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 addresed to the Dockets Management Branch (HFA-305) (address above). Received data and comments may also be seen in the above office 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 March 17, 1986. 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.

Dated: December 31, 1984.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

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Part X

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 357

Poison Treatment Drug Products for Over-the-Counter Human Use; Tentative Final Monograph

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 357

[Docket No. 81N-0050]

Poison Treatment 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) poison treatment drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the reports and recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products and the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, public comments to the advance notices of proposed rulemaking on OTC emetic drug products and OTC drug products for the treatment of acute toxic ingestion that were based on the respective Panels' recommendations, and public comments on the agency's proposed regulation on OTC emetic drug products, which was issued in the form of a tentative final monograph. 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 May 15, 1985. Written comments on the agency's economic impact determination by May 15, 1985.

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 March 21, 1975 (40 FR 12902) 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 laxative, antidiarrheal, emetic,and antiemetic drug products, together with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in these drug classes. Interested persons were invited to submit comments by June 19, 1975. Reply comments in response to comments filed in the initial comment period could be submitted by July 19, 1975.

In the **Federal Register** of September 5, 1978 (43 FR 39544), the agency published a proposed rule, in the form of a tentative final monograph, for OTC emetic drug products. Interested persons were invited to file by October 5, 1978 written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs on the proposed regulation.

In response to the emetic tentative final monograph 16 poison control centers, 18 hospitals, 8 medical schools, 6 state health departments, 5 state pharmaceutical associations, 1 trade association, and 6 individuals submitted comments.

In a notice published in the **Federal Register** of March 21, 1980 (45 FR 18398), the agency advised that it had reopended the administrative record for OTC emetic drug products to allow for consideration of data and information that had been filed in the Dockets Management Branch after the date the administrative record previously had officially closed. The agency concluded that any new data and information filed prior to March 21, 1980 should be available to the agency in developing a proposed regulation in the form of a tentative final monograph.

In the **Federal Register** of January 5, 1982 (47 FR 444.), 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 drug products for the treatment of acute toxic ingestion, 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 active ingredients in this drug class. Interested persons were invited to submit comments by April 5, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by May 5, 1982. In response to this advance notice of proposed rulemaking, 3 poison control centers and 3 pharmaceutical companies submitted comments.

In accordance with § 303.10(a)(10), the data and information considered by the Panels and the agency are 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. Copies of the comments received are also on public display in the Dockets Management Branch.

There is considerable overlap between in the rulemaking on OTC emetic drug products and the rulemaking on OTC drug products for the treatment of acute toxic ingestion. The intent of both rulemakings is to identify those ingredients that are generally recognized as safe and effective in the treatment of poisonings. Ipecac syrup, the one ingredient included in the rulemaking on emetic drug products, was also included in the rulemaking on OTC drug products for the treatment of acute toxic ingestion. Because of the overlap between the two rulemakings and because of the large number of comments submitted to the emetic tentative final monograph, the agency has decided to combine the two rulemakings and to publish a single tentative final monograph (proposed rule) to establish Subpart A of Part 357 entitled "Poison Treatment Drug Products." Part 337, previously designated for Emetic Drug Products for Over-The-Counter Human Use, will be reserved.

In this tentative final monograph (proposed rule) to establish Subpart A of Part 357 (21 CFR Part 357, Subpart A), FDA states for the first time its position on the establishment of monograph for OTC poison treatment 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 poison treatment drug products.

This proposal constitute FDA's tentative adoption of the Miscellaneous Internal Panel's conclusions and recommendations on OTC drug products for acute toxic ingestion as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report, and the agency's re-evaluation of the previously published proposed rule on OTC emetic drug products. 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. Based on the comments received, the agency has proposed in this tentative final monograph a number of changes in the content and format of the labeling of posion treatment drug products. FDA recognizes that it is

important for the labeling of these products to be very easily and rapidly comprehensible, because the products would almost always be used in an emergency situation. Therefore, the agency invites specific comment on the revised labeling proposed in this tentative final monograph.

The OTC procedural regulations (21 CFR 330.10) have been revised to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). (See the **Federal Register** of September 29, 1981; 46 FR 47730.) The court in *Cutler* held that the OTC drug review regulations were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision has been deleted from the regulations, which 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 OCT drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, 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 regulations in § 330.10(a)(7)(iii) provide for a 12-month period to submit data and information to support a condition excluded from the monograph in the tentative final order. The only ingredients reviewed and considered for poison treatment, ipecac syrup and activated charcoal, have been placed in Category I and are included in this tentative final monograph. The agency is unaware of any other ingredients that have potential for OTC use in poison treatment drug products. Therefore, the agency believes the usual 12-month period for submission of new data or information is unnecessary in developing a final monograph for OTC poison treatment drug products. Because there is no need for this 12-month period, the time for filing written comments or objections or requesting an oral hearing before the Commissioner following publication of a tentative final monograph (§ 330.10(a)(7)(i)) is 60 days. However, because of the number of OTC drug review documents being published concurrently, the agency is providing 120 days for comments or objections rather than the usual 60 days.

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 products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions 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 they are the subject of an approved new drug application (NDA). Further, any OTC drug products subject to this monograph that are 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 proposed rulemaking for OTC emetic drug products (published in the **Federal Register** of September 5, 1978 (43 FR 39544)) and in the advance notice of proposed rulemaking for OTC drug products for the treatment of acute toxic ingestion (published in the **Federal Register** of January 5, 1982 (47 FR 444), the agency suggested different effective dates for the final monographs. 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. However, 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.

I. The Agency's Tentative Conclusions on the Comments and Objections

A. General Comments

1. One comment urged the agency to recognize explicitly the legal status of the monographs issued under the OTC drug review as being interpretive, as distinguished from substantive, regulations.

The agency addressed this issue in paragraphs 85 through 91 of the preamble of the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F. 2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D. N.Y. 1980), *aff'd*, 637 F. 2d 887 (2d Cir. 1981).

2. One comment argued that the indications for OTC drug products should not be limited to the precise words as set forth in quotation marks in proposed monographs. The comment

argued that since there are other ways and other words that can be used to convey the same meaning as the phrases set forth in the proposed monographs, it is unduly restrictive, unlawful, and unconstitutional to prevent the use of such alternatives. The comment further charged that this restriction is arbitrary and capricious because the agency's arguments, which support this policy (OTC Nighttime Sleep-aid and Stimulant Products Tentative Final Monographs, June 13, 1978, paragraph 5 (43 FR 25545)) as necessary to prevent consumer deception and unsafe use, are unsupported by any objective evidence that such negative effects might occur.

During the course of the OTC drug review, 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. (This policy has become known as the "exclusivity rule.") The agency's position has been that it is necessary to limit the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the review exhausts all the possibilities of terms that appropriately can be used in OTC drug labeling. Suggestions for additional terms or for other labeling changes may be submitted as comments to proposed or tentative final monographs within the specified time periods or through petitions to amend monographs under § 330.10(a)(12).

During the course of the review, FDA's position on the "exclusivity rule" has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by The Proprietary Association to reconsider its position. In a notice published in the **Federal Register** of July 2, 1982 (47 FR 29002), FDA announced that a hearing would be held to assist the agency in resolving this issue. On September 29, 1982, FDA conducted an open public forum at which interested parties presented their views. The forum was a legislative type administrative hearing under 21 CFR Part 15 that was held in response to a request for a hearing on the tentative final monographs for nighttime sleep-aids and stimulants (published in the **Federal Register** of June 13, 1978; 43 FR 25544). The agency's decision on this matter will be announced in the **Federal Register** following conclusion of its review of the material presented at the hearing.

3. One comment suggested that FDA should sponsor a study on developing labeling which can be easily understood by individuals with limited education.

FDA has sponsored several labeling studies over the past few years. The first phase of the contract entitled "Consumer Comprehension of OTC Drug Labeling Language" (contract no. 223–80–3023) was completed in 1981. Unfortunately, budgeting restrictions forced the agency to cancel plans for the second phase of this study, which was designed to provide guidance in drafting labeling that can be easily understood by the public.

4. One comment objected to the current wording of the statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately," which is required for all orally administered OTC drugs. The comment argued that such a statement seems to imply that Poison Control Center personnel are not professionals. The comment suggested rewording this warning to read "In case of accidental overdose, contact a Poison Control Center or seek other professional assistance immediately."

FDA is proposing to exempt OTC poison treatment drug products from that portion of the warning in § 330.1(g) (21 CFR 330.1(g)) that is referred to by the comment. The comment is, therefore, not applicable to the labeling of these drugs. However, the agency recognizes that some change in the wording of this general warning may be necessary because the Advisory Review Panel on OTC Miscellaneous Internal Drug Products also has suggested a change in this warning (47 FR 55681). However, this issue will not be addressed in this document but will be addressed at a later date in another **Federal Register** document.

B. General Comments on Poison Treatment Drug Products

5. One comment disagreed with the Miscellaneous Internal Panel's statement that large volumes of water or milk should be ingested to dilute acidic or alkaline corrosive substances (47 FR 447). The comment pointed out that although the role of dilution with large volumes of fluid for poisoning in general is presently controversial, some evidence suggests that excessive dilution may have detrimental effects, especially in the case of caustics where large volumes of fluid may induce emesis and expose the esophagus again to the caustic. The comment suggested that it would be more prudent to suggest dilution of caustics with one glassful or less or water or milk.

Although the comment raises a valid point regarding the proper amount of fluid to be used in diluting caustics, the Panel's statement was made as part of a general discussion of poisoning and was not a specific recommendation to be included in the labeling of products covered by the monograph.

Labeling proposed in this tentative final monograph is limited to that necessary to insure the proper use of ipecac syrup and activated charcoal in treating poisoning. The labeling for both activated charcoal and ipecac syrup clearly states that these drugs are not to be administered in a poisoning that involves corrosives. Thus, there is no labeling proposed in this tentative final monograph regarding the amount of fluid to be used in diluting corrosive poisons because ipecac syrup and activated charcoal are only to be used in conjunction with noncorrosive poisons.

6. Four comments urged that the labeling be amended to include the word "pharmacist" in all phrases that include the word "physician." The comments argued that because pharmacists are readily available and extremely well informed regarding drugs, they should be named in the labeling as a contract for information regarding treatment on poisonings. Several of the comments reported the results of a recent survey as showing a good pharmacist-patient communication relationship because although 87 percent of the people surveyed were seen by more than one doctor, 86 percent will have their prescriptions filled at only one pharmacy. These comments further pointed out that former FDA Commissioner Kennedy, in a 1978 address to the American Pharmacists Association meeting in Canada, stated that "the pharmacist's knowledge of drugs, including adverse reactions, usually exceeds that of the physician."

Although physicians or pharmacists would be likely health professionals to be consulted because of their availability and recognized expertise, the agency does not believe that the labeling of OTC drug products should specify one or both of these health professionals. Many professional groups, such as nurses, nurse practitioners, and physician's assistants, are also sources of sound information on poison treatment. Consumers who are looking for poison treatment information are in the best position to choose the health professional to help them, and the warning should not limit their source of information. Therefore, the agency is revising the labeling in this tentative

final monograph for poison treatment drug products to advise consumers to contact a "health professional" for advise rather than any particular health professional.

7. A number of comments urged that the sentence "Call a physician, poison control center, or emergency room . . . ." in proposed § 337.50(c)(1) be revised to list "poison control center" first because poison control centers possess greater expertise in treating poisoning cases and are more easily reached by phone on a 24-hour basis than the other listed sources. The comments also pointed out that this change in wording would be consistent with national public education efforts to make the public aware that contacting a poison control center is the first action to take when a poisoning occurs or is suspected. Other comments suggested, in addition, that emergency room be listed second and physician last to assure that the most experienced sources are listed first.

FDA recognizes that poison control centers are the first source of information in treating poisonings and occurs with the suggested change in the labeling. The agency also believes that emergency personnel may be more readily available than other health professionals and should be listed second. (See also comment 8 below.)

8. Two comments requested that the term "emergency room" be replaced in labeling by the term "emergency medical facility" or "emergency medical center" because many emergency treatment centers are not situated within a hospital as the term "emergency room" implies. A third comment objected to the phrase "emergency medical facility" as being meaningless because the word "hospital" is the listing most often found in telephone books. The comment suggested revising the warning to read, "If you can, before using, call a poison control center, hospital, or doctor for advice."

FDA acknowledges that "emergency medical facility" or "emergency medical center" is a more descriptive term than "emergency room" because, as the comments pointed out, many emergency treatment centers are not located in hospitals. The agency does not agree that the term "emergency medical facility" is meaningless. In many parts of the United States, treatment or advise for poisoning can be obtained from hospitals, small clinics, poison control centers, medical centers, fire and emergency rescue services, etc. The term "emergency medical facility" encompasses all of these sources of information. Therefore, the agency is proposing that this term be used throughout the tentative final monograph.

9. Several comments expressed concern over the amount and complexity of labeling proposed for poison treatment drug products arguing that such labeling might be difficult to read because of the small print size and difficult to understand under rushed emergency conditions. Some of the comments urged the use of simple and brief labeling similar to the following:

> Before Use: Call your Poison Center, Physician, or Emergency Room. Do Not Use in a patient who is Comatose, Convulsing, or who has taken a Caustic. Dose: 30 mL (1 oz)—adult, 15 mL (½ oz)—child over 1 yr.

Another comment suggested the use of a package insert or an oversize bottle to allow adequate room for the labeling.

The comments raise a valid concern with respect to all poison treatment drug products. A simple, brief label is more likely to be read and understood under emergency conditions. However, it is equally important that adequate directions and warnings regarding the use of poison treatment drug products be available to the consumer when professional emergency help cannot be reached quickly.

In an effect to accomplish both objectives, FDA is proposing to divide the labeling for poison treatment drug products into two distinct segments. First, the agency proposes that the principal display panel contain the following brief emergency instructions in a conspicuously boxed area: "If possible call a poison control center, emergency medical facility, or health professional for help before using this product. If help cannot be reached quickly follow the directions (manufacturer to indicate location of directions, e.g., on the back of the bottle). Read the warnings and directions as soon as you buy this product. Insert emergency phone number(s) in space provided on the label." A space should also be provided, on the principal display panel, for writing in the phone number(s) of the appropriate poison control center or other emergency medical facility.

Second, the agency proposes that full warnings and directions be placed on a separate portion of the label. Wrap around or fold-over labels may be used to provide more label space with room for larger and more legible print. A package insert would not be acceptable because of the risk that it might become separated from the product. An oversize bottle might create confusion in the case of ipecac syrup because the quantity that may be sold OTC is limited to 30 milliliters (mL) per container, and determining a children's dose of ½ bottle as provided for in § 357.56(d)(2) of this tentative final monograph could be difficult under emergency conditions.

10. Three comments agreed with the proposed labeling for ipecac syrup (proposed § 337.50(c)(1)), which advises consumers to seek professional help before administering ipecac syrup. One of the comments stated that if consumers did not contact a professional before using ipecac syrup, it may be given many times when it is contraindicated, e.g., in instances of petroleum distillate or corrosive poisonings. Two other comments expressed the opposite opinion that attempting to contact professional help before using the product could result in a critical delay in an emergency situation. Another comment objected to a similar warning recommended for activated charcoal and poison treatment kits (recommended § 357.50(c)(1) and § 357.54(a)(1), respectively) because a written warning could be interpreted as prohibiting the administration of the product if a health professional could not be reached.

The agency believes that is any poisoning situation it would be best to seek professional help before using poison treatment drug products. However, there are times when such contact may not be possible. In those cases, the consumer should not be discouraged from using poison treatment drug products.

The agency is proposing that the principal display panel contain statements advising consumers to contact professional help if possible, but if help cannot be reached, to follow the directions provided elsewhere on the label. These statements will replace the warnings previously recommended in §§ 337.50(c)(1), 375.50(c)(1), and 357.54(c)(1). In those cases where professional help cannot be reached, the warnings contained on the labels of poison treatment drug products will list those poisoning situations in which the products should not be used.

11. One comment urged that labeling for ipecac syrup be printed in languages other than English in view of the extensive non-English speaking populations in many large cities.

The agency agrees that it would be valuable to have both emetics and adsorbents available with foreign language labeling. The regulations at 21 CFR 201.15(c) provide for labeling in other languages in addition to English. The foreign language version of the labeling statements must be a complete

and accurate translation of the required English labeling.

12. One comment pointed out that many poisoning reference sources, such as the Poisindex, recommend the administration of a saline cathartic when activated charcoal is administered in the management of poisoning. The comment questioned whether the Panel has considered the use of cathartics in poisoning.

The agency has reviewed the Miscellaneous Internal Panel's report and summary minutes of meetings and determined that the Panel did not consider the use of cathartics in acute poison treatment. A number of sources suggest the use of cathartics in poison treatment to remove unabsorbed poisons from the intestinal tract or to speed the passage of activated charcoal through the intestinal tract (Ref. 1, 2, and 3). According to Levy (Ref. 1), it has been customary to administer a saline laxative together with an adsorbent to prevent constipation or impaction. However, Levy noted that it would be advisable to use a conservative dose of a laxative to prevent excessive fluid loss and electrolyte disturbances. Dreisbach (Ref. 2) noted that catharsis or intestinal lavage can be used to remove unabsorbed poisons or poisons that have passed into the intestinal tract, but pointed out that catharsis should not be used in patients showing distrubed electrolyte balance. Cashman and Shirkey (Ref. 3) agree that laxatives may hasten transit through the bowel, thus decreasing the absorption of poisons that cannot be recovered by emesis or absorbed by activated charcoal, but believe judgment must be exercised by comparing the risk of poisoning to the theoretical value of the laxative. In view of these opinions, the agency believes that professional judgment is necessary to assess the appropriateness of using laxatives in poisoning situations. Thus, the agency does not believe that the labeling of OTC poison treatment drug products should mention the use of laxatives.

