
Bare Steel	☐	☐	☐	☐	☐
Galvanized Steel	☐	☐	☐	☐	☐
Fiberglass Reinforced Plastic	☐	☐	☐	☐	☐
Cathodically Protected	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Please Specify	_____	_____	_____	_____	_____
8. Substance Currently or Last Stored in Greatest Quantity by Volume *(Mark all that apply ☒)*					
a. Empty	☐	☐	☐	☐	☐
b. Petroleum					
Diesel	☐	☐	☐	☐	☐
Kerosene	☐	☐	☐	☐	☐
Gasoline (including alcohol blends)	☐	☐	☐	☐	☐
Used Oil	☐	☐	☐	☐	☐
Other, Please Specify	_____	_____	_____	_____	_____
c. Hazardous Substance	☐	☐	☐	☐	☐
Please Indicate Name of Principal CERCLA Substance	_____	_____	_____	_____	_____
OR					
Chemical Abstract Service (CAS) No.	_____	_____	_____	_____	_____
Mark box ☒ if tank stores a mixture of substances	☐	☐	☐	☐	☐
d. Unknown	☐	☐	☐	☐	☐
9. Additional Information (for tanks permanently taken out of service)					
a. Estimated date last used (mo/yr)	/	/	/	/	/
b. Estimated quantity of substance remaining (gal.)	_____	_____	_____	_____	_____
c. Mark box ☒ if tank was filled with inert material (e.g., sand, concrete)	☐	☐	☐	☐	☐

APPENDIX II to §280.3

List of Agencies Designated to Receive Notifications

Alabama (EPA Form)
Alabama Department of Environmental Mgmt.
Ground Water Section/Water Division
1751 Federal Drive
Montgomery, Alabama 36130

Alaska (EPA Form)
Department of Environmental Conservation
Pouch O
Juneau, Alaska 99811
907/465-2653

American Samoa (EPA Form)
Executive Secretary
Environmental Quality Commission
Office of the Governor
American Samoan Government
Pago Pago, American Samoa 96799
Attention: UST Notification

Arizona (EPA Form)
Attention: UST Coordinator
Arizona Department of Health Services
Environmental Health Services
2005 N. Central
Phoenix, Arizona 85004

Arkansas (EPA Form)
Arkansas Department of Pollution Control and Ecology
P.O. Box 9583
Little Rock, Arkansas 72219
501/562-7444

California (State Form)
Ed Anton
California Water Resources Control Board
P.O. Box 100
Sacramento, California 95801
916/445-9552

Colorado (EPA Form)
Kenneth Mesch, Section Chief
Colorado Department of Health
Waste Management Division
Underground Tank Program
4210 East 11th Avenue
Denver, Colorado 80220
303/320-8333 Ext. 4364

Connecticut (State Form)
Hazardous Materials Management Unit
Department of Environmental Protection
State Office Building
165 Capitol Avenue
Hartford, Connecticut 06106

Delaware (State Form)
Division of Air and Waste Management
Department of Natural Resources and Environmental Control
P.O. Box 1401
89 Kings Highway
Dover, Delaware 19903
302/736-5409

District of Columbia (EPA Form)
Attention: UST Notification Form
Department of Consumer and Regulatory Affairs
Pesticides and Hazardous Waste Management Branch
Room 114
5010 Overlook Avenue, S.W.
Washington, D.C. 20032

Florida (State Form)
Florida Department of Environmental Regulation
Solid Waste Section
Twin Towers Office Building
2600 Blair Stone Road
Tallahassee, Florida 32301
904/487-4398

Georgia (EPA Form)
Georgia Department of Natural Resources
Environmental Protection Division
Underground Storage Tank Program
3420 Norman Berry Drive
Hapeville, Georgia 30354

Guam (State Form)
James B. Branch, Administrator
Guam Environmental Protection Agency
P.O. Box 2999
Agana, Guam 96910
Overseas Operator (Commercial Call 646-8863)

Hawaii (EPA Form)
Chief, Noise and Radiation Branch
Hawaii Department of Health
591 Ala Moana Boulevard
Honolulu, Hawaii 96801
808/548-4129

Idaho (EPA Form)
Underground Storage Tank Coordinator
Water Quality Bureau
Idaho Department of Health & Welfare
Division of Environment
450 W. State Street
Boise, Idaho 83720
208/334-4251

Illinois (EPA Form)
Underground Storage Tank Coordinator
Division of Fire Prevention
Office of State Fire Marshal
3150 Executive Park Drive
Springfield, Illinois 62703-4599