References

(1) Levy, G., "Gastrointestinal Clearance of Drugs with Activated Charcoal," *New England Journal of Medicine*, 307:676–678, 1982.

(2) Dreisbach, R.H., "Handbook of Poisoning," Lange Medical Publication, Los Altos, CA, p. 23, 1980.

(3) Cashman, T.M., and H.C. Shirkey, "Emergency Management of Poisoning," *Pediatric Clinics of North America*, 17:525–534, 1970.

13. One comment stated that the Miscellaneous Internal Panel appeared to mandate the use of ipecac syrup at all times before the use of activated charcoal. The comment stated that ipecac-induced emesis is not suitable in certain cases, such as ingestion of caustic substances or petroleum distillates, because it takes an average of 19 minutes to induce emisis, and sometimes a second dose is needed to induce emesis. The comment added that these delays could permot absorption of toxins that could be prevented by prompt administration of activated charcoal (Ref. 1). The comment stated that in at least one study an average of only 28 percent (range 0 to 78 percent) of stomach contents were recovered by ipecac-induced emesis (Ref. 2). The comment added that "the consensus now emerging among clincial physicians is that the best way of handling overdoses consists of the immediate administration of large amounts (100 grams (g) or more) of powdered charcoal" (Ref. 3). The comment requested that the labeling be modified to permit the use of activated charcoal without first ingesting ipecac syrup and having vomiting occur, because activated charcoal is safe under virtually all conditions.

As the Panel discussed in its report (47 FR 448), the efficiency of activated charcoal varies considerably according to the chemical ingested. A number of substances, including inorganic acids, certain alkalies (sodium and potassium hydroxide), sodium metasilicate, cupric copper, ferrous iron, boric acid, drugs that are solids and insoluble in acidic aqueous solutions, and certain insecticides, are not very well absorbed. In addition, in those situations in which ipecac syrup is contraindicated (corrosives and petroleum distillates), activated charcoal is not very effective (see comment 51 below). Although the agency acknowledges the one report that showed an average of only 28 percent recovery of stomach contents, there are numerous reports in the literature (Refs. 4 through 8), plus vast experience reported in poison control centers and emergency medical facilities, attesting to ipecac syrup's effectiveness in treating poisonings. The agency agrees with the Panel that in the majority of poisoning cases it is best to remove as much of the ingested substance as possible from the stomach by inducing vomiting before administering activated charcoal. However, the agency recognizes that in certain specific poisoning cases, a physician or other health professional may choose to administer activated charcoal rather than ipecac syrup. Therefore, the agency is proposing that the labeling for activated charcoal be modified to include this provision. (See comment 43 below.)

References

(1) Robertson, W.O., "Syrup of Ipecac: A Fast or Slow Emetic," *American Journal of Diseases in Children*, 103:136–139, 1962.

(2) Corby, D.G., et al., "Clinical Comparison of Pharmacologic Emetics in Children," *Pediatrics*, 42:361–364, 1968.

(3) Cooney, D.O., "Activated Charcoal, Antidotal and Other Medicinal Uses," Marcel Dikker, Inc., New York, p. 3, 1980.

(4) King, W.D., "Syrup of Ipecac: A Drug Review," *Clinical Toxicology*, 17:353–358, 1980.

(5) Krenzelok, E.P., "How to Manage Poisoning Emergencies," *Pharmacy Times*, 45:71–82, 1979.

(6) Rauber, A., "The Cardiac Safety of Ipecac Used as a Therapeutic Emetic," *Veterinary and Human Toxicology*, 20:166–168, 1978.

(7) Veltri, J.C., and A.R. Temple, "Telephone Management of Poisonings Using Syrup of Ipecac," *Clinical Toxicology*, 9:407–417, 1976.

(8) Ilett, K.F., S.M. Gibb, and R.W. Unsworth, "Syrup of Ipecacunha as an Emetic in Adults," *The Medical Journal of Australia*, 2:91–93, 1977.

14. Two comments suggested that the phase "or as directed by a physician" be deleted from the directions statement because advice on doses of ipecac syrup or activated charcoal may not be given by a physician, but may be given by a pharmacist, nurse, or other health professional working in a poison control center or emergency medical facility.

The agency agrees with the comment. The assistance from a poison control center or emergency medical facility may be provided by specially trained professional personnel other than physicians. Therefore, the agency is proposing that the phrase "or as directed by a physician" read "or as directed by a health professional" in the directions of poison treatment drug products.

15. One comment urged that the indication statement for emetics be revised to state clearly that ipecac syrup is to be used for the treatment of poisoning. A second comment suggested that the indications statement "for the treatment of acute poisoning" recommended for adsorbents and poison treatment kits be revised by deleting the word "acute" because it has no meaning to the general public in describing the type of poisoning. This comment further suggested that the indications statement for poison treatment drug products permit alternative language that is more understandable to the public, such as "emergency first aid treatment for poisoning," "emergency treatment for poisoning," "emergency treatment for accidental poisoning," "for the treatment of accidental poisoning," "emergency

first aid treatment for accidential poisoning," "emergency poison treatment," or "first aid poison treatment."

The agency believes that the labeling of any OTC drug product should clearly reflect the intended action of the product. In the case of ipecac syrup the agency believes it is important for consumers to be advised that vomiting is expected. Therefore, the agency is proposing the following statement as the indication for ipecac syrup: "For emergency use to cause vomiting of swallowed poisons." In the case of activated charcoal the agency believes that consumers should be informed that it is intended to absorb poisons and the indication proposed in this tentative final monograph reads "For emergency use to absorb swallowed poisons." The agency agrees with the one comment that the word "acute" is meaningless to the general public and has not included it in the proposed indications. The other statements suggested by the comments are acceptable as additional statements for inclusion on poison treatment drug products, but the agency does not believe that these statements should appear in conjunction with the required information.

C. Comments of Emetics

16. One comment contended that zinc sulfate, rather than ipecac syrup, is the emetic of choice in the treatment of accidental poisoning. The comment submitted an article stating that zinc sulfate, which produces vomiting by a purely local action in its action on the gastrointestinal tract, is both faster and more certain in its action then ipecac syrup (Ref. 1). The comment also emphasized that zinc sulfate lacks the central nervous system depressant action of ipecac syrup.

The agency recognizes that zinc sulfate is often effective as an emetic; however, its potential toxicity is too great to recommend its use as an OTC emetic drug product (Refs. 2, 3, and 4). The emetic dose of zinc sulfate is 2 g dissolved in 200 mL of water, repeated in 15 minutes if necessary. If emesis does not occur after the second dose, the zinc sulfate must be removed by stomach tube. If it is not removed, its absorption into the bloodstream can cause hemolytic effects and renal toxicity or even death (Refs. 2, 3, and 4). The lethal dose is estimated in the literature to be anywhere from 3 to 15 g (Refs. 2, 5, 6, and 7). The article submitted by the comment discussed a 1950 animal study conducted to develop a method for prevention of suicidal deaths caused by barbiturates. This study does not, however, support the general use of zinc sulfate as an OTC emetic.

In view of the reported toxicity of zinc sulfate and the narrow margin of safety between its effective dose (2 g) and its lowest reported lethal dose (3 g), the agency concludes that zinc sulfate is not suitable for use as an OTC emetic drug product.

References

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(2) "The United States Dispensatory," 27th Ed., J.P. Lippincott Co., Philadelphia, p. 1256, 1973.

(3) "AMA Drug Evaluations," 4th Ed., American Medical Association, New York, pp. 1435–1440, 1980.

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(5) Moeschlin, S., "Poisoning. Diagnosis and Treatment," 1st Ed., Grune and Stratton, New York, pp. 121–123, 1965.

(6) Dreisback, R.H., "Handbook of Poisoning," 9th Ed., Lange Medical Publications, Los Altos, CA, pp. 406–407, 1977.

(7) Arena, J.M., "Poisoning. Toxicology—Symptoms—Treatments," 3rd Ed., Charles C. Thomas, Springfield, IL, pp. 37–40 and 241, 1974.

17. Four comments took exception to the agency's statement at 43 FR 39545 in the preamble to the prvious emetic tentative final monograph that "ipecac acts directly on the vomiting reflex center in the brain to produce vomiting." The comments were concerned that this statement implied that this is the only mechanism by which ipecac syrup produces emesis. Two of comments submitted documentation showing that ipecac syrup induces emesis via two mechanisms (Refs. 1, 2, and 3). The first mechanism is direct irritation of the upper gastrointestinal tract by ipecac, i.e., the "gas reflex." When this mechanism is operative, vomiting usually occurs within a relatively short period of time after the ipecac syrup is ingested. The second mechanism is the action of ipecac alkaloids on the vomiting reflex center of the brain. Because absorption from the gastrointestinal tract and distribution to the brain are required before ipecac syrup can induce emesis via this second mechanism, there is usually a delay between the ingestion of the ipecac syrup and the onset of vomiting.

The agency did not intend to imply that ipecac syrup induces emesis solely by acting on the vomiting reflex center of the brain. As the comments correctly point out, ipecac may act either by direct irritation of the upper gastrointestinal tract, i.e., "gas reflex," or by central action on the vomiting center of the brain.

References

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(2) Oderda, G.M., and S. West, "Emetic and Antiemetic Products," *in* "Handbook of Nonprescription Drugs," 5th Ed., American Pharmaceutical Association, Washington, pp. 57–58, 1977.

(3) Rollo, I.M., "Drugs Used in the Chemotherapy of Amebiasis," *in* "The Pharmacological Basis of Therapeutics," 5th Ed., L.S. Goodman and A. Gilman, editors, Macmillan Publishing Co., Inc., New York, pp. 1075–1077, 1975.

18. Two comments were concerned about possible confusion between tincture of ipecac, fluidextract of ipecac, and the more dilute syrup of ipecac and the toxicity that could result if confusion occurred. One comment pointed out that vitually all published reports which discuss the toxicity of ipecac refer to toxicity resulting from the administration of fluidextract of ipecac rather than ipecac syrup. The fluidextract of ipecac contains over 10 times the concentration of the alkaloids, emetine and cephaline, found in ipecac syrup. The second comment urged that a sentence be added to the labeling of ipecac syrup advising individuals that syrup of ipecac and not the more concentrated and extremely dangerous tincture of ipecac is to be used in poisoning situations.

The first comment correctly identifies a misconception regarding the toxicity of ipecac syrup. As the comment indicated, most of the articles and reports discussing ipecac toxicity or ipecac overdose deal with situations in which the fluidextract of ipecac was administered rather than the more dilute ipecac syrup. In the past the fluidextract was frequently mistaken for the syrup. The tincture of ipecac and the fluidextract of ipecac are no longer recognized in the official compendia and are no longer commercially available. Further, such products are proposed as Category II because of their potential toxicity if incorrectly used. Therefore, the possibility of confusing the fluidextract or tincture of ipecac for the syrup of ipecac has been eliminated and the need for a label warning as suggested by the second comment is not necessary.

19. One comment urged that ipecac syrup be restricted to sale by pharmacists only because the public might consider ipecac syrup to be a specific poison antidote rather than an emetic, and may use it erroneously for

certain types of poisonings for which vomiting is contraindicated.

The issue of restricting the sale of OTC drugs to pharmacists only was discussed previously by the agency in the **Federal Register** of June 4, 1974 (39 FR 19880). There, the agency concluded that there was no public health concern that would justify the creation of a third class of drugs to be dispensed only by a pharmacist or in a pharmacy. Although the agency recognizes that the pharmacist is a health professional who can offer sound advice concerning poisoning situations, the agency believes that the proposed labeling of ipecac syrup provides adequate safeguards against its erroneous use.

20. A number of comments disagreed with the statement that ipecac syrup should be recovered by gastric lavage if a second dose does not induce vomiting (43 FR 39545). Some of the comments pointed out that the amount of ipecac syrup consumed in two doses (30 mL) is lower than the dosage (90 to 120 mL) that would have to be consumed without emesis before any cardiac arrhythmias might be induced. One comment added that a study on adults to see if syrup of ipecac in therapeutic doses would affect stress electrocardiograms (EKG's) indicated that syrup of ipecac produced no effect on the stress EKG (Ref. 1). The comments opposed any use of gastric lavage unless it was necessary to remove the poison or toxic substance that the patient had originally ingested. The comments stressed that it was not necessary to remove the ipecac syrup. One comment stated that any mention of gastric lavage in labeling is not appropriate as people of all educational levels would be using these products. An opposing comment urged that the labeling for ipecac syrup emphasize the necessity for gastric lavage if a second dose of ipecac syrup does not produce vomiting within 30 minutes. This comment was not accompanied by any supporting documentation.

The agency concluded in paragraph 9 of the emetic tentative final monograph, published on September 5, 1978 (43 FR 39545), that "gastric lavage" was inappropriate terminology for use on a label designed to be read and entirely understood by consumers in emergency situations. FDA thus deleted any mention of gastric lavage from the labeling provisions proposed in that tentative final monograph. The agency has not been presented with any data or reasoning that persuades it to change that conclusion. FDA further agrees that gastric lavage need not necessarily be performed if emesis fails to occur within 30 minutes of giving a second dose of ipecac syrup (a total of 60 mL in adults or 30 mL in children age 1 to 12), because data show that a therapeutic dose (up to 60 mL) of ipecac syrup is not cardiotoxic and produces only a mild drowsiness and diarrhea (Refs. 1 through 4). In fact as much as 105 mL of ipecac syrup have been retained by a child with only minor electrocardiograph changes occurring (Ref. 2).

References

(1) Comment No. OB0018, Docket No. 81N-0050, Dockets Management Branch.

(2) King, W.D., "Syrup of Ipecac: A Drug Review," *Clinical Toxicology*, 17:353-358, 1980.

(3) Meester, W.D., "Emesis and Lavage," *Veterinary and Human Toxicology*, 22:225-234, 1980.

(4) Rauber, A., "The Cardiac Safety of Ipecac Used as a Therapeutic Emetic," *Veterinary and Human Toxicology*, 20:166-168, 1978.

D. Comments on Emetic Labeling

21. One comment suggested that it may be more appropriate to use metric units in addition to English units when indicating the volume of water to be given along with ipecac syrup in the directions in § 357.50(e).

The agency is aware of the trend towards using metric units. However, the volume of water or other clear liquid to be given after the ipecac syrup is large (120 to 480 mL). The agency believes that American consumers would be more familiar with the English volume measures (ounces) when the volume is large and that the English measures should be used in the labeling in addition to "glassful" measures. The agency would have no objection to using the metric units in addition to the English units. However, the use of metric units will not be required in this tentative final monograph.

22. Two comments suggested that the recommended doses of ipecac syrup be expressed in terms of container size, i.e., 1 tablespoonful (15 mL or ½ bottle), in addition to the presently proposed units of teaspoonful and tablespoonful, and their metric equivalents. The comments argued that this would be more meaningful to the consumer because teaspoons and tablespoons found in the home vary in size, and many people are not yet familiar with the metric system.

While there may be some variation in teaspoons and tablespoons from home to home, they represent a common form of measurement with which most people are readily familiar. The agency has no objection to manufacturers expressing the 30 mL or 15 mL dose in terms of bottle size equivalent in addition to the tablespoon measures and is proposing this option in the monograph. However, the dose for children from 6 months to 1 year of age of 1 teaspoon (5 mL) should not be expressed in terms of bottle size equivalent, i.e., ⅙ bottle, because of the obvious difficulty in accurately measuring such a dose in that manner.

23. A number of comments urged that the warning, "Do not use in semiconscious or unconscious persons," in § 337.50(c)(2) of the emetic tentative final monograph, be amended because it does not include all of the conditions which might contraindicate the use of ipecac syrup. Five comments urged that the warning be written to include persons suffering seizures or convulsions because such people might choke while vomiting. Two comments suggested that the warning be expanded to include people who are drowsy or comatose or who might be expected to lose consciousness within 20 minutes after administering ipecac syrup. Two other comments suggested that the warning could be conveyed more simply and succinctly if it was changed to read: "Do not use in persons who are not fully conscious."

FDA agrees that reference to "semi-conscious or unconscious persons" may not be correctly interpreted as including all of the conditions under which ipecac syrup should be used. Because the average consumer does not have the experience to diagnose the onset of a seizure or convulsion or that a person may lose consciousness within 20 minutes, this information should not be included in the warning. The warning "Do not use in persons who are not fully conscious," suggested by two of the comments, would more accurately and simply convey the various states of consciousness in which ipecac syrup is contraindicated. Therefore, FDA is proposing this wording in the warning included in this tentative final monograph.