Indiana (EPA Form)
Division of Land Pollution Control, UST Program
Indiana State Board of Health
P.O. Box 7015
Indianapolis, Indiana 46207
317/243-5060

Iowa (State Form)
Iowa Department of Water, Air and Waste Management
900 East Grand
Des Moines, Iowa 50319
515/281-8692

Kansas (EPA Form)
Office of Environmental Geology
Kansas Department of Health & Environment
Forbes Field, Building 740
Topeka, Kansas 66620
913/862-9360 Ext. 221

Kentucky (State Form)
Natural Resources Cabinet
Division of Waste Management, Attention: Vicki Pettus
18 Reilly Road
Frankfort, Kentucky 40601
502/564-6716

Louisiana (State Form)
Patricia L. Norton, Secretary
Louisiana Department of Environmental Quality
P.O. Box 44066
Baton Rouge, Louisiana 70804
504/342-1265

Maine (State Form)
Attention: Underground Tanks Program
Bureau of Oil & Hazardous Material Control
Department of Environmental Protection
State House — Station 17
Augusta, Maine 04333
207/289-2651

Maryland (EPA Form)
Science and Health Advisory Group
Office of Environmental Programs
201 West Preston Street
Baltimore, Maryland 21201

Massachusetts (EPA Form)
UST Registry, Department of Public Safety
1010 Commonwealth Avenue
Boston, Massachusetts 02215
617/566-4500

Michigan (EPA Form)
Ground Water Quality Division
Department of Natural Resources
Box 30157
Lansing, Michigan 48909

Minnesota (State Form)
Underground Storage Tank Program
Division of Solid and Hazardous Wastes
Minnesota Pollution Control Agency
1935 West County Road, B-2
Roseville, Minnesota 55113

Mississippi (EPA Form)
Department of Natural Resources
Bureau of Pollution Control
P.O. Box 10385
Jackson, Mississippi 39209

Missouri (EPA Form)
Gordon Ackley, UST Coordinator
Missouri Department of Natural Resources
P.O. Box 176
Jefferson City, Missouri 65102

Montana (EPA Form)
Solid and Hazardous Waste Bureau
Department of Health and Environmental Science
Cogswell Building, Room B201
Helena, Montana 59620

Nebraska (EPA Form)
Nebraska State Fire Marshal
P.O. Box 94677
Lincoln, Nebraska 68509-4677

Nevada (EPA Form)
Attention: Underground Storage Tanks
Division of Environmental Protection
Department of Conservation and Natural Resources
Capitol Complex
201 S. Fall Street
Carson City, Nevada 89710
800/992-0900 Ext. 4670

New Hampshire (EPA Form)
Water Supply and Pollution Control Commission
Hazen Drive
P.O. Box 95
Concord, New Hampshire 03301
Attention: UST Registration
603/271-3503

New Jersey (State Form)
Underground Storage Tank Coordinator
Department of Environmental Protection
Division of Water Resources (CN-029)
Trenton, New Jersey 08625
609/292-0424

New Mexico (EPA Form)
New Mexico Environmental Improvement Division
Ground Water/Hazardous Waste Bureau
P.O. Box 968
Sante Fe, New Mexico 87504
505/827-2933 or 505/827-2918

New York (EPA Form)
Bulk Storage Section
Division of Water
Department of Environmental Conservation
50 Wolf Road, Room 326
Albany, New York 12233-0001
518/457-4351

North Carolina (EPA Form)
Division of Environmental Mgmt./Ground Water Section
Dept. of Natural Resources & Community Development
P.O. Box 27687
Raleigh, North Carolina 27611
919/733-5083

North Dakota (State Form)
Division of Hazardous Waste Mgmt. and Special Studies
North Dakota Department of Health
Box 5520
Bismarck, North Dakota 58502-5520

Northern Mariana Islands (EPA Form)
Chief
Division of Environmental Quality
P.O. Box 1304
Commonwealth of Northern Mariana Islands
Saipan, CM 96950
Overseas Operator: 6984
Cable Address: GOV. NMI Saipan

Ohio (State Form)
State Fire Marshal's Office, UTN
Department of Commerce
8895 E. Main Street
Reynoldsburg, Ohio 43068
State Hotline 800/282-1927

Oklahoma (EPA Form)
Underground Storage Tank Program
Oklahoma Corporation Comm.
Jim Thorpe Building
Oklahoma City, Oklahoma 73105

Oregon *
Underground Storage Tank Program
Hazardous and Solid Waste Division
Department of Environmental Quality
P.O. Box 1760
Portland, Oregon 97207
503/229-5788

Pennsylvania (EPA Form)
Pennsylvania Department of Environmental Resources
Bureau of Water Quality Management/Ground Water Unit
9th Floor, Fulton Building
P.O. Box 2063
Harrisburg, Pennsylvania 17120

Puerto Rico (EPA Form)
Director, Water Quality Control Area
Environmental Quality Board
Commonwealth of Puerto Rico
P.O. Box 11488
Santurce, Puerto Rico 00910
809/725-0717

Rhode Island (EPA Form)
UST Registration
Department of Environmental Management
204 Cannon Building
75 Davis Street
Providence, Rhode Island 02908
401/277-2234

South Carolina (State Form)
Attention: Susana Workman
Groundwater Protection Division
South Carolina Dept. of Health and Environmental Control
2600 Bull Street
Columbia, South Carolina 29201
803/758-5213

South Dakota (EPA Form)
Office of Water Quality
Department of Water and Natural Resources
Joe Foss Building
Pierre, South Dakota 57501

Tennessee (EPA Form)
Terry K. Cothron, Director
Division of Ground Water Protection
Tennessee Department of Health and Environment
150 Ninth Avenue, North
Nashville, Tennessee 37219-5404
615/741-7206

Texas (EPA Form)
Underground Storage Tank Program
Texas Water Commission
P.O. Box 13087
Austin, Texas 78711

Utah (EPA Form)
Kenneth L. Alkema
Division of Environmental Health
P.O. Box 45500
Salt Lake City, Utah 84145-0500

Vermont (State Form)
Underground Storage Tank Program
Vermont AEC/Waste Management Division
State Office Building
Montpelier, Vermont 05602
802/828-3395

Virginia (EPA Form)
Russell P. Ellison, III, P.G.
Virginia Water Control Board
P.O. Box 11143
Richmond, Virginia 23230-1143
804/257-6685

Virgin Islands (EPA Form)
205(J) Coordinator
Division of Natural Resources Management
14 F Building 111, Watergut Homes
Christianstead, St. Croix, Virgin Islands 00820

Washington (State Form)
Earl W. Tower, Supervisor
Department of Ecology, M/S PV-11
Management Division, Solid and Hazardous Waste
Olympia, Washington 98504-8711
206/459-6316

West Virginia (EPA Form)
Attention: UST Notification
Solid and Hazardous Waste/Ground Water Branch
West Virginia Department of Natural Resources
1201 Greenbriar Street
Charleston, West Virginia 25311

Wisconsin (State Form)
Bureau of Petroleum Inspection
P.O. Box 7969
Madison, Wisconsin 53707
608/266-7605

Wyoming (EPA Form)
Water Quality Division
Department of Environmental Quality
Herschler Building, 4th Floor West
122 West 25th Street
Cheyenne, Wyoming 82002
307/777-7781

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* May be using a State form. Owners should consult EPA to determine whether such form is in compliance with Section 9002. -3-

BILLING CODE 6560-50-C

Appendix III to § 280.3

Statement for Shipping Tickets and Invoices

Note.—A new Federal law (the Resource Conservation and Recovery Act (RCRA), as amended (PL 98–616)) requires owners of certain underground storage tanks to notify designated State or local agencies by May 8, 1986 of the existence of their tanks. Notifications for tanks brought into use after May 8, 1986 must be made within 30 days. Consult EPA's regulations, issued on ——, 1985, to determine if you are affected by this law.

One-Time Notification Letter

Dear Customer: A new Federal law directs the Environmental Protection Agency (EPA) to develop a comprehensive regulatory program for underground storage tanks. As part of the new law, owners of certain underground tanks used to store petroleum or hazardous substances must notify designated State or local agencies of the existence of their tanks by May 8, 1986. This includes owners of tanks currently used to store such substances and owners of tanks taken out of operation after January 1, 1974, but still in the ground. Owners who bring tanks into use after May 8, 1986, must notify within 30 days.

The purpose of the notification program is to assist EPA and the States in locating and evaluating underground storage tanks. Enclosed is a copy of EPA's regulations concerning owners of underground storage tanks, and a notification form.

Please review the regulations to determine if you are affected by the notification requirements. A list of the addresses of the State or local agencies designated to receive the notifications is contained in the discussion to the regulations.