24. Four comments disagreed with the statement proposed in § 337.50(c)(3) that ipecac syrup should not be used if petroleum distillates such as kerosene, gasoline, paint thinner, or cleaning fluid have been ingested. The comments argued that the ingestion of petroleum distillates or hydrocarbons is not an absolute contraindication to the use of ipecac syrup. The comments asserted that emesis can be safely induced with ipecac syrup in the alert patient who has swallowed a large quantity of a petroleum distillate (i.e., two ounces or more) or when the petroleum distillate contains a substance in a quantity that is toxic to the patient. One comment cited FDA's "Handbook of Common Poisonings in Children" (Ref. 1), an

editorial (Ref. 2), and an unpublished study (Ref. 3) as examples that current thinking among toxicologists is that emesis can be induced safely in petroleum distillate poisonings.

Four other comments urged a revision or expansion of § 337.50(c)(3). Two of these comments suggested that furniture polish be included in the warning. One of the comments states that, although the generic term "paint thinner" includes "turpentine," turpentine should be specifically mentioned in the labeling. However, the other comment countered this view stating that turpentine is not a petroleum distillate and, therefore, should not be included under the generic term "paint thinner." The comment argued that turpentine has a minimal potential for pulmonary toxicity and a high potential for central nervous system toxicity if systemically absorbed, a fact which would warrant inducing vomiting.

The agency recognizes that induction of emesis may be indicated in certain cases of hydrocarbon ingestion. However, the agency is also aware that controversy exists whether or not emesis should be induced in these cases. Some sources recommend induction of emesis when certain hydrocarbons are ingested (Ref. 2) or when the amount of hydrocarbon ingested exceeds a certain volume (Refs. 1, 2, 4, and 5). Other sources state that emetics are definitely contraindicated (Ref. 6). The major argument against inducing emesis in the pulmonary complications that occur from aspiration of the ingested substance into the lung when vomiting is induced. Some investigators have shown that vomiting is associated with a higher incidence of pulmonary complications and central nervous system involvement (Refs. 7 through 10). Others (Ref. 4) have shown that patients treated with ipecac syrup had a lower incidence of pneumonia and that the pneumonia was less severe than in those treated with gastric lavage.

In view of the controversy regarding the treatment of ingestions of hydrocarbons, the agency believes that emesis should be induced in such cases only under the guidance of a health professional. Therefore, the agency is proposing to retain in this tentative final monograph the warning that ipecac syrup should not be given in petroleum distillate poisonings unless directed by a health professional.

Because "furniture polish" is a petroleum distillate commonly found in the home, the agency agrees with the comments that it should be added to the warning as an additional example of petroleum distillates. As one comment pointed out, turpentine in not a petroleum distillate, but is a hydrocarbon commonly found in the household. Therefore, the agency proposes to add it to the warning proposed in § 337.54(c)(2). Because other paint thinners may consist of petroleum distillates, this example will be retained in the warning. The agency is proposing that the warning in § 337.54(c)(2) read, "Do not use this product, unless directed by a health professional, if turpentine, corrosives, such as alkalies (lye) and strong acids, or petroleum distillates, such as kerosene, gasoline, paint thinner, cleaning fluid, or furniture polish, have been ingested."

References

(1) American Academy of Pediatrics, "Handbook of Common Poisonings in Children," Food and Drug Administrative, pp. 1, 52, 53, and 76, 1976.

(2) Rumack, B.H., "Hydrocarbon Ingestions in Perspective," *Annals Of Emergency Medicine*, 6:172, 1977.

(3) Rumack, B.H., "Hydrocarbons-Poisoning Emesis or Not," draft of unpublished paper, in Comment No. OB0001, Docket No. 78N-0036E, Dockets Management Branch.

(4) NG, R.C., et al., "Emergency Treatment of Petroleum Distillate and Turpentine Ingestion," *Canadian Medical Association Journal*, 3:537–538, 1974.

(5) Dreisbach, R.H., "Handbook of Poisoning," Lange Medical Publications, Los Altos, CA, pp. 19 and 181–182, 1960.

(6) Gosselin, R.E., et al., "Clinical Toxicology of Commercial Products," 4th Ed., The Williams and Wilkins Co., Baltimore, pp. 188–192, 1976.

(7) Press, E., et al., "Cooperative Kerosene Poisoning Study: Evaluation of Gastric Lavage and Other Factors In the Treatment of Accidental Ingestions of Petroleum Distillate Products," *Pediatrics*, 29:648–674, 1962.

(8) Wolfsdorf, J., and H. Kundig, "Kerosene Poisoning In Primates," *South African Medical Journal*, 46:619–621, 1972.

(9) Sperling, E., "In Vivo and In Vitro Toxicology of Turpentine," *Clinical Toxicology*, 2:21–35, 1969.

(10) Beamon, R.F., et al., "Hydrocarbon Ingestion in Children: A Six-Year Retrospective Study," *Annals of Emergency Medicine*, 5:771–775, 1976.

25. Two comments asked for revision of the warning proposed in § 337.50(c)(3) for ipecac syrup which reads, "ordinarily, this product should not be used if strychnine, corrosives such as alkalies (lye) and strong acids, or petroleum distillates, such as kerosene, gasoline, paint thinner, or cleaning fluid have been ingested." One comment suggested that, although strychnine is the most rapidly acting convulsant, other convulsants such as camphor should be mentioned. The other comment argued that ingestions of strychnine are extremely rare in the United States, and the presence of strychnine in the warning may distract the consumer from the more important contradictions to ipecac-induced emesis. The comment added that the experiences of both medical and poison control centers indicate that the risks associated with inducing emesis after ingestion of convulsant drugs (e.g., camphor, amphetamines, tricyclic antidepressants, isoniazid) is small compared to the risk of allowing these extremely toxic compounds to be absorbed into the bloodstream. The comment urged that specific references to convulsant drugs be avoided.

The agency believes that in cases of overdoses of convulsants (e.g., camphor, amphetamines, tricyclic antidepressants, isoniazid), an emetic such as ipecac syrup should be given unless the patient is comatose, convulsing, has no gag reflex, or is rapidly declining in levels of consciousness (Ref. 1 through 4). The agency agrees with the latter comment that the risk of administering ipecac to a person who has ingested a toxic dose of a rapidly acting convulsant is considerably less than the risk of allowing these toxic compounds to be absorbed into the bloodstream. Therefore, the agency is proposing not to include strychnine or any other convulsant, such as camphor, in the warning. As discussed in comment 23 above, the agency is proposing the warning "do not use in persons who are not fully conscious" to include the various stages of consciousness in which ipecac syrup is contraindicated.

References

(1) Polson, C.J., "Clinical Toxicology," J.B. Lippincott Co., Philadelphia, pp. 17–20, 1959.

(2) Callahan, M., "Tricyclic Antidepressant Overdose," *Emergency Medicine*, 8:413–425, 1979.

(3) Arena, J.M., "Poisoning, Toxicology—Symptoms—Treatments," 3d Ed., Charles C. Thomas, Springfield, pp. 368–369 and 399–400, 1974.

(4) Czajka, P.A., and J.P. Duffy, "Poisoning Emergencies. A Guide for Emergency Medical Personnel," The C.V. Mosby Co., St. Louis, pp. 39, 40, and 47–50, 1980.

26. Two comments urged that ipecac syrup labeling indicates the need for prompt administration or the need for caution when a delay occurs in administering the product after ingestion of toxic doses of phenothiazines, central nervous system depressants (i.e., alcohol, barbiturates, sedative hypnotics, narcotics), or convulsants that have a slow-to-moderate onset of action. One comment cited a study which showed that, despite the antemetic action of the phenothiazines, the induction of emesis with syrup of ipecac was successful (Ref. 1). The comment also cited one case in which

emesis failed to occur and fatal ipecac cardiotoxicity resulted (Ref. 2). The comment stated that the risk of emesis failing to occur increases with the delay between the ingestion of the toxic dose and the administration of ipecac syrup because of the amount of the drug absorbed. Both comments pointed out that this delay, along with the 15 to 30 minute or longer latency period for emesis to be induced by ipecac syrup, increases the chance that the patient may lose consciousness or experience convulsions before the onset of emesis.

The comments raise a valid concern which the agency shares. However, it is usually impossible for the average consumer to determine whether a particular substance ingested is a central nervous system depressant or convulsant, let alone decide whether it possesses a slow-to-moderate onset of action. The agency is proposing a warning on the principal display panel of the ipecac syrup label instructing the consumer to "If possible call a poison control center, emergency medical facility, or health professional for help before using this product." These sources are qualified to identify the nature of the toxic substance ingested and provide guidance in the correct emergency treatment. The labeling also instructs consumers to read and follow the directions for use elsewhere on the bottle in an emergency situation when help cannot be reached quickly. The purpose of this statement is to advise consumers not to delay administering ipecac syrup in those cases when professional help cannot be contacted immediately.

The agency believes that in the case of overdoses of phenothiazines, central nervous system depressants, or convulsants, the risk of giving ipecac syrup when professional help cannot be contacted is considerably less than the risk of allowing the patient to absorb a toxic dose of these compounds. However, for the reasons stated above, a specific labeling statement mentioning these drugs in particular is not being proposed.

References

(1) Thoman, M.E., and H.L. Verhulst, "Ipecac Syrup in Antiemetic Ingestion," *Journal of the American Medical Association*, 196:147–148, 1966.

(2) MacLeod, J., "Hazards to Health. Ipecac Intoxication—Use of a Cardiac Pacemaker in Management," *The New England Journal of Medicine*, 268:146–147, 1963.

27. One comment questioned whether ipecac syrup would be effective in patients who had ingested an antiemetic drug and whether it should be contraindicated in such cases. A second comment referred to several studies that demonstrated the effectiveness of ipecac syrup in inducing vomiting in patients who had ingested a variety of antiemetic drugs including phenothiazines, tricyclic antidepressants, antihistamines, and anticholinergics (Refs. 1 and 2). The comment attributed the effectiveness of ipecac syrup in these cases to local gastrointestinal irritation rather than to an action on the vomiting center of the brain.

As discussed in comment 17 above, ipecac syrup induces vomiting either by local gastrointestinal irritation or, following systemic absorption, by the effect of its alkoloids on the vomiting reflex center of the brain. In the case of ingestion of antiemetic drugs, which may depress the vomiting center in the brain, ipecac syrup may still induce emesis by virtue of its local gastrointestinal irritation. Manoguerra and Krenzelok (Ref. 1) reported that of 63 patients who ingested drugs with antiemetic properties, 51 (81 percent) vomited following the first dose of ipecac, 9 (14 percent) vomited after a second dose, and only 3 (5 Percent) failed to vomit. These results are consistent with the studies of Ilett et al. (Ref. 2) and Thoman and Verhulst (Ref. 3) who reported that the emetic efficiency (percentage of patients vomiting) was not decreased when either phenothiozines or antihistamines were identified as the ingested substance. Ilett et al. (Ref. 2) reported 100 percent emetic efficacy in seven persons who had ingested drugs with antiemetic properties. Thoman and Verhulst (Ref. 3) reported that the administration of ipecac syrup induced vomiting in 94.5 percent of a group of 291 patients who had ingested antiemetic drugs. Based on these data, the agency concludes that there is no need to contraindicate the use of ipecac syrup in cases where antiemetic drugs have been ingested.

References

(1) Manoguerra, A.S., and E.P. Krenzelok, "Rapid Emesis from High-Dose Ipecac Syrup in Adults and Children Intoxicated with Antiemetics or Other Drugs," *American Journal of Hospital Pharmacy*, 35:1360–1362, 1978.

(2) Ilett, K.F., S.M. Gibb, and R.W. Unsworth, "Syrup of Ipecacuanha as an Emetic in Adults," *The Medical Journal of Australia*, 2:91–93, 1977.

(3) Thoman, M.E., and H.L. Verhulst, "Ipecac Syrup in Antiemetic Ingestion," *Journal of the American Medical Association*, 196:433–434, 1966.

28. A number of comments discussed the warning in proposed § 337.50(c)(4), which reads "Do not administer milk or carbonated beverages with this product [ipecac syrup]." Two comments strongly supported the reference to milk in this warning because milk reduces the effectiveness of ipecac syrup; one of these comments also supported the contraindication to the use of carbonated beverages as a diluent. Another comment suggested that the warning in § 337.50(c)(4) be revised to make it less dogmatic, i.e., *"It is preferable* not to administer milk or carbonated beverages with this product," rather than, "do not." The comment argued that the administration of fluid followed by ambulation is important to the successful induction of emesis when syrup of ipecac is used.

Several comments suggested deleting the reference to "carbonated beverages" from the proposed warning. The comments asserted that there are no reports in the published literature that contraindicate the administration of carbonated beverages, instead of water, as a diluent after giving ipecac syrup. One comment stated that the administration of carbonated beverages after giving syrup of ipecac could have been confused with the administration of carbonated beverages where caustics have been ingested and the resulting gastric distention might lead to perforation. Ipecac syrup is already contraindicated in such cases.

Two comments stated that the administration of fluid is important to successful induction of emesis; however, it is sometimes difficult to get children, who are most likely to need ipecac syrup, to drink water, and clear juices or carbonated beverages may be more acceptable. These comments cited a study showing that the use of carbonated beverages caused no adverse affects or alteration of the effectiveness of ipecac syrup in inducing emesis, leading the authors of the study to conclude that carbonated beverages do not appear to affect the patient adversely or alter the effectiveness of ipecac syrup (Ref. 1). A final comment argued that the entire warning in § 337.50(c)(4) is not warranted, is likely to be in error, and should be deleted.

After reviewing the data, the agency concludes that carbonated beverages can be safely administered after ingesting ipecac syrup. The agency agrees that administration of fluids is important to assure successful induction of emesis. The agency also recognizes the difficulty in getting children to drink water. Therefore, the agency is proposing that the directons be revised to state that water or other clear liquids are to be given with ipecac syrup. Because studies have shown that milk interfers with the ability of ipecac syrup

to induce emesis, the agency disagrees that the entire warning should be deleted (Ref. 2).

References

(1) Uden, D.L., G.J. Davison, and D.P. Kohen, "The Effect of Carbonated Beverages on Ipecac-Induced Emesis," *Annals of Emergency Medicine*, 10:79–81, 1981.

(2) Varipapa, R.J., and G.M. Oderda, "Effect of Milk on Ipecac-Induced Emesis," *Journal of the American Pharmaceutical Association*, 17:510, 1977.

29. Two comments strongly supported the need for a drug interaction precaution to guard against the use of activated charcoal in conjunction with ipecac syrup.

As discussed in the tentative final monograph for emetic drug products (43 FR 39545), the agency agrees that a drug interaction precaution is necessary on ipecac syrup to warn against the simultaneous use of activated charcoal and ipecac syrup. The agency is modifying this statement in this tentiative final monograph and proposing is as follows: "*Drug Interaction Precaution:* Activated charcoal will adsorb ipecac syrup. Do not give activated charcoal until after patient has vomited, unless directed by a health professional." This modification is being proposed in order to be consistent with the wording of a warning proposed for activated charcoal. (See comment 43 below.)

30. Two comments pointed out that the first sentence of § 337.50(d) "Drug interaction precautions" incorrectly states that "Activated charcoal will *absorb* ipecac syrup" instead of stating that "Activated charcoal will *adsorb* ipecac syrup." One comment contended that the basis of this drug interaction is the adsorption of ipecac alkaloids to the surface of activated charcoal particles.

This error was corrected in a notice published in the **Federal Register** of November 28, 1978 (43 FR 55417).

31. One comment suggested that the labeling of ipecac syrup include a statement warning that an overdose of ipecac syrup could be toxic in a child who fails to vomit. The comment stated that there is no statement in the labeling that would make the consumer aware that an overdose of ipecac syrup itself can be toxic.

FDA has reduced the likelihood of an overdose by placing a 30-mL container size limit on ipecac sprup that is sold OTC. Thirty mL of ipecac syrup is not a toxic dose, even for children. (See comment 20 above.) In addition, the labeling of ipecac syrup has been revised to instruct consumers to call a Poison Control Center, emergency medical facility, or health professional for help before using the product and to call again if the patient fails to vomit within 30 minutes. For these reasons, the agency concludes that the warning suggested in the comment is unnecessary.

32. Two comments supported the recommended dose of 15 mL (1 tablespoonful) of ipecac syrup. One comment expressed the opinion that although 15 mL of ipecac syrup is the usual dose in children less than 5 years of age, and 30 mL is the usual dose for adults and children over 5 years of age, standardizing the dose at 15 mL for everyone as proposed is a suitable alternative and would alleviate any possible confusion. However, five comments by poison control centers disagreed with the recommended 15-mL dose of ipecac syrup for persons over 1 year of age. These comments urged that this dosage be increased to 30 mL for adults. One comment submitted supporting data showing that 30 mL of ipecac produced an 81-percent incidenced of vomiting in adults. The incidence of vomiting was increased to 96-percent when a second 30-mL dose was administered to those patients who failed to vomit initially (Ref. 1). Another study (Ref. 2) demonstrated that the incidence of vomiting was only 55 to 68 percent when a 15-mL dose of ipecac was administered. The comments stated further that, in the experience of poison control centers and according to current articles (Ref. 3), the appropriate adult dose of ipecac syrup is recognized as 30 mL followed by 1 to 2 glasses of water.

FDA agrees with the position and supporting data submitted by the poison control centers. The agency is proposing that the recommended dose of ipecac syrup for adults, i.e., individuals over 12 years of age, in § 337.54(d)(1) be an initial dose of 2 tablespoonsful (30 mL) rather than the previously proposed 1 tablespoonful (15 mL) dose, with a second dose of 2 tablespoonsful to given if vomiting does not occur within 30 minutes.