[FR Doc. 85–26778 Filed 11–7–85; 8:45 am]

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Federal Register

Friday
November 8, 1985

Part VII

Department of Justice

Office of Juvenile Justice and Delinquency Prevention

Guidelines for Implementation of S. 1195 by Executive Departments and Independent Establishments of the United States Government; Notice of Preliminary Guidelines

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

Guidelines for Implementation of S. 1195 by Executive Departments and Independent Establishments of the Government of the United States

AGENCY: Office of Juvenile Justice and Delinquency Prevention, Justice.

ACTION: Notice of Preliminary Guidelines.

SUMMARY: Section 1(a) of S. 1195, Pub. L. 99-87, 99 Stat. 290, August 9, 1985, amends Chapter 32 of title 39, United States Code, to authorize every Federal department and independent establishment, and the United States Congress, to use official mail to aid in the location and recovery of missing children. 39 U.S.C. 3220(a)(1) directs the Office of Juvenile Justice and Delinquency Prevention (OJJDP), after consultation with appropriate public and private agencies, to prescribe general guidelines under which penalty mail may be used to assist in the location and recovery of missing children.

39 U.S.C. 3220(a)(2), in turn, authorizes and requires each executive department and independent establishment of the Government of the United States to prescribe regulations under which penalty mail sent by such departments and establishments may be used in conformance with the OJJDP guidelines. This notice provides preliminary guidelines pursuant to 39 U.S.C. 3220(a)(1) within the 90-day timeframe established by Section 2(a) of S. 1195..

FOR FURTHER INFORMATION CONTACT: Michelle Easton, Missing Children's Program Coordinator, Office of Juvenile Justice and Delinquency Prevention, 633 Indiana Avenue, NW., Room 1110, Washington, DC 20531, telephone (202) 724-7655.

SUPPLEMENTARY INFORMATION: The passage of S. 1195 reflects an increasing public concern with the problem of missing and exploited children. The Missing Children's Assistance Act of 1984, added as title IV of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, by the Comprehensive Crime Congrol Act of 1984 (Pub. L. 98-473, October 12, 1984), recognized the problem and provided a Federal coordination and assistance role in combating this interstate problem. The Missing Children's Assistance Act authorized and directed the establishment and support of a National center to serve as a clearinghouse for information and to provide direct assistance in locating missing children. The National Center for Missing and Exploited Children (National Center) was created to carry out these functions.

One activity which the National Center has undertaken in its first year of operation is the dissemination of photographs and biographical information on hundreds of missing children. The National Center has established criteria for obtaining parent or custodian consent, determining which photographs are to be printed, and for what duration. Provision has also been made for timely recalling and withdrawal from general circulation of photographs of children who have been found.

This National Center activity has been successful, particularly in the private sector. ABC-TV has aired pictures of missing children weekly on its *Good Morning America* Program. CBS is airing one missing child per week on prime time TV as a Public Service Announcement. Efforts using milk cartons, grocery bags, mailing labels, bottle colars, and other means have been established and continue. The American Gas Association, for example, places two pictures of missing children in monthly billings that go to 54 million homes per month. Currently, the National Center is servicing over 315 various organizations and publications with missing children's photos and biographical information.

The objective of S. 1195 is to supplement and expand upon these efforts by authorizing the use of official U.S. Government penalty and Congressional Franked mail to assist in the location and recovery of missing children. Section 1(a) of the Act authorizes the use of official mail in the location and recovery of missing children by adding a new section 3220 to title 39 of the United States Code. Subsection (a) of the new section 3220 of title 39 provides for the establishment of guidelines and regulations for the use of penalty mail by executive departments and independent establishments of the Federal government.

Subsection (a)(1) of the new section 3220 of title 39 directs the Office of Juvenile Justice and Delinquency Prevention (OJJDP), after consultation with appropriate public and private agencies, to prescribe general guidelines under which penalty mail may be used to assist in the location and recovery of missing children. This subsection provides that the guidelines shall provide information relating to—

"(A) the form and manner in which materials and information relating to missing childen (such as biographical data and pictures, sketches, or other likenesses) may be included in penalty mail;

"(B) appropriate sources from which such materials and information may be obtained;

"(C) the procedures by which such materials and information may be obtained; and

"(D) any other matter which the Office considers appropriate.