References

(1) Comment OB0003, Docket No. 81N–0033, Dockets Management Branch.

(2) Ilett, K.F., S.M. Gibb, and R.W. Unsworth, "Syrup of Ipecacuahna as an Emetic in Adults," *Medical Journal of Australia*, 2:91–93, 1977.

(3) Velri, J.C., and A.R. Temple, "Telephone Management of Poisonings using Syrup of Ipecac," *Clinical Toxicology*, 9:407–417, 1976.

33. Several comments objected to the proposed directions for use, which recommend the administration of ipecac syrup in infants under 1 year of age without medical supervision. The comments argued that infants under 1 year of age need to be carefully attended when vomiting occurs in order to help the child become properly positioned to prevent aspiration of vomitus. Some comments further argued that because many people believe incorrectly that ipecac is an "antidote" rather than an emetic and because ipecac takes approximately 30 minutes to be effective, a large number of children may not be properly attended during this critical period, thereby needlessly exposing them to accidents involving aspiration of vomitus and possible death by suffocation or aspiration pneumonitis. Two other comments urged that the use of ipecac syrup for infants under 6 months of age be restricted to a physician's office or emergency room. One of the comments cited a statement in a recently published text supporting this proposed restriction (Ref. 1).

Although the agency shares the comments' concern that it is best to use ipecac syrup in infants under 1 year of age only under professional advice and guidance because of the risk that infants might aspirate their vomitus, the comments have not provided adequate or convincing justification for deletion of the dosage statement for infants under 1 year of age. The labeling contains directions to seek professional assistance before administering ipecac syrup to any age group. The agency recognizes there may be situations when professional assistance cannot be obtained and believes that the risk of aspiration may be less in such situations than the risk of allowing a toxic substance to be absorbed. The agency also recognizes that infants between the ages of 6 months and 1 year are quite mobile and thus susceptible to accidental poisoning and believes that a dosage for this age group should be provided in this tentative final monograph. Because the chance of accidental poisoning in infants under 6 months would be extremely rare, a dose for this age group is not being proposed in the monograph. A statement has been added advising that ipecac syrup should not be given to children under 6 months of age unless directed by a health professional.

Reference

(1) Goldfrank, L.R., "Managing of the Overdosed or Poisoned Patient who is Alert," *in* "Toxicological Emergencies," Appleton, Century, Crofts, New York, p. 12, 1982.

34. Three comments recommended against administering a second dose of ipecac syrup. Two of the comments stated that a second dose of ipecac syrup at home would delay treatment at

a hospital or other medical facility. The third comment stated that the only time that a second dose of ipecac syrup would be needed is for overdoses in adults who fail to vomit following the first dose. The comment stated that overdoses in adults are usually intentional and involve ingestion of large amounts of drugs and multiple combinations. According to the comment, these patients should be treated in emergency facilities and should receive psychiatric evaluation. The comment stated that, because home treatment would involve no more than administration of the first dose of ipecac syrup and then transportation of the patient to the hospital, only one dose of ipecac syrup is necessary.

The agency does not agree that directions to give a second dose of ipecac should be deleted from the monograph. One of the basic reasons for having ipecac syrup in the home is so that consumers can treat cases of poisoning even if professional help cannot be obtained. The agency fully supports the idea that professional help should be sought before ipecac syrup is used but realizes that some cases may exist where help cannot be obtained quickly. In those cases, consumers should have directions for the proper use of ipecac syrup, including directions to administer a second dose. In further support of giving a second dose Veltri and Temple (Ref. 1) report that the ability to induce emesis at home is a significant advantage because the average delay between ingestion and arrival at an emergency room has been reported to be in excess of 60 minutes, and delays longer than 60 minutes are associated with a decrease in the efficiency of emesis. The need for psychiatric evaluation is unrelated to the safe and effective use of OTC poison treatment drug products. Therefore, this subject is not covered in the monograph for OTC poison treatment drug products.

Reference

(1) Veltri, J.C., and A.R. Temple, "Telephone Management of Poisoning Using Syrup of Ipecac," *Clinical Toxicology*, 9:407–417, 1976.

35. Three comments opposed the recommendations, proposed in §§337.50 (c)(1), (e)(i), and (e)(ii), to repeat the dose of ipecac syrup if vomiting does not occur within 20 minutes. The comments noted that Rauber (Ref. 1) has reported that after administering ipecac syrup the time to emesis was as high as 26 minutes in the 24 patients studied, and, in the author's personal experience, 25 to 30 minutes is more often the time to emesis. One comment stated that in a recent series of experiments in normal healthy male volunteers, the average time to induce emesis was 22 minutes (Ref. 2). The comments, therefore, urged that the recommended time limit before repeating the dose of ipecac syrup be raised to 30 minutes. Three other comments recommended deletion of the recommendation that a second dose of ipecac syrup be given if the first dose does not induce vomiting within 20 minutes because waiting for a second dose to take effect could cause excessive delay and loss of valuable time before transporting the patient to a medical facility. One of these comments recommended that the patient be advised to call a physician immediately if vomiting does not occur within 20 minutes.

The agency has reviewed the data cited by the comments and is persuaded that the directions for ipecac syrup should be revised to indicate that a second dose of ipecac syrup should be administered if vomiting has not occurred within 30 minutes. Veltri and Temple (Ref. 2) reported that of 776 cases, 419 subjects (54 percent) vomited within 15 minutes of ipecac administration. The number increased to 689 cases (88.9 percent) within 30 minutes. This finding is supported by Rauber (Ref. 1) who found a mean time to vomiting of 26 minutes. Similar results were obtained in a study by Manoguerra and Krenzelok (Ref. 3) on 232 patients and in a study by Robertson (Ref. 4) on 214 patients. Analysis of the data from the Manoguerra and Krenzelok study shows that 144 of 232 patients (62.1 percent) vomited in the 0-to-20-minute interval, while 44 patients (18.9 percent) vomited in the 20-to-30-minute interval. Similarly, the Robertson data showed that 33 of 214 patients (15.4 percent) vomited in the 20-to-30-minute interval, while successful emesis occurred in 156 of 214 patients (72.9 percent) within the 0-to-20-minute interval. The agency believes that the increases in successful emesis shown by the above studies for the 20-to-30-minute time interval represent a significant increase in successful emesis. The agency does not agree that directions to give a second dose of ipecac should be deleted from the monograph. As discussed in response to comment 34 above, a principal reason for having ipecac in the home is to permit treatment of poisoning when professional help cannot be reached. Ideally, professional help should be sought before ipecac syrup is used; however, in some cases it may not be possible to obtain help promptly. In those cases, consumers should have directions for the proper use of ipecac syrup. If vomiting does not occur within 30 minutes, a second dose should be given to take advantage of any cumulative effect of the second dose of ipecac. In further support of giving a second dose, Veltri and Temple (Ref. 2) report that the ability to induce emesis at home is a significant advantage because the average delay between ingestion and arrival at an emergency room has been reported in excess of 60 minutes, and delays longer than 60 minutes are associated with a decrease in efficiency of emesis.

References

(1) Rauber, A., "The Cardiac Safety of Ipecac Used as a Therapeutic Emetic," *Veterinary and Human Toxicology*, 20:166–168, 1978.

(2) Veltri, J.C., and A.R. Temple, "Telephone Management of Poisoning Using Syrup of Ipeca," *Clinical Toxicology*, 9:407–417, 1976.

(3) Manoguerra, A.S., and E.P. Krenzelok, "Rapid Emesis from High-Dose Ipecac Syrup in Adults and Children Intoxicated with Antiemetics or Other Drugs," *American Journal of Hospital Pharmacy*, 35:1360–1362, 1978.

(4) Robertson, W.O., "Syrup of Ipecac—A Slow or Fast Emetic?," *American Journal of Diseases of Children*, 103:58–61, 1962.

36. Several comments supported the second portion of the warning proposed in § 337.50(c)(1), "Call a physician, Poison Control Center, or emergency room . . . immediately if vomiting does not occur within 20 minutes after a second dose has been given." However, one comment believed this information should also appear as a direction because most people would look in the directions for further advice if vomiting does not occur.

The directions being proposed in this tentative final monograph for ipecac syrup include the dosages to be given and instructions to repeat the dose if vomiting has not occurred within 30 minutes. The principal display panel of an ipecac syrup container will contain advice to call a poison control center, emergency medical facility, or health professional for help before using the product. The agency agrees that the directions should reinforce the importance of continued attempts to obtain professional help when using any poison treatment product and, therefore, proposes the following statement for inclusion in the directions of all poison treatment drug products: "If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying."

37. One comment urged that ipecac syrup labeling contain a recommendation to check the label of

the ingested substance for pertinent first aid instructions because many commercial chemical products containing caustic substances or organic solvents now carry warnings against inducing emesis in case of ingestion. The comment added that the Consumer Product Safety Commission is currently considering a requirement that labeling on all chemical products under its jurisdiction carry first aid instructions, including instructions on whether or not to induce vomiting.

The agency recognizes that the Federal Hazardous Substances Act (15 U.S.C. 1261.2(p)(1)(G)) and related regulations (16 CFR 1500.3(b)(14)(i) and 21 CFR 1230.14) contain requirements for labeling hazardous or caustic substances with instructions for first aid treatment. However, many household products are labeled with inadequate, incorrect, and potentially misleading first aid instructions. Alderman, et al. (Ref. 1) surveyed 1,019 household product labels and found that 85 percent had inadequate first aid information. In view of this information, the agency believes that it would be inappropriate and potentially harmful to include such a statement in the ipecac syrup labeling. At some future time, if product first aid labeling becomes more reliable, the agency will reevaluate its position.

Reference

(1) Alderman, D., et al., "How Adequate are Warnings and First Aid Instructions on Consumer Product Labels?: An Investigation," *Veterinary and Human Toxicology*, 24:1:8–11, 1982.

38. Three comments stressed the importance of keeping the patient ambulatory after the administration of ipecac syrup. One of these comments, from a poison control center, stated that its experience had shown that emesis is greatly delayed if the patient is kept inactive following the administration of ipecac syrup. The comment urged that labeling be modified to mention this concern. Another comment submitted a study showing no significant difference in the time it took to induce emesis in patients kept in motion versus those assigned bedrest (Ref. 1).

Keeping the person who has been given ipecac syrup active may or may not speed up emesis; however, regardless of the poison treatment used, activity may prevent loss of consciousness, which is a particular problem with people who have ingested an overdose of a central nervous system depressant. Therefore, the agency is proposing that the statement, "Keeping patient active and moving," be added to the directions for use of all poison treatment drug products.

Reference

(1) Meester, W.D., "Emesis and Lavage," *Veterinary and Human Toxicology*, 22:225–234, 1980.

39. Referring to the Miscellaneous Internal Panel's statement that, "when retching and vomiting begin, the patient should be placed face down with head lower than hips" (47 FR 447), one comment suggested that children be seated or held on an adult's lap near a basin or sink while vomiting so that the mouth can be cleared of any vomitus. The comment stated that it is difficult to expect a child or adult to be placed face down with head lower than hips, when vomiting begins.

The agency agrees with the Panel that when vomiting begins the head-lower-than-hip position helps prevent aspiration of the vomitus into the lungs. However, as the comment pointed out, this position would be difficult for a patient to maintain under some circumstances. Although the Panel included the statement in its report, it was not included in the labeling recommended in its monograph. In view of the potentially conflicting results, the agency does not believe a statement regarding positioning of the patient should be included in the monograph.

Reference

(1) Goldfrank, L.R., "Managing of the Overdosed or Poisoned Patient who is Alert," *in* "Toxicological Emergencies," Appleton, Century, Crofts, New York, p. 12, 1982.

40. Four comments urged that ipecac syrup should be packaged and marketed only in 30-mL containers, arguing that this container size provides two 15-mL doses, which would be convenient, safe, and effective; any larger amount could lead to overdoses in children and any less might be ineffective. Two other comments supported the 30-mL size, but suggested that two 15-mL containers should also be permitted. Three comments favored the 15-mL size only, arguing that 15 mL is the unit dose for a child. One of these comments suggested that the 15-mL containers should be marketed in packages of four to permit simultaneous treatment of several patients.

Current FDA regulations (21 CFR 201.308(c)) require that the OTC marketing of ipecac syrup be limited to 30 mL containers. This package size is convenient in that it provides one adult dose or two 15 mL doses for children age 1 to 12. The comments did not present any convincing arguments to warrant a change in the container size. Therefore, the 30 mL container size requirement is proposed in this tentative final monograph.

41. One comment urged that safety caps not be used on bottles of ipecac syrup.

The Poison Prevention Packaging Act (15 U.S.C. 1471–1476), which requires safety packaging for certain drug products, is administered by the Consumer Product Safety Commission (CPSC). Where necessary, FDA can request CPSC to require safety closures on OTC drugs. However, because ipecac syrup is packaged only in 30 mL containers, each of which contains a less-than-toxic dose for a small child, and the presence of safety closures could result in unwarranted delay and confusion in the administration of ipecac syrup to treat poisoning victims in emergency situations, the agency agrees that safety closures should not be used on bottles of ipecac syrup sold OTC.

42. One comment suggested that, to prevent misunderstanding by dispensing pharmacists, every bottle of ipecac syrup larger than 30 mL should bear the following statement on the label: "Remember, 30 mL may be dispensed without a prescription."

This monograph establishes conditions of marketing of OTC drugs only. It does not address prescription labeling. Thus the statement suggested by the comment is not included in the monograph. The agency has no objection to a statement similar to that suggested by the comment appearing in the labeling of prescription size bottles of ipecac syrup and is aware that such labeling is currently used (Ref. 1). However, the agency suggests that when such labeling is used it should also include a statement that complete labeling information as specified in the poison treatment drug products monograph (21 CFR Part 357 Subpart A) must be provided to consumers to whom the product is sold. The agency suggests that manufacturers of prescription size bottles of ipecac syrup provide pharmacists complete auxillary labeling to provide to consumer when smaller quantities are sold from prescription size bottles.

Reference

(1) Physician's Desk Reference, 37th Edition, Medical Economics Company, Orandell, NJ, p. 1141, 1983.

E. Comments on Adsorbents

43. Two comments objected to the OTC availability of activated charcoal as a poison adsorbent. The comments contended that poisoning cases serious enough to require the use of activated charcoal should be treated in an emergency room or other health care

facility. A comment from a poison control center stated that its experience indicates that only about 10 percent of toxic ingestion exposures are serious enough to require both the induction of emesis and the additional decontamination provided by activated charcoal. The other comment expressed that use of activated charcoal in the home may create a false sense of security and delay consultation with a poison control center.

Although syrup of ipecac has long been recognized as the first line of defense in the home treatment of poisoning, a number of studies have shown that vomiting induced by ipecac is often not complete, with recovery of stomach contents varying from 0 to 78 percent (Ref. 1). Activated charcoal has been demonstrated to be safe and effective in adsorbing poison that may remain in the gastrointestinal tract after vomiting has occurred. The Miscellaneous Internal Panel recognized (47 FR 448) and the agency concurs that, generally, the use of activated charcoal should be restricted to administration following the induction of vomiting. The agency is therefore proposing the following statement for inclusion on activated charcoal products as a drug interaction precaution: "Do not give activated charcoal until after patient has vomited unless directed by a health professional." There are situations in which activated charcoal can be administered without inducing vomiting. However, the agency believes that this decision should be made by a health professional on an individual case basis. This warning will replace the warning recommended by the panel in § 357.20(c)(3).

Reference

(1) Meester, W.D., "Emesis and Lavage," *Veterinary and Human Toxicology*, 22:225–234, 1980

44. Three comments commended the Panel for both anticipating and encouraging the development of new and more palatable dosage forms of activated charcoal, but expressed concern over the Panel's recommended criteria for comparison of the adsorptive capacity of new dosage forms with the existing dosage form. One comment urged development of a methodology for an in vivo comparison of dosage forms. Another comment asserted that the testing criteria recommended by the Panel are unnecessary because there are adequate compendial standards for measuring the adsorptive capacity of activated charcoal in the United States Pharmacopeia (U.S.P.) (Ref. 1). The comment stated that any product containing activated charcoal U.S.P. as its active ingredient would have to meet these standards for adsorptivity, and that these standards, which can be applied to final formulations, make in vivo testing scientifically and legally unnecessary.

The agency agrees that additional testing criteria for activated charcoal beyond final formulation conformity to U.S.P. adsorptivity standards (Ref. 1) should not be necessary for any activated charcoal product. The agency is proposing that the monograph specify that final formulations, in amounts equivalent to one gram (g) of activated charcoal, must meet or exceed the standards for adsorptivity for activated charcoal, U.S.P. However, the U.S.P. adsorptivity standard is specific to a dry powdered dosage form and may not be readily applicable to the testing of other dosage forms. The agency invites specific comment on suitable testing standards and methods, including modifications of the U.S.P. adsorptivity standard, for dosage forms other than the traditional dry powdered activated charcoal.

Reference

(1) "United States Pharmacopeia XX—National Formulary XV," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 128–129, 1980.

45. One comment questioned the possibility of aspiration of activated charcoal in powdered form.

Athough activated charcoal is normally packaged in powdered form, the likelihood of aspiration is minimal because the directions for use instruct the consumer to mix the activated charcoal in water before it is administered.