Preliminary guidelines in these four areas are set forth below. The guidelines are designated as preliminary because, although they provide general guidance in the development of agency regulations under subsection (a)(2) of the new section 3220 of title 39, OJJDP plans to expand the consultation process with respect to area (A) above. In this way, OJJDP hopes to explore with agencies such as GSA, GPO, the U.S. Postal Service, and the various executive departments and independent establishments, a variety of options that are designed to result in a maximum use of missing children information in penalty mail yet be cost-effective in terms of existing fiscal and staff resources. OJJDP intends to hold at least one public hearing to obtain further input from public and private agencies who have ideas, suggestions, or concerns to offer. Written comments and suggestions will also be welcome. Additional guidance and information that will assist in the implementation of S. 1195 will then be published in the **Federal Register** and directed to agency contact persons.

As noted, subsection (a)(2) of 39 U.S.C. 3220 requires each executive department and independent establishment of the Government of the United States to prescribe regulations under which penalty mail sent by such department or establishment may be used in conformance with the guidelines prescribed by OJJDP. While S. 1195 as passed by the Senate required that 50 percent of the penalty mail sent by each executive branch department and establishment contain photographs and biographies of missing children, the final bill provided each department and establishment with the flexibility to determine how their official mail can best be utilized to achieve the important objectives of the bill. In written comments and testimony, certain executive departments had indicated that a large portion of their official mail is sent overseas or intra-agency. Consequently, Congress determined that each department and establishment should exercise its sound discretion to ensure that use of its official mail to distribute information on missing children is both cost-effective and in furtherance of the primary objective of

the bill: to locate and return missing children.

Section 1(b) of the Act adopts the definition of "missing child" provided by section 403(1) of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended:

> The term "missing child" means any individual less than 18 years of age whose whereabouts are unknown to such individual's legal custodian if—
>
> (A) the circumstances surrounding such individual's disappearance indicate that such individual may possibly have been removed by another from the control of such individual's legal custodian without such custodian's consent; or
>
> (B) the circumstances of the case strongly indicate that such individual is likely to be abused or sexually exploited;

Under this definition, a missing child may fall under one of three basic categories:

(1) Kidnapped by a nonfamily member;

(2) kidnapped by a noncustodial family member; and

(3) runaway or throwaway under the circumstances set forth in paragraph (B) of the definition.

Section 2(a) of the Act provides that OJJDP shall prescribe the general guidelines described in section 3220 not later than 90 days after enactment (November 7, 1985) and section 2(b) that each department and establishment shall prescribe its implementing regulations not later than 180 days after enactment (February 5, 1986).

Section 3 of the Act requires that OJJDP submit, within two years from the date of passage of the Act, a written report to the Congress to include—

(1) An assessment of the effectiveness with which authority provided by section 3220 of title 39, United States Code, has (during the period covered by the report), been used, insofar as such authority was subject to guidelines prescribed by OJJDP;

(2) recommendations as to whether the authority under such section should, insofar as such authority was subject to such guidelines, be extended beyond the termination date otherwise applicable under section 5; and

(3) any other information which OJJDP considers appropriate.

Finally, section 5 contains a sunset provision for the Act, the OJJDP guidelines, and the implementing regulations, providing that they shall cease to be effective two and one-half years after the date of enactment of S. 1195. Because of this "sunset" provision, it is imperative that Federal departments and independent establishments provide full and timely information to OJJDP, as requested under Section D of the guidelines, in order to assist in the preparation of the report required under section 4, above.

In forumulating the guidelines that follow, OJJDP has consulted with representatives of the U.S. Postal Service, the General Services Administration, and the National Center for Missing and Exploited Children.

Guidelines for Implementation of S. 1195

A. Form and Manner in Which Materials and Information Relating to Missing Children May Be Included in Penalty Mail

Departments and independent establishments and their subunits (hereinafter "agencies") can choose from a variety of *types* of penalty mail which may include (on or inside) pictures and biographical data related to missing children. These include:

1. Standard letter-size envelopes (4¼" x 9½").

2. Document-size envelopes (9½" x 12", 9½" x 12½", 10" x 13").

3. Other envelopes (misc. size).

4. Self-mailers and other publications (newsletters, bulletins, etc.).

In using these types of penalty mail, there are options available with respect to the *manner* in which pictures and biographical data related to missing children may be printed or presented:

1. *Printed* on envelopes at the time they are initially printed with agency identifying information.

2. *Overprinted* on existing agency envelopes.