46. One comment supported the Miscellaneous Internal Panel's 30 g minimum dosage recommendation for activated charcoal and urged the agency to restrict the OTC marketing of activated charcoal products to a unit dose form containing a minimum of 30 g. The comment expressed concern that the dosage of activated charcoal may not be adequate if the Panel's volume measure recommendation (6 level tablespoonsful) was used because of the varying densities of charcoal powder and because 1 tablespoonful could supply from 3.5 to 6 g of activated charcoal (Refs. 1 and 2).

Another comment disagreed with the Panel's 30-g recommendations and requested that the dose be changed to 25 g. The comment supplied information indicating that a much wider effective dosage range (from 5 to 60 g) exists in actual practice and that a product containing 25 g activated charcoal is in widespread use with general acceptance by emergency medical facilities (Ref. 3).

The agency recognizes that the density of activated charcoal may vary considerably. As pointed out by one comment, a tablespoonful of activated charcoal can contain anywhere from 3.5 to 6 g (Refs. 1 and 2); thus, 6 tablespoonsful could contain from 21 to 36 g. The dose of activated charcoal generally recommended is 8 to 10 times the amount of the toxic substance ingested (Refs. 1 and 2) with the maximum limit determined only by the feasibility of administration (47 FR 449). For these reasons, the agency does not believe the dose of activated charcoal needs to be limited to a specific weight amount. Instead, the agency is proposing a range of 20 to 30 g as a dose of activated charcoal. Taking into consideration the varying densities of activated charcoal, this dosage approximates the Panel's recommendation of 6 tablespoonsful. It will also include the 25 g product that is recommended by one comment. As the comment and the Panel pointed out, there is a wide effective dosage range for activated charcoal, and the agency is proposing that a second dose be given if possible. (See comment 50 below.)

References

(1) Greensher, J., et al., "Activated Charcoal Updated," *Annals of Emergency Medicine*, 8:261–263, 1979.

(2) Dipalma, J.R., "Activated Charcoal—A Neglected Antidote," *Clinical Pharmacology*, 20:155–156, 1979.

(3) Comment No. C00005, Docket No. 81N-0050, Dockets Management Branch.

F. Comments on Adsorbent Labeling

47. One comment suggested that the statement of identity recommended in § 357.50(a) for poison treatment drug products containing activated charcoal be changed from the term "adsorbent" to a more easily understood term such as "poison antidote," "emergency poison antidote," or "first aid poison antidote."

Webster defines antidote as a remedy to counteract the effect of a poison (Ref. 1). Activated charcoal acts by means of adsorbing poisons, not by counteracting their effects. Thus, it would be false and misleading to replace the term "adsorbent" with any term implying that activated charcoal is a poison antidote. However, acceptable statements of identity are provided by replacing the word "antidote" with the word "adsorbent" in the phrases suggested by the comment, i.e., "poison adsorbent," "emergency poison adsorbent" or "first aid poison adsorbent." Therefore, the agency is proposing that any one of

these phrases may be used as the statement of identity in place of the word "adsorbent" for poison treatment drug products containing activated charcoal.

Reference

(1) "Webster's New Collegiate Dictionary," G. and C. Merriam Co., Springfield, MA, 1979, s.v. "antidote."

48. One comment believed that the Miscellaneous Internal Panel's recommended directions of mixing 4 ozs (120 mL) of water with 30 g of activated charcoal would result in too thick a slurry with increased chances of complications if aspiration of the charcoal mixture occurs. The comment cited a case in which a mixture of 9 g of charcoal in 35 mL of water was administered to a patient who regurgitated and aspirated the mixture, resulting in the immediate development of airway obstruction (Ref. 1). The comment pointed out that the water to charcoal ratio in this case (3.89:1) is very close to the ratio (4:1) recommended by the Panel. The comment recommended that the charcoal be mixed with 8 oz (240 mL) of water, adding that such a mixture allows for a better dispersion of the charcoal in water and has the advantage of making the charcoal more palatable.

Upon evaluation of the report of the case of airway obstruction resulting from the aspiration of a thick charcoal-water slurry, the agency agrees with the comment that increasing the amount of water mixed with activated charcoal will reduce this danger, aid in the dispersion of the charcoal in water, and make the mixture more palatable and thus more likely to be ingested. Therefore, the agency is proposing that the directions for activated charcoal provide that the dose is to be administrated in a minimum of 8 oz of liquid.

Reference

(1) Pollack, M.H., et al., "Aspiration of Activated Charcoal and Gastric Contents," *Annals of Emergency Medicine*, 10:528–529, 1981.

49. Several comments stated that the directions for activated charcoal recommened by the Panel in § 357.50(d) are too specific and restrictive in that they do not allow the mention of dosage forms other than aqueous solutions. The comments requested that the directions be modified to allow these alternative dosage forms to be mentioned.

The agency agrees. As pointed out in comment 44 above, the agency has no objection to alternative dosage forms as long as suitable testing methods can be developed to insure that the final product meets USP XX standards for adsorbency. Accordingly, the agency has revised the directions in this tentative final monograph to allow for alternative dosage forms.

50. Two comments suggested that the labeling of activated charcoal include a statement that the dose of activated charcoal should be repeated if possible. One comment stated that the upper limits of charcoal administration are governed only the feasibility of administration.

The agency agrees. Doses of activated charcoal up to 120 g have been administered with no reported side effects (Refs. 1 and 2) and, in general, the larger the does of activated charcoal the greater the adsorption of the ingested poison. Therefore, the agency is proposing the following statement in the directions for activated charcoal: "Repeat dose immediately, if possible."

References

(1) Greensher, J., et al., "Activated Charcoal Updated," *Annals of Emergency Medicine*, 8:261–263, 1979.

(2) Dipalma, J.R., "Activated Charcoal—A Neglected Antidote," *Clinical Pharmacology*, 20:155–156, 1979.

51. One comment suggested that the warning "Do not give activated charcoal to people who have swallowed petroleum distillate or corrosive products" be added to the warnings for products containing activated charcoal because the administration of activated charcoal is not infrequently followed by vomiting and the induction of emesis for corrosive products is contraindicated. The comment added that an additional complication to the use of activated charcoal with corrosives is that it may obscure visual observation of gastroesophageal lesions by endoscopy. The comment concluded that there is a lack of evidence documenting the beneficial effects of activated charcoal in humans who have ingested corrosives or petroleum distillates, and, therefore, activated charcoal should not be used following ingestion of these substances.

The agency agrees with the comment. Decker, Combs, and Corby (Ref. 1) found that corrosives such as inorganic acids, sodium and potassium hydroxides, and sodium metasilicate are not adsorbed to any measurable extent by activated charcoal. Picchioni, Chin, and Laird (Ref. 2) reported that, in rats, kerosene is adsorbed by activated charcoal, but that there is a lack of data on the ability of activated charcoal to adsorb other petroleum distillates. Some authors report that activated charcoal is ineffective in petroleum distillate ingestions (Ref. 3). For these reasons, the agency believes that the labeling of activated charcoal should include the same corrosive, petroleum distillate warning as that required for ipecac syrup.

References

(1) Decker, W.J., H.F. Combs, and D.G. Corby, "Adsorption of Drugs and Poisons By Activated Charcoal," *Toxicology and Applied Pharmacology*, 13:454–460, 1968.

(2) Picchioni, A.L., L. Chin, and H.E. Laird, "Activated Charcoal Preparations—Relative Antidotal Efficacy," *Clinical Toxicology*, 7:97–108, 1974.

(3) Czajka, P.A., and J.P. Duffy, "Drugs for the Management of Acute Poisonings," *in* "Poisoning Emergencies. A Guide for Emergency Medical Personnel," The C.V. Mosby Co., St. Louis, p. 15, 1980.

G. Comments on Poison Treatment Kits

52. Nine comments supported the concept of poison treatment kits containing both activated charcoal and ipecac syrup and encouraged their availability. Eight other comments, While supporting the OTC availability of ipecac syrup, opposed the OTC marketing of kits containing activated charcoal as well as ipecac syrup. The comments pointed out that the kits would be more expensive than ipecac syrup alone, that activated charcoal could be administered at the wrong time and interfere with the functioning of the ipecac syrup, and that ingestion serious enough to warrant the use of activated charcoal should properly be treated in an emergency room.

The agency appreciates the concerns and objections raised by the comments opposing the marketing of activated charcoal with ipecac syrup in poison treatment kits. The kits will undoubtedly be more expensive than ipecac syrup alone, but they are not intended to replace or prevent the sale of ipecac syrup packaged alone. Although activated charcoal can adsorb ipecac syrup and prevent its functioning if administered before the ipecac syrup has had time to induce vomiting, the agency believes that the direction and warnings for both activated charcoal and ipecac syrup being proposed in this tentative final monograph adequately caution against such use. In addition, the labeling for a poison treatment kit clearly instructs the user to ". . . call a poison control center, emergency medical facility, or health professional for help before using this product." While most cases of poisoning may call for the use of ipecac syrup only, the presence of both ipecac syrup and activated charcoal in the kit would provide the poison control center personnel or other health professional flexibility in responding to the needs of

any individual case of poisoning. In addition, when professional advice cannot be obtained, the administration of activated charcoal after vomiting had occurred provides an added margin of protection because the activated charcoal can adsorb residual poison.

The agency therefore concludes that poison treatment kits containing both activated charcoal and ipecac should be available OTC.

53. One comment urged that the poison treatment monograph contain a statement expressing a preference for ipecac syrup alone rather than the more costly dual ingredient kit containing both ipecac syrup and activated charcoal.

The agency agrees that ipecac syrup is the first line of defense in poison treatment and is less costly than the dual ingredient poison treatment kit. It would, however, be inappropriate to attempt to influence purchasing practices by requiring a label statement expressing an opinion as to the agency's preference between two products, both of which have been determined to be safe and effective.

54. Numerous comments objected to the ingredient and dosage specifications recommended by the Panel in proposed § 357.14 for a poison treatment kit. Two comments did not believe that there was any potential safety problems with the amount of ipecac syrup present in the kit. Most of the comments objected to the requirement that the kit contain 60 mL of ipecac syrup because of the potential for ipecac overdose, especially in small children. Two of these comments stated that 60 mL of ipecac syrup would not pose a safety problem if "child resistant" tops were used on the bottles, and another comment stated that a warning against overdosing could adequately handle this risk. The majority of the comments urged that the kit be limited to some smaller quantity of ipecac syrup; three suggested a limit of 15 mL of ipecac syrup, and one suggested a 45 mL limit. Thirty mL was, however, the most commonly suggested limit.

In addition, two comments objected to the requirement that the kit contain exactly four (30 g) containers of activated charcoal, with one comment suggesting that the requirement be changed from 30 g containers to 25 g containers. One of these comments also questioned the agency's authority to establish exact numerical limits on the size and type of dosage forms in such a kit.

The agency has authority under sections 502(f) and 701(a) of the Act (21 U.S.C. 352(f) and 371(a)) to establish limits on size and types of dosage forms and limits on package contents, e.g., the 36-tablet limitation per container of 1¼ grain (pediatric) aspirin tablets specified in § 201.314(c)(2). The agency has, however, reviewed both the Panel's report and the comments and agrees that the Panel's action in establishing exact ingredient and dosage specifications for a poison treatment kit, including the exact size and number of containers, is overly restrictive. The agency is proposing that the tentative final monograph establish that poison treatment kits contain one adult dose of ipecac syrup, 30 mL, and a minimum of one dose of activitated charcoal, 20 g. This requirement will provide a minimum of one dose each of both an emetic and an adsorbent. As discussed in comment 30 above, containers of ipecac syrup are limited to 30 mL due to the potential toxicity of this ingredient. The kit can therefore contain only one 30-mL container of ipecac syrup. There is no reason, however, for any restriction on the size or number of containers of activitated charcoal beyond the minimum dosage requirement of 20 g. As discussed in comment 44 above, new dosage forms of activated charcoal are also acceptable. The agency has also considered the suggestion that 60 mL of ipecac syrup could be safely packaged in a kit if placed in separate containers equipped with "child resistant" caps. The safety advantage of using such caps to permit inclusion of more ipecac syrup in the kit would, however, be offset by the risk that such caps could delay administration of the initial dose of ipecac syrup. There is, of course, no restriction on the number of kits that an individual can purchase.

55. One comment pointed out that the description of the acute toxic ingestion kit recommended by the Panel in § 357.14, which specifies charcoal containers that facilitate mixing the contents, is in contradiction to the directions in § 357.50(d) which state "Mix 6 level tablespoonfuls in ½ glassful of water."

The agency agrees that there was a discrepancy. The revisions that have been made in this tentative final monograph have resolved this discrepancy. (See comments 48 and 49 above.)

56. Three comments suggested revising the direction statements recommended by the Panel in § 357.54(d). One comment suggested deleting the direction in § 357.54(d)(1) "When professional advice is not available, first give ipecac * * * " because professional advice in the form of a poison control center, an emergency facility, or a health professional is always available by telephone. The comment contended that this direction on the outside of a poison treatment kit could cause parents not to review the additional labeling in the kit and to give activated charcoal or ipecac syrup unnecessarily.

A second comment suggested rewording the directions statements by reversing the order of § 357.54(d)(1) and § 357.54(d)(3) to give greater prominence to the statement "Save the container of poison" and to require that the statement recommended in § 357.54(d)(2) "Read instruction at time of purchase and insert phone numbers" be placed on the principal or front display panel rather than just the outside of the kit. The third comment suggested that the directions be expanded to allow inclusion of a booklet containing more detailed first aid instruction in the kit.

The agency disagrees that professional help can always be reached by telephone. There are circumstances such as in isolated locations or during severe weather when such advice will not be available. As discussed in comment 9 above, the agency has revised the labeling of poison treatment drug products to require the following statements on the principal display panel: "If possible call a poison control center, emergency medical facility, or health professional for help before using this product." "If help cannot be reached quickly, follow the directions on * * * (manufacturers to indicate location of directions, e.g., on the back of the bottle)" and "Read the warnings and directions as soon as you buy this product. Insert emergency phone number(s) in space provided on the label."

The remainder of the warnings and directions are to be placed on a separate portion of the label. The agency disagrees that the statement "Save the container of poison" should be given any special prominence as compared with other labeling. However, the agency believes that this statement is applicable to all poison treatment drug products and thus is proposing that the monograph include the statement on ipecac syrup as well as activated charcoal products. The agency has no objection to the inclusion of labeling, folders, booklets, or leaflets containing more detailed first aid or poison treatment information as long as such information does not distract from required labeling.

II. The Agency's Tentative Adoption of the Panels' Reports

A. Summary of Ingredient Categories

The agency has reviewed the only active emetic ingredient submitted to the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products, ipecac syrup, and the single claimed active adsorbent ingredient submitted to the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, activated charcoal, as well as other data and information available at this time, and concurs with the Panels' Category I classification of these ingredients as OTC poison treatment drugs.

For the convenience of the reader, the following table is included as a summary of the agency's categorization of OTC poison treatment active ingredients.

	Category
Emetics:	
Ipecac fluidextract	II.
Ipecac syrup	I.
Ipecac tincture	II.
Zinc sulfate	II.
Poison Adsorbents:	
Charcoal, activated	I.

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

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panels' reports and recommended monographs and will combine them into a single monograph for OTC poison treatment drug products 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 Panels' conclusions and recommendations and to the previous tentative final monograph for OTC emetic drug products follows:

1. The process of combining the emetic rulemaking (proposed 21 CFR Part 337) and the acute toxic ingestion rulemaking (proposed 21 CFR Part 357, Subpart A) into the present tentative final monograph under 21 CFR Part 357 (entitled Poison Treatment Drug Products for OTC Human Use,) has required the redesignation of many section and paragraph numbers.

2. The term "health professional" is being proposed in labeling in place of the term "physician," "doctor," or "pharmacist." (See comments 6 and 14 above.)

3. The term "emergency medical facility" is being proposed in labeling in place of the term "emergency room." (See comment 8 above.)

4. Labeling for all poison treatment drug products has been revised to change the order of listing of sources of help and information for poison treatment from "physician, poison control center or emergency room" to "poison control center, emergency medical facility, or health professional." (See comment 7 above.)

5. Labeling is being divided into two distinct sections: First, the principal display panel would contain the following instruction in a conspicuously boxed area: "If possible, call a poison control center, emergency medical facility, or health professional for help before using this product. If help cannot be reached quickly, follow the directions (manufacturer to indicate location of directions, e.g., on the back of the bottle)." The statements, "Read the warnings and directions as soon as you buy this product." "Insert emergency phone number(s) in space provided on the label," must also appear prominently on the principal display panel. Second, full warnings and directions are to be placed on a separate portion of the label. (See comment 9 above.)

6. A space for writing in the phone number(s) of the appropriate poison control center or other emergency medical facility must be provided on the principal display panel. (See comment 9 above.)

7. The terms "for the treatment of poisoning," "emergency first aid treatment for poisoning," "emergency treatment for poisoning," "emergency treatment for accidental poisoning," "for the treatment of accidental poisoning," "emergency first aid treatment for accidental poisoning," "emergency poison treatment," and "first aid poison treatment" have been proposed as other allowable statements for all poison treatment drug products. (See comment 15 above.)

8. The indication statement for ipecac syrup has been revised to read "for emergency use to cause vomiting of swallowed poisons." The indication statement for activated charcoal has been revised to read "for emergency use to adsorb swallowed poisons." (See comment 15 above.)