3. Presented through printed *inserts* that are placed in envelopes along with other agency mailing material.

4. Presented through *stickers* that are printed and placed on envelopes prior to mailing.

5. Printed as part of the content of *self-mailers* such as agency newsletters, bulletins, etc.

In considering these tyes of penalty mail and the options for the manner of presentation of photographs and biographical data on missing children, there are a number of matters which need to be taken into account by implementing agencies:

1. Restrictions on placement of information on standard size envelopes.

2. Restrictions on the "shelf-life" of missing children information.

3. Agency procedures for obtaining and using penalty mail envelopes.

4. The types of mailings utilized by the agency, their frequency, and audience (addressee).

5. Agency procedures for the routine collection, sorting, and dissemination of penalty mail.

First, the U.S. Postal Service has established recommended standards for the placement of address, return address, and penalty indicia on letter-size mail. When agencies follow these standards by not placing other information in the areas specified by the Postal Service, the efficient processing of letter-size mail by automated optical character readers (OCRs) and bar code sorters (BCSs) is furthered. Following the Postal Service standards for letter-size envelopes results in the availability of an area approximately 1¾" x 4" on the front of the envelope for the placement of a photograph and biographical information on a missing child. This space is available for printing, overprinting or for the use of missing child stickers.

Consequently, agency regulations implementing these guidelines should provide that missing children information will not be placed in the areas specified on the letter-size envelope facsimile set forth in Appendix A by the designations "Penalty Indicia", "OCR Read Area", "Bar Code Read Area", and "Return Address". Missing children information may, however, be placed on standard letter-size envelopes in the area specified as available on the front of the letter size envelope facsimile or on the back.

Second, under its Missing Children Picture Selection Procedure (S.1195) (Appendix B), the National Center for Missing and Exploited Children will ensure that all camera-ready and other photographic and biographical materials to be disseminated for use by executive departments and independent establishments of government: (1) Have been properly released by the parent(s) or guardian of the missing child; and (2) are current. In addition, the "shelf-life" of printed penalty mail material is to be limited to *three months* for all missing child cases. This means that the receiving agency must provide for the removal of all printed penalty mail envelopes and other materials from circulation or other use by the agency (i.e.: use or destroy) within a three-month period from the date the National Center receives information or notice that a child has been recovered or that parent(s) or guardian permission to use the child's photograph and biographical information has been withdrawn. The National Center will immediately notify each designated agency contact person, in writing, of the need to withdraw penalty mail envelopes and other materials related to a particular child from circulation.

Third, the size and structure of a department or independent

establishment and its envelope ordering, storage, and dissemination practices and procedures, coupled with the shelf-life constraints noted above, will impact an agency's choices from among the range of possible options and procedures that are to be established by agency regulation for the printing or placement of missing children information on penalty mail envelopes and other materials.

Fourth, agencies who use mass mailings to members of the public, particularly where such mailings are monthly or otherwise regularly scheduled, are in a position to target this mail for the inclusion of missing children material. Whether envelope printing, overprinting, or the use of inserts is the most practical and cost-effective method of presenting the informational material will need to be evaluated. An agency which is highly automated and uses machinery to "stuff" envelopes that are cut and printed as part of the same mailing operation, would need to consider both an envelope printing option and an insert option. An agency which does no mass mailings but sends a variety of mailed materials to members of the public should consider all available options to determine which type best suits its needs.

Fifth, agency procedures for the collection, sorting, and information that is selected. For example, where individual offices address mail to the public and seal envelopes which have not been printed or overprinted with missing children information prior to agency mail pick-up, it may be possible to provide these offices with inserts or stickers to insert in or attach to penalty mail prior to pick-up and mailing. In other agencies, this could be done as a part of the mail room operation.

OJJDP has concluded as a result of its consultation with the National Center on the implementation of S. 1195 that sketches and other likenesses of missing children are not sufficiently reliable to justify their use. Instead, photographs which were reasonably current as of the time of the child's disappearance (or perhaps in the future those which have been updated to reflect the missing child's current age through computer enhancement techniques) offer a more reliable guide to identification. They will, therefore, be the only acceptable form of visual media or pictorial likeness used on or in penalty mail.

The National Center will, as provided under C. below, provide camera-ready copy of photographs and biographical data on missing children in a variety of formats. All such materials provided by the National Center are approved for agency penalty mail use. In addition, agencies may have occasion to request photographs and biographical data on missing children selected by the National Center under its procedure in order to prepare their own camera-ready copy. In such case, the National Center may, at its option, require the inclusion of specific biographical data or subject the agency's print proofs to review and approval prior to their use by the agency.

In preparing and implementing regulations based on these guidelines, agencies are encouraged to give priority to penalty mail that is addressed to members of the public and that will be received within the United States, its territories and possessions. Use of photographs and biographical information on or in penalty mail envelopes that are addressed inter- or intra-agency or overseas is not likely to be productive or cost-effective. However, use of such information in inter- and Intra-agency publications and other media which will be widely disseminated to and viewed by agency employees is encouraged. For example, the U.S. Postal Service, in conjunction with the National Association of Letter Carriers, recently announced a coordinated, voluntary effort to locate missing children through the monthly publication of missing children's photographs in Postal Service and Union publications. Under this new "Child Alert" program, pictures and biographical information on missing children have been published in the *Postal Bulletin*, *Postal Life*, and a variety of Union publications.

B. Appropriate Sources From Which Missing Children Materials and Information May Be Obtained

OJJDP has determined that, because of its Washington, DC location, extensive files of missing children information, and national toll-free telephone number, the National Center for Missing and Exploited Children shall be designated as the exclusive source from which missing children materials shall be otained for implementation of S. 1195 by Federal departments and independent establishments.

Materials and information related to the general implementation of S. 1195 and the Missing Children Program may be obtained from OJJDP or the National Center.

Pictures and biographical information will, as noted, be available in camera-ready copy in a variety of sizes and formats appropriate to the type and manner of missing children information uses determined to be most appropriate by each agency. The National Center will use its Missing Children Picture Selection Procedure (Appendix B) to select, each month, a missing child or children who are appropriate subjects for broad distribution of photographs and biographical information. In addition to providing photographic and biographical information, the camera-ready copy will request that individuals who have information regarding the child or children call the National Center's toll-free hotline telephone number (1-800-843-5678).

The contact person at the National Center will be: David L. Shapiro, Program Director, National Center for Missing and Exploited Children, 1835 K Street, NW., Suite 700, Washington, DC 20006. Telephone: (202) 634-7161.

C. Procedures by Which Materials and Information May Be Obtained

The National Center will have general information on the program available immediately and will respond to questions from agencies at any time. The National Center will have the camera-ready copy available for distribution to agencies beginning in January, 1986.

Orders for camera-ready copy or other photographic and biographical material may be placed periodically by the Federal department or independent establishment contact(s) specified in the regulations published in the **Federal Register** pursuant to 39 U.S.C. 3220(a)(2) as provided in D. below. The National Center will develop and distribute an appropriate order form for this purpose.

D. Other Matters

1. Each Federal department and independent establishment of the Government of the United States publishing regulations pursuant to 39 U.S.C. 3220(a)(2) shall, at a minimum, provide the following information in their regulation:

(a) Information as to whether the department or establishment is publishing a single regulation to be effective department or establishment-wide, whether it is authorizing subunits of the agency to establish their own regulation to implement S. 1195 and, if so, identifying information, including the designated contact person, for each such subunit.

(b) A plan, taking into consideration the information provided in these guidelines, for the department or establishment to maximize the use of missing children photographs and biographical information in the agency's penalty mail. Such plan shall establish appropriate procedures for identifying additional opportunities to use photographs and biographical data on

missing children in agency penalty mail, contain an estimate of the percentage of agency penalty mail which will contain such information once it is fully implemented, and estimate the first year cost of the program.

2. Each Federal department and independent establishment shall submit to OJJDP, by June 30, 1987, a report on its experience in implementation of S. 1195, the OJJDP Guidelines, and the department or estsablishment's implementing regulation. The report shall cover the period from the date of publication of implementing regulations through March 31, 1987 and shall detail:

(a) The department or establishment's experience in implementation, including problems encountered, successful and or innovative methods adopted to use missing children photographs and information on or in penalty mail, the estimated number of pieces of penalty mail containing such information, and the percentage of total agency penalty mail, domestic penatly mail, and domestic penalty mail directed to members of the public which number represents.