9. The dosage of ipecac syrup for individuals 1 year of age and over has been revised to allow manufacturers to express the dosage in terms of container size i.e., 1 or ½ bottle. (See comment 22 above.)

10. The warning "Do not use in semiconscious or unconscious persons" previously proposed for ipecac syrup has been revised to read "Do not use in persons who are not fully conscious." (See comment 23 above.)

11. The corrosive-petroleum distillate warning for ipecac syrup has been revised to read "Do not use this product, unless directed by a health professional, if turpentine, corrosives, such as alkalies (lye) and strong acids, or petroleum distillates, such as kerosene, gasoline, paint thinner, cleaning fluid, or furniture polish, have been ingested." (See comment 24 above.) This same warning is being proposed for activated charcoal products. (See comment 51 above.)

12. The warning "Do not administer milk or carbonated beverages with this product" previously proposed for ipecac syrup has been revised to read "Do not administer milk with this product." (See comment 28 above.)

13. The directions for ipecac syrup have been revised to provide for water or other clear liquids to be administered following ipecac syrup. (See comment 28 above.)

14. The drug interaction precaution for emetics has been revised to read "*Drug Interaction Precaution*: Activated charcoal will adsorb ipecac syrup. Do not give activated charcoal until after patient has vomited unless directed by a health professional." (See comment 29 above.)

15. The adult dose of ipecac syrup has been increased from 15 mL to 30 mL. (See comment 32 above.)

16. A dosage of ipecac syrup for children under 6 months of age is no longer provided in the monograph. A statement advising that ipecac syrup should not be given to children under 6 months of age unless directed by a health professional has been added to the monograph. (See comment 33 above.)

17. The time interval between the first and second doses of ipecac syrup has been increased from 20 to 30 minutes. (See comment 35 above.)

18. The directions for all poison treatment drug products have been revised to include the statement "If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying." (See comment 36 above.)

19. The directions for poison treatment drug products have been revised to include the statement "Keep patient active and moving." (See comment 38 above.)

20. The warning against use of activated charcoal before vomiting has occurred has been revised to read "Do not give activated charcoal until after patient has vomited unless directed by a health professional." (See comments 29, 43, and 51 above.)

21. Formulations for activated charcoal now provide for dosage forms other than a powder. (See comment 44 above.)

22. The dosage for activated charcoal has been revised to provide a range of 20 to 30 g. (See comment 46 above.)

23. The statement of identity for activated charcoal, "adsorbent," has been revised to "poison adsorbent" or optionally "emergency poison adsorbent" or "first aid poison adsorbent." (See comment 47 above.)

24. The directions for use of activated charcoal have been revised to require that the dose be administered in a minimum of 8 oz of liquid. (See comment 48 above.)

25. The statement "Repeat dose immediately, if possible" has been added to the directions for activated charcoal. (See comment 50 above.)

26. The contents of the poison treatment kit have been revised to provide for a content of one 30-mL container of ipecac syrup and a minimum of 1 adult dose of activated charcoal (20 g). Although kit contents are limited to 30 mL of ipecac syrup, there is no restriction on the size or number of containers of activated charcoal in the kit. (See comment 54 above.)

27. The direction "Save the container of poison" has been proposed for all poison treatment drug products. (See comment 56 above.)

28. The agency advises that those portions of § 201.308 and § 369.21 applicable to ipecac syrup will be revoked at the time that the final monograph becomes effective.

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 not one of these rules, including this proposed rule for OTC poison treatment 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, Public Law 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 poison treatment 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 poison treatment 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 poison treatment 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 poison treatment 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 determined that under 21 CFR 25.24(d)(9) (proposed in the **Federal Register** of December 11, 1979, 44 FR 71742) this proposal is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 357

OTC drugs, Poison treatment drug products, Anthelmintic drug products, and Cholecystokinetic drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act (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)) and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)) and under 21 CFR 5.11, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 357, Subpart A, to read as follows:

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

Subpart A—Poison Treatment Drug Products

Sec.

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); secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—Poison Treatment Drug Products

§ 357.1 Scope.

(a) An over-the-counter poison treatment drug product 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 of regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.3 Definitions.

As used in this subpart:

(a) *Adsorbent.* An agent that causes another substance to adhere to its surface.

(b) *Emesis.* Vomiting.

(c) *Emetic.* An agent that causes vomiting (emesis).

§ 357.10 Active ingredients for poison treatment.

The active ingredients of the product consist of any of the following when used within the dosage limits established for each ingredient:

(a) *Charcoal, activated.* The active ingredient is in a formulation such that the equivalent of one gram activated charcoal mets or exceeds the standards of adsorption for activated charcoal, U.S.P.

(b) *Ipecac syrup.* The active ingredient of the product is powdered ipecac. It is marketed as ipecac syrup, U.S.P. in the

quantity of 1 fluid ounce (30 milliliters) only.

§ 357.14 Poison treatment kit.

The kit is a single outer package labeled according to §§ 357.50 and 357.58 that consists of one 30 milliliter container of ipecac syrup identified in § 357.10(b) and a minimum of one dose 20 gram of activated charcoal identified in § 357.10(a).

§ 357.50 Principal display panel of all poison treatment drug products.

In addition to the statements of identity required in §§ 357.52, 357.54, or 357.56, the principal display panel contains the following information:

(a) The following statements should appear in a conspicuously boxed area.

(1) "If possible call a Poison Control Center, emergency medical facility, or health professional for help before using this product."

(2) "If help cannot be reached quickly, follow the directions" (manufacturer to indicate location of directions, e.g., on the back of the bottle).

(3) "Read the warnings and directions as soon as you buy this product. Insert emergency phone number(s) in space provided on the label."

(b) A space must also be provided for writing in phone number(s) of the appropriate Poison Control Center, emergency mecical facility, or health professional.

§ 357.52 Labeling of activated charcoal drug products.

In addition to the labeling identified in § 357.50, the labeling of the product containing the ingredient identified in § 357.10(a) contains the following:

(a) *Statement of identity.* The labeling of the product includes the established name of the drug, if any, and identifies the product as a "poison adsorbent" "emergency poison adsorbent," or "first aid poison adsorbent."

(b) *Indication.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the phrase "For emergency use to adsorb swallowed poisons."

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

(1) "Do not give activated charcoal until after the patient has vomited unless directed by a health professional."

(2) "Do not use in persons who are not fully conscious."

(3) "Do not use this product, unless directed by a health professional, if turpentine, corrosives, such as alkalies (lye) and strong acids, or petroleum distillates, such as kerosene, gasoline, paint thinner, cleaning fluid or furniture polish, have been ingested."

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

(1) Oral dosage: 20 to 30 grams of activated charcoal in a minimum of 8 ounces of liquid or as directed by a health professional.

(2) "Repeat dose immediately, if possible."

(3) "If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying."

(4) "Keep patient active and moving."

(5) "Save the container of poison."

§ 357.54 Labeling of ipecac syrup drug products.

In addition to the labeling identified in § 357.50 the labeling of the product containing the ingredient identified in § 357.10(b) contains the following:

(a) *Statement of identity.* The labeling of the product includes the established name of the drug, if any, and identifies the product as an "emetic."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to the phrase "For emergency use to cause vomiting of swallowed poisons."

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

(1) "Do not use in persons who are not fully conscious."

(2) "Do not use this product, unless directed by a health professional, if turpentine, corrosives, such as alkalies (lye) and strong acids, or petroleum distillates, such as kerosene, gasoline, paint thinner, cleaning fluid, or furniture polish, have been ingested."

(3) "Do not administer milk with this product."

(4) "*Drug Interaction Precaution:* Activated charcoal will adsorb ipecac syrup. Do not give activated charcoal until after the patient has vomited, unless directed by a health professional."

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

(1) Adults and children 12 years of age and over: oral dosage is 2 tablespoonsful (30 milliliters of 1 bottle) followed by 1 to 2 glasses (8 to 16 ounces) of water or other clear liquid or as directed by a health professional.

(2) Children 1 to under 12 years of age: oral dosage is 1 tablespoonful (15 milliliters or ½ bottle) followed by 1 to 2 glasses (8 to 16 ounces) of water or other clear liquid or as directed by a health professional.

(3) Children 6 months to under 1 year of age: oral dosage is 1 teaspoonful (5 milliliters) followed by ½ to 1 glass (4 to 8 ounces) of water or other clear liquid or as directed by a health professional.

(4) Children under 6 months of age: Do no administer unless directed by a health professional."

(5) "If vomiting does not occur within 30 minutes, repeat the dose."

(6) "If previous attempts to contact a poison control center, emergency medical facility, or health professional were unsuccessful, continue trying."

(7) "Keep patient active and moving."

(8) "Save the container or poison."

§ 357.56 Labeling of poison treatment kits.

The individual components of the kit must contain the labeling identified in §§ 357.52 and 357.54. The outer label of the kit must contain the information identified in § 357.50 and, in addition, the following:

(a) *Statement of identity.* The labeling of the product includes the established name of the drugs, if any, and identifies the product as a "Poison treatment kit," "Emergency poison treatment kit," or "Emergency first aid poison treatment kit."

(b) *Directions.* The labeling contains the following information under the heading "Directions": "When professional advice is not available, first give ipecac syrup to induce vomiting; after vomiting has occurred, give activated charcoal to help adsorb any remaining toxic substance."

§ 357.58 Other allowable statements for poison treatment drug products.

The following additional statements may be included in the labeling of poison treatment drug products, but should not be included in conjunction with the required labeling identified in §§ 357.50, 357.52, 357.54, and 357.56:

(a) "For the treatment of poisoning."

(b) "Emergency first aid treatment for poisoning."

(c) "Emergency treatment for poisoning."

(d) "Emergency treatment for accidental poisoning."

(e) "For the treatment of accidental poisoning."

(f) "Emergency first aid treatment for accidental poisoning.

(g) "Emergency poison treatment."

(h) "First aid poison treatment."

§ 357.60 Nonapplicability of § 330.1(g) to poison treatment drug products.

The second portion of the warning required by § 330.1(g) concerning

accidental overdose is not required on poison treatment drug products.

Interested persons may, on or before May 15, 1985 submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 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. The agency has provided this 120 day period (instead of the normal 60 days) because of the number of OTC drug review documents being published concurrently. Written comments on the agency's economic impact determination may be submitted on or before May 15, 1985. 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**.

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 May 15, 1985. 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.

Dated: December 31, 1984.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

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Part XI

Department of the Interior

Minerals Management Service to Delineate Areas of Interest for Further Evaluation for Potential Leasing of Strategic and Nonenergy Minerals Found in the Exclusive Economic Zone and Outer Continental Shelf

Call for Information

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Call for Information to Delineate Areas of Interest for Further Evaluation for Potential Leasing of Strategic and Nonenergy Minerals Found in the Exclusive Economic Zone and Outer Continental Shelf

AGENCY: Minerals Management Service, Interior.

ACTION: Call for Information.

SUMMARY: The Minerals Management Service is requesting comments and information from interested parties to assist in the delineation of areas to be included in more detailed resource, environmental and economic reviews for possible leasing of minerals other than oil, gas, and sulphur in the Exclusive Economic Zone (EEZ) and Outer Continental Shelf (OCS). Responses to this Call will be used to establish priority areas for such reviews for the possible leasing of construction materials, placer deposits, phosphorites, polymetallic sulfides, cobalt-manganese minerals, or other nonenergy minerals within the EEZ and OCS on a case-by-case basis.

DATES: Comments and information in response to this request should postmarked or hand delivered no later than May 15, 1985.

ADDRESSES: Comments and information may be mailed or delivered to the Minerals Managment Service, Office of Strategic and International Minerals, Attention: Program Director, 11 Golden Shore, Suite 260, Long Beach, California 90802.

Proprietary Information

If information of a privileged nature is submitted, it should be enclosed in a separate sealed envelope and market PROPRIETARY. This information will be exempt from disclosure pursuant to the Freedom of Information Act (5 U.S.C. 552). Indications of interest are considered to be privileged information; however, the names of persons or entities indicating interest or submitting comments will be of public record.

FOR FURTHER INFORMATION CONTACT

Mr. Reid T. Stone, Office of Strategic and International Minerals, 11 Golden Shore, Suite 260, Long Beach, California 90802, telephone (213) 548–2901. FTS 796–2901.

SUPPLEMENTARY INFORMATION:

Background

Recent task force studies, workshops, and symposia included (1) a program feasibility study on nonenergy minerals leasing (with 23 appendices) of August 1979; (2) a workshop on OCS hard minerals at OCEANS '83, San Francisco, California, in September 1980; (3) a study entitled "National Ocean Goals and Objectives for the 1980's, MARINE MINERALS: An Alternative Mineral Supply," by the National Advisory Committee on Oceans and Atmosphere, July 1983; and (4) a symposium on a National Program for the Assessment and Development of the Mineral Resources of the United States Exclusive Economic Zone by the U.S. Geological Survey, Minerals Management Service, and Bureau of Mines at Reston, Virginia, in November 1983. These have each indicated substantial potential resources of strategic and other nonenergy minerals off our shores.

The resources may be classified basically in five groups: Construction materials, including sands, gravels, shells, and other high-bulk, low unit-value materials, placer deposits of metals or minerals containing gold, platinum, tin, titanium, thorium, or rare earths; phosphorites used primarily for the production of phosphatic fertilizers and found as shallow bedded deposits or as deposits formed as nodules, sands, or encrustations on the seabed; metalliferous oxides occurring as nodules or crusts in water depths from several hundred to several thousands of meters and containing significant amounts of the metals manganese, copper, nickel, and cobalt; and metalliferous sulfides found in a variety of possible forms at the surface of the seabed and beneath the surface in water depths, generally, of several thousand meters containing significant amounts of such as copper, zinc, cadmium, molybdenum, chromium, barium, strontium, silver, or gold.

The possibility of offering leases for the exploration and possible development of both metalliferous oxides and metalliferous sulfides is being evaluated for the area of Hawaiian Islands and the Gorda Ridge off Oregon and northern California, respectively. The initial step in each case will be to prepare an impact statement on the economic, engineering, and environmental impact of exploration and development in these areas, including any unavoidable adverse effects, appropriate alternatives, and other factors. No decision has been made to offer yet in either area. In the case of the other three commodity groups, no such specific proposals are under consideration.

In keeping with the mandates of the Mining and Minerals Policy Act of 1970 and the National Materials and Minerals Policy Research and Development Act of 1980 in which the Secretary of the Interior is required among other things to promote and encourage private enterprise in the development of economically sound and stable domestic materials industries, the advisability of developing a program for leasing of nonenergy minerals on the OCS on a case-by-case basis is being considered.

Purpose of Call

The purpose of the Call is to assist the Secretary of the Interior in carrying out his responsibilities under the OCS Lands Act (43–U.S.C. 1331–1343), as amended (92 Stat. 629), and to assist various Federal/State Task Forces and Regional Technical Working Groups in delineating areas of interest for strategic and other nonenergy minerals. Interested parties are requested to outline on a map areas within the EEZ and OCS that they believe have potential for development of construction materials, placer deposits, phosphorites, polymetallic sulfides, cobalt-rich manganese crust, and/or other nonenergy minerals that may occur and for which they may have an interest in leasing. Interested parties are also requested to identify areas that they believe should be excluded from consideration for leasing and the reasons therefore.

Use of Information for Call

Information submitted in response to this Call will be considered in the advisability of examining and possibly formulating a case-by-case leasing program for strategic and other nonenergy minerals. Comments received on possible environmental effects and use conflicts may be used in the analysis of specific environmental conditions within the Call area so that the potential effects of exploration, development, and mining, other than the benefits accruing to the Nation as a result of inventorying and producing minerals, can be assessed.

Description of the Areas

Construction Materials: The potential resources of construction materials on the U.S. continental shelves are considered excellent. In 1979, the OCS Mining Policy Task Force estimated sand and gravel resources of 830, 269, 29, and 19 billion cubic meters on the Atlantic, Gulf of Mexico, Pacific, and Hawaiian offshore areas, respectively. There is a large potential for sand and gravel offshore of Alaska.

A study of the northeastern continental margin to approximately 2,000 meters of water depth showed that

much of the shelf is mantled with sand of up to 3 meters thick and of considerable lateral continuity and that gravel is also present in a more discontinuous patchy distribution. These sand deposits were estimated at 400 billion tons. The inner continental shelf areas of the Atlantic, Gulf of Mexico, and southern California have been surveyed from the shore to 20 km seaward to assess marine sand and gravel resources. The results indicate nearly 17 billion cubic meters of sand and gravel within the upper 6 m of the seafloor. Seismic data suggest that in some regions the thicknesses and volumes are considerably greater. Sand is abundant in many regions; however, it varies considerably in textural properties and in some places is admixed with or covered by mud. Gravel is most common on glaciated shelf regions of the northeast and northwest, but south of about 40°N, gravel appears limited to a carbonate shall fraction or residual coarse sediment overlying outcrops of relict fluvial channel deposits or coastal plain strata. The most promising sand and gravel deposits ar associated with glacial moraines and drift, outwash-sand plains, and glaciofluvial deltas. Also promising are ancestral river channels that crossed the shelf in the Quaternary period prior to the Holocene transgression, as well as the various classes of shoals (e.g. linear, cape-associated, and tidal-inlet-associated) that are present from the shoreface to the shelf edge.

On the Pacific coast, deposits of sand and gravel occur near Grays Harbor off central Washington within shipping distance of the Portland and Seattle metropolitan areas. Deposits offshore of California are relatively small and fine-grained, consisting of relict beach and fluvial materials. One of the most promising deposits, because of its proximity to Los Angeles and San Diego, lies off Imperial Beach and consists of reworked gravel on the submerged former delta of the Tijuana River.

In Hawaii, a potential white-sand supply is located 35 km from Honolulu on Penguin Bank in water depths of 50–60 m. This area is believed to be part of a deposit containing 350 million cubic yards. This calcareous sand is located on drowned Pleistocene sea level terraces.

Placer deposits: Placer deposits show most potential for their heavy mineral content. Heavy-mineral sands of variable composition and grade on the Atlantic shelf have been estimated to be about 1.3 billion cubic meters or more. Surficial relict sand bodies, often occurring as ridges (submarine highs), are present over most of the Atlantic shelf. They range in thickness from about 20 m to 80–140 m near the shelf edge. Some of these relict features are interpreted as ancient shore deposits that formed as the ocean transgressed the shelf at the end of the most recent glaciation. Supporting evidence for this interpretation is the presence of submerged terraces and beach ridges which are the types of features associated with interim stages of change in sea level. It has been inferred that concentrations of heavy minerals are associated with these former shoreline features.

Heavy minerals have been identified in sediments within the inner New York Bight area. Marine sediments offshore of Virginia may have greater heavy mineral concentration than offshore areas to the south and are almost as rich as an onshore control area in South Carolina. Heavy-mineral placers have been mined onshore from ancient beach sands along the coasts of New Jersey, Georgia and Florida and from coastal plain deposits in New Jersey. Kyanite, sillimanite, ilmenite, zircon, and other heavy minerals occur in beach and nearshore sediments around the Apalachicola River and in various locations along the coasts of Florida, Alabama, Louisiana, and Texas.

No quantitative estimates of heavy-mineral sand on the Gulf of Mexico continental shelf are available. Identified or indicated heavy minerals of economic interest include many of the species found on the Atlantic shelf, but very little mineralogic information is available.

In northern California, gold occurrences have been reported in offshore sediments near Crescent City and offshore of rivers in southern California. Other heavy-minerals occurrences, especially zircon and chromite, have been reported in offshore sediments near Crescent City. Platinum has been reported in beach sediments near Crescent City, north of Orick, and at Monterey Bay. Heavy-minerals occurrences have been reported offshore of Oregon, seaward of rivers including Neholem, Rogue, Siltcoas, and Umpqua to water depths of 185 meters. Heavy-minerals occurrences also have been reported seaward of Cape Blanco and near the shelf break adjacent to the Rogue Submarine Canyon.

Discontinuous placer deposits have been identified along the coast of Washington from Cape Flattery to the Columbia River. Favorable locations for placer deposits are relict sand bodies paralleling the coast, submerged beaches, and offshore of the Columbia River. On the Pacific continental shelf, heavy-mineral sand of various composition and grade is estimated to be about 2.06 billion cubic meters. Gold and heavy-mineral sand deposits occur rather extensively in relict beaches, buried river channels, and in reworked Pleistocene gravels. High-grade titanium and zircon sands have been inferred to be widespread.

Submerged shorelines and stream channels offshore Alaska near Nome and Goodnews Bay are prime localities for gold placers. A shoal north-northeast of Cape Prince of Wales may contain heavy-mineral placers including gold. Other areas where onshore lode deposits of gold are near enough to the continental shelf to merit serious investigations included Captains Bay located within the western part of Alaska; the Aleutian Islands; west of Kodiak Island; lower Cook Inlet in Kamishak Bay extending around the lower end of Kenai Peninsula; and possibly Resurrection Bay near Seaward Peninsula.

Other offshore areas possessing potential for placers include offshore of the western part of St. Lawrence Island, Shelikof Straits, offshore of the Copper River Delta, and most of southeast Alaska.

No definite estimates are available for these resources in Alaskan waters, although there are some indications that heavy-mineral deposits may far exceed those of all the remaining EEZ.

Phosphorite deposits: Phosphorite deposits are known to occur off both the east and west coasts of the United States. Phosphorite has been dredged, cored, and/or photographed at the surface of the continental shelf from the sourthern part of Florida to the shelf off North Carolina. Drilling has shown that these deposits also occur at depth beneath the shelf in Middle Tertiary rocks.

Although the size of these deposits can be only roughly estimated, they represent an enormous resource of phosphorite. Approximately 2 billion metric tons of phosphorite are present on the Blake Plateau alone. About half this much is also present as a pavement in which the phosphorite is associated with ferromanganese oxides. An equal amount of phosphorite may exist off the coast of North Carolina in the form of bedded deposits below the seabed.

Phosphorites off the coast of California have been widely recovered from the tops of submarine banks and ridges in the continental borderland and have been dredged from rather steep slopes at depths as great as 3,000 meters

and from the shelf to the north near Monterey Bay. This deposit represents a resource of approximately 115 million metric tons.

Phosphorite has been recovered from several seamounts in the Pacific Ocean, where it is usually associated with cobalt-rich ferromanganese oxides. The size of these deposits is only superficially delineated at present.

Surficial phosphorite deposits off both coasts are considered to be lag deposits that have been eroded from rocks of Middle Tertiary age. The phosphorite ranges in size from pellets to pavements but most often occurs as irregular-shaped nodules. The phosphate mineral is francolite and is associated with caronate sands. The source beds crop out on land, and in Florida they are dominantly limestones. In California, they include dolomite and highly siliceous rocks, many with high concentrations of organic carbon.

In Onslow Bay, about 100 kilometers offshore of North Carolina, preliminary evaluations have indicated a vast phosphate resource potential occurring in the Miocene Pungo River formation. This formation is a major sedimentary phosphorite unit under the coastal plain and outcrops offshore as a northeast-southwest belt about 150 kilometers long by 40 kilometers wide and dips into the subsurface to the southeast. The economically valuable beds within this formation have been estimated to contain 1.36 billion metric tons of phosphate concentrated grading between 28 to 30 percent phosphate.

Polymetallic sulfide deposits: Polymetallic sulfides have been found along several seafloor spreading centers in the Pacific Ocean. The active zone of spreading can be hundreds of kilometers long but is usually less than 2 km wide. Deeply circulating hot seawater leaches heavy metals (zinc, silver, copper, manganese, cadmium, iron, etc.) and sulphur at high temperatures from the surrounding rocks. The upward movement of these hot mineral-rich waters is confined to narrow channels. Upon reaching the seafloor, the water discharges upward in a plume called a smoker. The sudden mixing with the cold seawater causes metallic sulfide minerals to be precipitated in mounds and chimneys around the vents. Subsurface concentrations of massive metallic sulfide minerals may also be formed in the vicinity of active vents and in areas of active spreading which are covered by thick sediment. Such deposits may be preserved and carried with the spreading plate—far from the spreading centers.

More than six smokers have been found on the Juan de Fuca Ridge. A sample recovered near a smoker just outside the EEZ was almost pure zinc sulfide (55 percent zinc) and contained 300 parts per million silver.

Microscopic amounts of metallic sulfides have been identified in rock samples recently collected from the Gorda Ridge suggesting the presence of hydrothermal activity in the area.

Polymetallic sulfides may also be deposited on the flanks of active volcanoes in back arc basins such as that of the Northern Marianas and around volcanoes formed over hot spots in the crust like the Hawaiian Islands.

Cobalt-rich manganese oxide crusts: These crusts occur on flank areas of islands and seamounts in the Pacific region including the Hawaiian archipelago. Measured cobalt content ranges from 0.4 percent in the crusts in deeper water to 1.2 percent in the crusts on seamount tops in waters less than 2,500 meters. The mean crust thickness is more than 2 centimeters (cm) in upper slope areas and may be as thich as 6–8 cm. Accessible concentrations could yield 16 kg per square meter of crustal surface. The monetary value per unit area of cobalt, nickel, manganese, copper, and molybdenum in these crusts is significantly greater than in known deepwater nodules.

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Department of the Interior, 1984. A national program for the assessment and development of the mineral resources of the United States Exclusive Economic Zone: Proceedings of a symposium sponsored by the Department of the Interior, Nov. 15, 16, 17, 1983, U.S.G.S. Circ. 929, p. 308.

Department of the Interior, 1979. Program feasibility document, OCS hard minerals leasing: National Technical Information Service, Springfield, VA 22161, p. 180 with 23 appendices. NTIS No. PB81–192551.

Evans, J.R., Da Bia, G.S. and Levine, C.R., 1982 Mining and Marketing of Sand and Gravel on the Outer Continental Shelf of Southern California, California Geology, Vol. 35, p. 259–276.

Riggs, S.R., and others, 1984. Phosphate resource potential in Onslow Bay, N. Carolina continental shelf: East Carolina University, Department of Geology, Greenville, NC 27834, in press.

Instructions on Call

Indications of interest should be limited to the OCS, as defined in the OCS Lands Act, which extends a minimum of 200 miles from the coasts of the states of the Union. Respondents are requested to rank areas according to priority of interest (e.g. priority 1, 2, and 3).

Dated: January 9, 1985.

William D. Bettenberg,

Director, Minerals Management Service.

[FR Doc. 85–1099 Filed 1–14–85; 8:45 am]

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federal register

Tuesday
January 15, 1985

Part XII

Department of Defense
General Services Administration
National Aeronautics and Space Administration

48 CFR Ch. 1
Federal Acquistion Regulation

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Ch. 1

[Federal Acquisition Circular 84-6]

Federal Acquisition Regulation

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Interim rule and request for comment.

SUMMARY: Federal Acquisition Circular (FAC) 84-6 amends the Federal Acquisition Regulation (FAR) with respect to the changes required to implement the publicizing provisions and the validation of proprietary restrictions of the Small Business and Federal Procurement Competition Enhancement Act of 1984 (Pub. L. 98-577), and the protest provisions of the Competition in Contracting Act of 1984 (CICA) (Pub. L. 98-369).

EFFECTIVE DATES: FAC 84-6 revisions to FAR Part 1 are effective November 29, 1984. The FAC 84-6 revision to FAR Part 27 is effective for solicitations issued on or after December 29, 1984. FAC 84-6 revisions to FAR Parts 12, 14, 33, and 52 are effective for protests filed on or after January 15, 1985. The FAC 84-6 revision to FAR Part 39 is effective January 15, 1985.

DATE: Comments must be received on or before March 18, 1985. Please cite FAC 84-6 in all correspondence on this subject.

ADDRESS: Interested parties should submit written comments to: General Services Administration, ATTN: FAR Secretariat (VR), 18th & F Street, NW., Room 4041, Washington, D.C. 20405.

FOR FURTHER INFORMATION CONTACT: Roger M. Schwartz, Director, FAR Secretariat, Room 4041, GS Building, Washington, D.C. 20405, Telephone (202) 523-4755.

SUPPLEMENTARY INFORMATION: A determination has been made under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration that the regulations in FAC 84-6 must be issued as temporary regulations in compliance with section 22 of the Office of Federal Procurement Policy Act, as amended.

Item I, FAC 84-6, describes changes to FAR Part 1 to conform the regulation to the publicizing provisions of Pub. L. 98-577. The FAR revisions described in Item I are effective November 29, 1984. Under the new coverage, agencies will be required to publicize acquisition regulations that have a significant effect beyond the internal operating procedures of the agency or have a significant cost or administrative impact on contractors or offerors. Such coverage may not take effect until 30 days after a notice (see 1.501-2(b)) inviting public comment is placed in the Federal Register unless the issuing officer waives the advance comment requirement after determining that urgent and compelling circumstances make such action impracticable.

Item II, FAC 84-6, describes changes to the FAR that require civilian agencies other than NASA to implement section 203 of Pub. L. 98-577 with respect to validation of restrictions asserted by a contractor or subcontractor on the right of the Government to use technical data. The FAR revisions described in Item II are effective for solicitations issued on or after December 29, 1984.

Item III, FAC 84-6, provides new procedures for submitting protests to the General Accounting Office or the General Services Board of Contract Appeals. The FAR revisions described in Item III are effective for protests filed on or after January 15, 1985. Agencies will have to issue internal operating procedures, for implementation prior to the effective date. These regulations were previously published for a brief comment period and comments received were considered.

Item IV, FAC 84-6, revises a reference in FAR Part 39 pertaining to policies, procedures, and guidelines peculiar to automatic data processing, telecommunications, and related resources.

Roger M. Schwartz,

Director, FAR Secretariat.

January 11, 1985.

Federal Acquisition Circular

[Number 84-6]

The material contained in FAC 84-6 is effective according to the following:

—The revisions to the Federal Acquisition Regulation (FAR) described in Item I, Publicizing Proposed Regulations, are effective November 29, 1984.

—The revisions to the FAR described in Item II, Validation of Proprietary Data Restrictions, is effective for solicitations issued by civilian agencies other than NASA on or after December 29, 1984.

—The revisions to the FAR described in Item III, Protest Provisions of the Competition in Contracting Act of 1984, are effective for protests filed on or after January 15, 1985.

—The revisions to the FAR described in Item IV, Editorial, is effective January 15, 1985.

Mary Ann Gilleece,

Deputy Under Secretary, (Acquisition Management), Department of Defense.

January 10, 1985.

Ray Kline,

Acting Administrator of General Services.

January 10, 1985.

S. J. Evans,

Assistant Administrator for Procurement, NASA.

January 10, 1985.

Federal Acquisition Circular (FAC) 84-6 amends the Federal Acquisition Regulation (FAR) as specified below. The following is a summary of the amendments:

Item I—Publicizing Proposed Regulations

The Small Business and Federal Procurement Competition Enhancement Act of 1984 (Pub. L. 98-577) requires that certain acquisition regulations receive public comment. The changes to FAR Part 1 conform the regulation to these publicizing provisions. Under this new coverage, agencies will be required to publicize acquisition regulations that have a significant effect beyond the internal operating procedures of the agency or have a significant cost or administrative impact on contractors or offerors. Such coverage may not take effect until 30 days after a notice (see 1.501-2(b)) inviting public comment is placed in the **Federal Register** unless the issuing officer waives the advance comment requirement after determining that urgent and compelling circumstances make such action impracticable.

Item II—Validation of Proprietary Data Restrictions

Section 203 of Pub. L. (98-577 amended the Federal Property and Administrative Services Act of 1949 by adding coverage on validation of restrictions asserted by a contractor or subcontractor on the right of the Government to use technical data. FAR 27.401 is amended to require civilian agencies other than NASA to implement section 203 of Pub. L. 98-577 pending the publication of detailed coverage on this subject in a later FAC.

Item III—Protest Provisions of the Competition in Contracting Act of 1984

The Competition in Contracting Act of 1984 provides revised procedures for filing protests with the General Accounting Office (GAO) and new procedures for filing Automatic Data Processing protests to the General Services Board of Contract Appeals (GSBCA). These protest procedures apply to protests filed on or after January 15, 1985.

FAR Parts 12, 14, 33, and 52 contain new protest coverage. Under the new coverage, agencies will be required to implement procedures for processing protests that are filed with the GAO and with the GSBCA. The protest coverage of the FAR is removed from 14.407–8 and the revised coverage is placed in Subpart 33.1. The Disputes and Appeals coverage of Part 33 is renumbered as Subpart 33.2.

Item IV—Editorial

The reference in FAR Part 39 is corrected to read "Chapter 201 of Title 41 of the Code of Federal Regulations".

List of Subjects in 48 CFR Ch. 1

Government procurement.

Therefore, 48 CFR is amended as set forth below.

The authority for 48 CFR Ch. 1 is:

Authority: 40 U.S.C. 486(c); 10 U.S.C. Chapter 137; and 42 U.S.C. 2453(c).

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

1.201–1 [Amended]

1. Section 1.201–1(e)(2) is amended by removing the reference "1.501(c)" and inserting in its place the reference "1.501–2(b)".

2. Section 1.301 is amended by redesignating paragraphs (a) and (b) as (a)(1) and (a)(2) and revising new paragraph (a)(1), removing the second sentence of the new paragraph (a)(2), and adding a new paragraph (b) to read as follows:

1.301 Policy.

(a)(1) Subject to the authorities in (c) below and other statutory authority, an agency head may issue or authorize the issuance of agency acquisition regulations that implement or supplement the FAR and incorporate, together with the FAR, agency policies, procedures, contract clauses, solicitation provisions, and forms that govern the contracting process or otherwise control the relationship between the agency, including any of its suborganizations, and contractors or prospective contractors.

* * * * *

(b) Agency heads shall establish procedures to ensure that issuances (including revisions) under 1.301(a)(1) shall be publicized for public comment in the **Federal Register** in conformance with the procedures in Subpart 1.5 and as required by section 22 of the Office of Federal Procurement Policy Act, as amended, and other applicable statutes when they have a significant effect beyond the internal operating procedures of the agency or have a significant cost or administrative impact on contractors or offerors. However, publication is not required for issuances that merely implement or supplement higher level issuances that have previously undergone the public comment process, unless such implementation or supplementation results in an additional significant cost or administrative impact on contractors or offerors or effect beyond the internal operating procedures of the issuing organization. Issuances under 1.301(a)(2) need not be publicized for public comment.