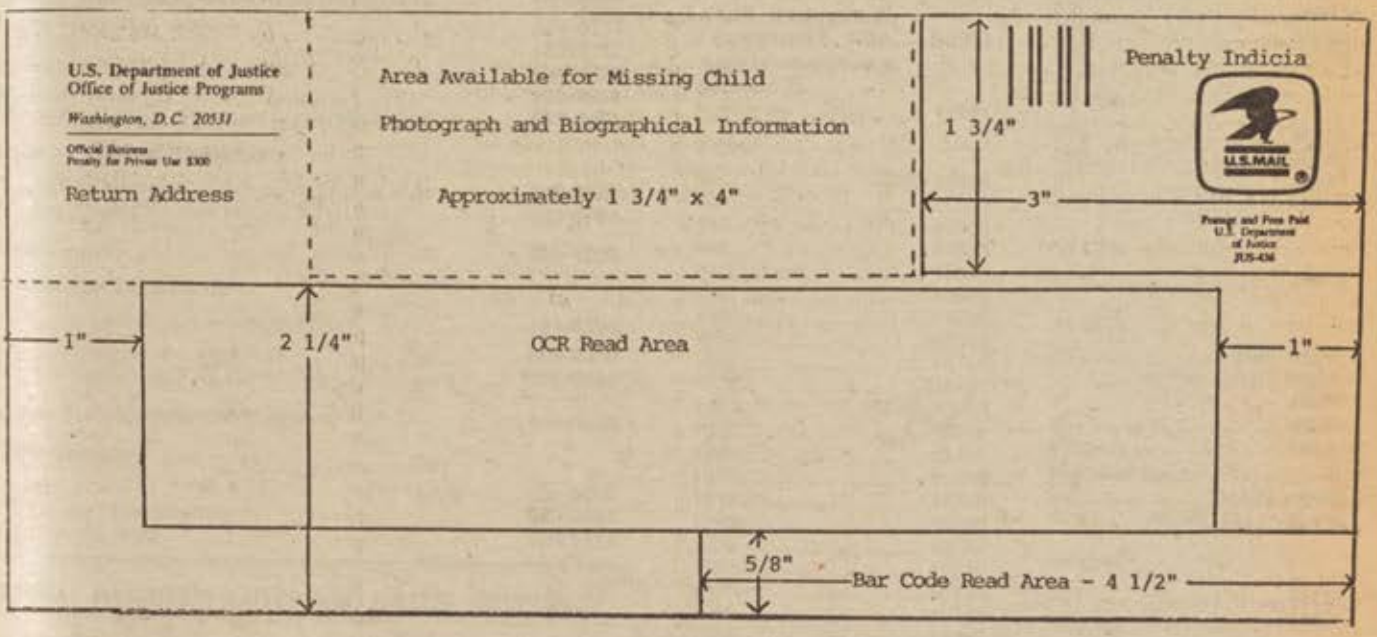
(b) The estimated total cost to implement the program, with supporting detail.

(c) Recommendations for changes in the program which would make it more effective.

3. Each Federal department and independent establishment shall specify, in its regulation, the name, address and telephone number of an individual who shall act as the point of contact for matters related to program and regulation implementation. In addition, where subunits are authorized to promulgate regulations, each such subunit shall specify a designated contact person.

Alfred S. Regnery,

Administrator, Office of Juvenile Justice and Delinquency Prevention.



Appendix A—Area Available for Missing Child Information on Standard Letter-Size Envelope Under U.S. Postal Service Guidelines

Note.—Drawing is *not* to scale.

Appendix B:

National Center for Missing and Exploited Children

Missing Children Picture Selection Procedure (S. 1195)

The procedure that follows is utilized by the National Center for compilation and selection of missing children's pictures and biographical information under S. 1195. It assists in basing judgements on facts and making more consistent the way in which missing children are selected. All selectins of missing children under this procedure are subject to the approval of the Deputy Director of the National Center.

1. Children selected shall represent a broad cross-spectrum of the entire country by sex, race, age and geographical region.

2. There shall be a current N.C.I.C. Missing Person File entry on EACH CHILD selected and for noncustodial parental kidnapping cases, priority will be given to cases were a U.F.A.P. warrant has been issued.

3. There shall be on file at the National Center ALL pertinent bio-information considered standard for the Center's 800-Hotline system to handle sightings, particularly including an original photograph of the child and signed parental permission forms. (1-800-843-5678)

4. Priority shall be given children never used before in high volume mail applications in order to assure fairness; children selected having been used before in high volume mail applications shall receive lower priority.

5. Priority shall be given to cases occuring most recently and to cases in which there have been substantial active leads and investigational contact with/through the National Center's 800-Hotline system and its Technical Advisors.

6. All procedure items will be re-checked monthly. A telephone call to the parent(s) or guardian of each child selected for printing and to the law enforcement officer/agent having case responsibility will be made during the week before initial printing of camera-ready copy as well as another N.C.I.C. check. "Shelf-life" of printed penalty mail material shall be limited to three months for all children selected under the S. 1195 procedure.

7. In the event that a missing child is located or permission to continue dissemination of photographic and biographical information is withdrawn, the Center will immediately notify all designated Federal contacts of this fact so that all materials related to such child can be used or withdrawn within 90 days from the date of notification.

[FR Doc. 85-26697 Filed 11-7-85; 8:45 am]

BILLING CODE 4412-01-M