3. Section 1.303 is amended by revising the title; the first sentence of paragraph (a); and paragraph (b) as follows:

1.303 Publication and codification.

(a) Agency-wide acquisition regulations shall be published in the Federal Register as required by law, shall be codified under an assigned chapter in Title 48, Code of Federal Regulations, and shall parallel the FAR in format, arrangement, and numbering system (but see 1.104–1(c)). * * *

(b) Issuances under 1.301(a)(2) need not be published in the **Federal Register**.

4. Subpart 1.5 is amended by redesignating in section 1.501 paragraph (a) as section 1.501–1; redesignating paragraphs (b), (c), and (d) as section 1.501–2; redesignating paragraph (e) as section 1.501–3; redesignating paragraph (f) as section 1.502 and redesignating section 1.502 as 1.503; and revising the subpart to read as follows:

Subpart 1.5—Agency and Public Participation

1.501 Solicitation of agency and public views.

1.501–1 Definition.

"Significant revisions," as used in this subpart, means revisions that alter the substantive meaning of any coverage in the FAR System having a significant cost or administrative impact on contractors or offerors, or a significant effect beyond the internal operating procedures of the issuing agency. This expression, for example, does not include editorial, stylistic, or other revisions that have no impact on the basic meaning of the coverage being revised.

1.502–2 Opportunity for public comments.

(a) Views of agencies and nongovernmental parties or organizations will be considered in formulating acquisition policies and procedures.

(b) The opportunity to submit written comments on proposed significant revisions shall be provided by placing a notice in the **Federal Register**. Each of these notices shall include—

(1) The text of the revision or, if it is impracticable to publish the full text, a summary of the proposal;

(2) The address and telephone number of the individual from whom copies of the revision, in full text, can be requested and to whom comments thereon should be addressed; and

(3) When 1.501–3(b) is applicable, a statement that the revision is effective on a temporary basis pending completion of the public comment period.

(c) A minimum of 30 days and, normally, at least 60 days will be given for the receipt of comments.

1.501–3 Exceptions.

(a) Comments need not be solicited when the proposed coverage does not constitute a significant revision.

(b) Advance comments need not be solicited when urgent and compelling circumstances make solicitation of comments impracticable prior to the effective date of the coverage, such as when a new statute must be implemented in a relatively short period of time. In such case, the coverage shall be issued on a temporary basis and shall provide for at least a 30 day public comment period.

1.502 Unsolicited proposed revisions.

Consideration shall also be given to unsolicited recommendations for revisions that have been submitted in writing with sufficient data and rationale to permit their evaluation.

1.503 Public meetings.

Public meetings may be appropriate when a decision to adopt, amend, or delete coverage is likely to benefit from significant additional views and discussion.

PART 12—CONTRACT DELIVERY OR PERFORMANCE

5. Section 12.505 is amended by revising paragraph (b) to read as follows:

12.505 Contract clauses.

* * * * *

(b)(1) The contracting officer shall insert the clause at 52.212–13, Stop-Work Order, in solicitations and contracts for automatic data processing under 40 U.S.C. 759 (see 33.105).

(2) Except as provided in (b)(1) above, the contracting officer may, when contracting by negotiation, insert the clause at 52.212–13, Stop-Work Order, in solicitations and contracts for supplies, services, or research and development.

(3) If a cost-reimbursement contract is contemplated, the contracting officer shall use the clause with its Alternate I.

* * * * *

PART 14—FORMAL ADVERTISING

14.407–8 [Amended]

6. Section 14.407–8 is amended by removing paragraphs (a) through (c) and inserting in their place the statement "See Subpart 33.1—Protests."

PART 27—PATENTS, DATA, AND COPYRIGHTS

7. Section 27.401 is amended by inserting a new sentence at the end of the paragraph to read as follows:

27.401 General.

* * * Civilian agencies other than NASA shall implement section 203 of Pub. L. 98–577 pertaining to validation of proprietary data restrictions.

8. Part 33 is amended by revising the title of the part and the text of section 33.000; redesignating sections 33.001 through 33.014 as sections 33.201 through 33.214 respectively; adding a new subpart 33.1; removing in the definition of "claim" in new section 33.201 the word "part" in the first sentence, the citation "33.007" in the third sentence, and the citation "33.006(a)" in the fifth sentence and inserting in their places, the word "subpart", the citation "33.207", and the citation "33.206(a)" respectively; removing in new section 33.203(b) the reference "Part 33" and inserting in its place the word "subpart"; removing in the first sentence of new section 33.208 the citation "33.007(a)" and inserting in its place the citation "33.207(a)"; removing in new section 33.210(b) the citation "33.009" and inserting in its place the citation "33.209"; and removing in the first sentence of new section 33.214 the citation "33.003" and inserting in its place the citation "33.203" as follows:

PART 33—PROTESTS, DISPUTES, AND APPEALS

Sec.

Authority: 40 U.S.C. 486(c); Chapter 137, 10 U.S.C.; and 42 U.S.C. 2453(c).

§ 33.000 Scope of part.

This part prescribes policies and procedures for filing protests and for processing contract disputes and appeals.

Subpart 33.1—Protests

33.101 Definitions.

"Interested party," as used in this subpart, means an actual or prospective offeror whose direct economic interest would be affected by the award of or failure to award a particular contract.

"Protest," as used in this subpart, means a written objection by an interested party to a soliciation by an agency for offers for a proposed contract for the acquisition of supplies or services or a written objection by an interested party to a proposed award or the award of such a contract.

33.102 General.

(a) Contracting officers shall consider all protests, whether submitted before or after award and whether filed directly with the agency, the General Accounting Office (GAO), or for automatic data processing acquisitions under 40 U.S.C. 759 (hereinafter cited as "ADP contracts"), the General Services Board of Contract Appeals (GSBCA). The protestor shall be notified in writing of the final decision of the protest. (See 19.302 for protests of small business status and 22.608–3 for protests involving eligibility under the Walsh-Healey Public Contracts Act.)

(b) An interested party wishing to protest—

(1) Is encouraged to seek resolution within the agency (see 33.103) before filing a protest with the GAO or the GSBCA;

(2) May protest to the GAO in accordance with GAO regulations (4 CFR Part 21). An interested party who has filed a protest regarding an ADP contract with the GAO may not file a protest with the GSBCA with respect to that contract.

(3) May protest to the GSBCA regarding an award of an ADP contract in accordance with GSBCA Rules of Procedure (48 CFR Part 61). An interested party who has filed a protest regarding an ADP contract with GSBCA (40 U.S.C. 759(h)) may not file a protest with the GAO with respect to that contract.

33.103 Protests to the agency.

(a) When a protest is filed only with the agency, an award shall not be made until the matter is resolved unless the contracting officer or other designated official first determines that one of the following applies:

(1) The supplies or services to be contracted for are urgently required.

(2) Delivery or performance will be unduly delayed by failure to make award promptly.

(3) A prompt award will otherwise be advantageous to the Government.

(b)(1) When a protest against the making of an award is received and award will be withheld pending disposition of the protest, the offerors whose offers might become eligible for award should be informed of the protest. If appropriate, those offerors should be requested, before expiration of the time for acceptance of their offer, to extend the time for acceptance in accordance with 14.404–1(d) to avoid the need for resolicitation. In the event of failure to obtain such extensions of offers, consideration should be given to proceeding with award under (a) above.

(2) Protests received after award filed only with the agency shall be handled in accordance with agency procedures. The contracting officer need not suspend contract performance or terminate the awarded contract unless it appears likely that an award may be invalidated and a delay in receiving the supplies or services is not prejudicial to the Government's interest. In this event, the contracting officer should consider seeking a mutual agreement with the

contractor to suspend performance on a no-cost basis.

33.104 Protests to GAO.

The Department of Justice has advised that the GAO stay provisions in 31 U.S.C. 3553 (c) and (d) and the GAO damages provision in 31 U.S.C. 3554(c) regarding payment of costs of filing and pursuing a protest and preparing the bid and proposal are unconstitutional; therefore, they neither bind the executive branch nor serve as the basis for any coverage in this section.

(a) *General.* (1) A protester shall furnish a copy of its complete protest to the official or location designated in the solicitation or, in the absence of such a designation, to the contracting officer, no later than one day after the protest is filed with the GAO. Failure to furnish a complete copy of the protest within one day may result in dismissal of the protest by GAO.

(2) When a protest, before or after award, has been lodged with the GAO, the agency shall prepare a report. The report should include a copy of—

(i) The protest;

(ii) The offer submitted by the protesting offeror and a copy of the offer which is being considered for award or which is being protested;

(iii) The solicitation, including the specifications or portions relevant to the protest;

(iv) The abstract of offers or relevant portions;

(v) Any other documents that are relevant to the protest; and

(vi) The contracting officer's signed statement setting forth findings, actions, and recommendations and any additional evidence or information deemed necessary in determining the validity of the protest. The statement shall be fully responsive to the allegation of the protest. If the contract action or contract performance continues after receipt of the protest, the report will include the determination(s) prescribed in paragraphs (b) or (c) below.

(3) Other persons, including offerors, involved in or affected by the protest shall be given notice of the protest and its basis in appropriate cases, within one work day after its receipt by the agency. The agency shall give immediate notice of the protest to the contractor if the award has been made or, if no award has been made, to all parties who appear to have a reasonable prospect of receiving an award if the protest is denied. These persons shall also be advised that they may submit their views and relevant information directly to the GAO with a copy to the contracting officer within a specified period of time. Normally, the time specified will be 1 week.

(4) The agency shall submit a complete report (see (a)(2) above) to GAO within 25 work days after receipt from GAO of the telephonic notice of such protest, or within 10 work days after receipt from GAO of a determination to use the express options, unless—

(i) The GAO advises the agency that the protest has been dismissed; or

(ii) The agency advises GAO in writing that the specific circumstances of the protest require a longer period and GAO establishes a new date. Any new date shall be documented in the agency's protest file.

(5)(i) Timely action on protests is essential. Upon notice that a protest has been lodged with the GAO, the contracting officer shall immediately begin compiling the information necessary for a report to the GAO. To further expedite processing, when furnishing a copy of the report including relevant documents to the GAO, the agency shall simultaneously furnish a copy of the report including relevant documents to the protester and a copy of the report without relevant documents to other interested parties who have responded to the notice in (a)(3) above. Upon request the agency shall also provide to any interested party a relevant document contained in the report.

(A) Documents previously furnished to or prepared by a party (e.g., the solicitation or the party's own proposal) need not be furnished to that party.

(B) Classified or privileged information or information that would give a party a competitive advantage and other information that the Government determines under appropriate authority to withhold should be deleted from the copy of the report or relevant documents furnished to that party.

(ii) The protester and other interested parties shall be requested to furnish a copy of any comments on the report directly to the GAO as well as to the contracting officer.

(6) Agencies shall furnish the GAO with the name, title, and telephone number of one or more officials (in both field and headquarters offices, if desired) whom the GAO may contact regarding protests. Each agency shall be responsible for promptly advising the GAO of any change in the designated officials.

(b) *Protests before award.* (1) When the agency has received notice from GAO of a protest filed directly with GAO, award shall not be made until the matter is resolved, unless the contracting officer or other designated official determines in writing that—

(i) The supplies or services to be contracted for are urgently required;

(ii) Delivery or performance will be unduly delayed by failure to make award promptly; or

(iii) A prompt award will otherwise be advantageous to the Government.

(2) When a protest against the making of an award is received and award will be withheld pending disposition of the protest, the offerors whose offers might become eligible for award should be informed of the protest. If appropriate, those offerors should be requested, before expiration of the time for acceptance of their offer, to extend the time for acceptance in accordance with 14.404–1(d) to avoid the need for resolicitation. In the event of failure to obtain such extensions of offers, consideration should be given to proceeding with award under (b)(1) above.

(c) *Protests after award.* Protests received after award shall be handled in accordance with agency procedures. Although persons involved in or affected by the filing of a protest may be limited, at least the contractor shall be furnished the notice of protest and its basis. The contracting officer need not suspend contract performance or terminate the awarded contract unless it appears likely that an award may be invalidated and a delay in receiving the supplies or services is not prejudicial to the Government's interest. In this event, the contracting officer should consider seeking a mutual agreement with the contractor to suspend performance on a no-cost basis.

(d) *Findings and notice.* If the decision is to proceed with contract award, or continue contract performance under (b) or (c) above, the contracting officer shall include the written findings or other required documentation in the file. The contracting officer also shall give written notice of the decision to the protester and other interested parties.

(e) *GAO decision time.* GAO will issue its recommendation on a protest within 90 work days, or within 45 calendar days under the express option, unless GAO establishes a longer period of time.

(f) *Notice to GAO.* The head of the agency or a designee (not below the level of the head of the contracting activity) responsible for the solicitation, proposed award, or award of the contract shall report to the Comptroller General within 60 days of receipt of the GAO's recommendation if the agency has decided not to comply with the recommendation. The report shall

explain the reasons why the GAO's recommendation will not be followed by the agency.

33.105 Protests to GSBCA.

(a)(1) An interested party may protest an ADP acquisition conducted under Section 111 of the Federal Property and Administrative Services Act (40 U.S.C. 759) by filing a protest with the GSBCA. ADP acquisition protests not covered under this statute may not be heard by the GSBCA, but may be heard by the agency, the courts, or GAO. A protester shall furnish a copy of its complete protest to the official or location designated in the solicitation, or in the absence of such a designation to the contracting officer, no later than one day after the protest is filed with GSBCA. Any request for a hearing on either a suspension of procurement authority or on the merits shall be in the protest.

(2) The GSBCA procedures state that—

(i) Within one working day after receipt of a copy of the protest, the agency shall give either oral or written notice of the protest to all parties who were solicited or, if the solicitation has closed, only to those who submitted a sealed bid or offer; and

(ii) Written confirmation of notice and a listing of all persons and agencies receiving notice should be given to the Board within five working days after receipt of the protest.

(b) The GSBCA procedures state that within 10 work days after the filing of a protest, or such longer time as the GSBCA may establish, the agency shall file with the GSBCA and all other parties a protest file. Except where the agency determines under appropriate authority to withhold classified or privileged information or information that would give a competitive advantage, the protest file shall include the following:

(1) A contracting officer's decision, if any.

(2) The contract, if any.

(3) All relevant correspondence.

(4) Affidavits or statements of witnesses on the matter under protest.

(5) All documents relied upon by the contracting officer in taking the action protested.

(6) A copy of the solicitation, the protestor's bid or proposal and, if bid opening has occurred and no contract has been awarded, a copy of any relevant bids and the bid abstract.

(7) In a negotiated acquisition, a copy of offers or proposals being considered for award and relevant to the protest should be included in the GSBCA file only, for *in camera* review by the Board. The agency shall serve all parties with a list of documents provided to the Board for *in camera* review.

(8) Any additional existing evidence or information necessary to determine the merits of the protest.

(9) Any information otherwise withheld, where it is appropriate for *in camera* review by the Board.

(c) The GSBCA procedures state that within 15 work days after the filing of the protest, or such longer time as the Board may establish, the agency shall submit its answer to the Board setting forth its defenses to the protest and its findings, actions, and recommendations in the matter.

(d)(1) If a protest contains a timely request for a suspension of procurement authority, a hearing will be held whenever practicable but no later than 10 calendar days after the filing of the protest. The Board shall suspend the procurement authority unless the agency establishes that—

(i) Absent suspension, the contract award is likely within 30 calendar days; and

(ii) Urgent and compelling circumstances which significantly affect interests of the United States will not permit waiting for the decision.

(2) Circumstances in (d)(1) above shall be established by a D&F executed by the agency head or designee.

(3) The Board's decision on suspension may be oral.

(e) A hearing on the merits, if requested, will be held within 25 work days after the filing of the protest and a GSBCA decision on the merits will be issued within 45 work days, unless the Board's chairman determines a longer period is required.

(f)(1) The GSBCA may declare an appropriate interested party to be entitled to the costs of—

(i) Filing and pursuing the protest, including reasonable attorney's fees; and

(ii) Bid and proposal preparation.

(2) Costs awarded under (f)(1) above shall be paid promptly by the agency out of funds available to or for the use of the acquisition of supplies or services.

(g) The GSBCA's final decision may be appealed by the agency or by any interested party, including any intervening interested parties, as set forth in Subpart 33.2.

33.106 Solicitation provision.

The contracting officer shall insert the provision at 52.233–2, Service of Protest, in solicitations for other than small purchases.

PART 39—MANAGEMENT, ACQUISITION, AND USE OF INFORMATION RESOURCES

9. The first sentence in Part 39 is revised to read as follows: Chapter 201 of Title 41 of the Code of Federal Regulations contains policies, procedures, and guidelines peculiar to automatic data processing (ADP), telecommunications, and related resources.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

10. Section 52.212–13 is amended by revising the introductory text to read as follows:

52.212–13 Stop-Work Order.

As prescribed in 12.505(b), insert the following clause. The "90-day" period stated in the clause may be reduced to less than 90 days.

* * * * *

11. A new section 52.233–2 is added as follows:

52.233–2 Service of Protest.

As prescribed in 33.106, insert the following provision:

Service of Protest (JAN 1985)

Protests, as defined in section 33.101 of the Federal Acquisition Regulation, shall be served on the Contracting Officer by obtaining written and dated acknowledgement of receipt from

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[Contracting Officer designate the official or location where a protest may be served on the Contracting Officer.]

(End of Provision)

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