borrower to RUS and the annual auditor's report on the borrower's operations. However, RUS may inspect the borrower's records at any time during the year to determine borrower compliance. If a borrower's most recent annual financial and statistical report shows the aggregate of the borrower's investments, loans and guarantees to be below the 15 percent level, that in no way relieves the borrower of its obligation to comply with its RUS mortgage, RUS loan contract, and this subpart with respect to Administrator approval of any additional investment, loan or guarantee that would cause the aggregate to exceed the 15 percent level.

§ 1717.658 Effect of this subpart on RUS loan contract and mortgage.

(a) Nothing in this subpart shall affect any provision, covenant, or requirement in the RUS mortgage, RUS loan contract, or any other agreement between a borrower and RUS with respect to any matter other than the prior approval by RUS of investments, loans, and guarantees made by the borrower. Also, nothing in this subpart shall affect any rights which supplemental lenders have under the RUS mortgage, or under their loan contracts or other agreements with their borrowers, to limit investments, loans and guarantees by their borrowers to levels below 15 percent of total utility plant.

(b) RUS reserves the right to change the provisions of the RUS mortgage and loan contract relating to RUS approval of investments, loans and guarantees made by the borrower, on a case-by-case basis, in connection with providing additional financial assistance to a borrower after [Date 30 days after the final rule is published in the **Federal Register**].

Dated: February 7, 1995.

Bob J. Nash,

Under Secretary, Rural Economic and Community Development.

[FR Doc. 95–3665 Filed 2–15–95; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 111, 170, and 310

[Docket Nos. 91P–0186 and 93P–0306]

Iron-Containing Supplements and Drugs; Label Warning Statements and Unit-Dose Packaging Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Supplemental proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a supplemental proposed rule to set forth its legal authority, after the passage of the Dietary Supplement Health and Education Act (DSHEA), to require unit-dose packaging of iron-containing dietary supplements that contain 30 milligrams (mg) or more iron per dosage unit. On October 6, 1994, the agency proposed this packaging requirement as part of a broader proposal to require unit-dose packaging of all iron-containing products in solid oral dosage form containing 30 mg or more iron per dosage unit and to require label warning statements on all iron-containing products in solid oral dosage form. The agency's authority to establish the labeling requirements and the packaging requirements for iron-containing products other than dietary supplements (i.e., iron-containing drugs) is unaffected by the DSHEA. To ensure that there is adequate time to comment on this supplemental proposed rule, as well as on the issues raised by the initial proposal, FDA is reopening the comment period for this rulemaking until April 17, 1995.

DATES: Written comments to the initial proposal (published at 59 FR 51030, October 6, 1994) and this supplemental proposal by April 17, 1995. The agency is proposing that any final rule that may be issued based upon this proposal become effective 180 days after its publication in the **Federal Register**.

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

FOR FURTHER INFORMATION CONTACT: John N. Hathcock, Center for Food Safety and Applied Nutrition (HFS–465), Food and Drug Administration, 8301 Muirkirk Rd., Laurel, MD 20708, 301–594–6006.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 6, 1994 (59 FR 51030), FDA issued a proposal on actions that it tentatively concluded were necessary to stem the recent epidemic of pediatric poisonings from accidental overdoses of iron-containing products. The available evidence shows that since the mid 1980's, there has been an upsurge in reported accidental pediatric poisonings from ingestion of iron-containing products (59 FR 51030). This upsurge in poisonings, and the many resultant injuries and deaths of children, have created a dilemma with respect to how to ensure that iron sources are available while still minimizing the risks to children.

To protect children, FDA proposed two new requirements: First, to ensure that consumers are fully informed about the consequences of consuming iron-containing products, FDA proposed to require a warning statement about the adverse effects of acute, high-dose iron ingestion by children to be included in the labeling of all iron-containing products in solid oral dosage form. FDA found that the fact that poisonings continue to occur, even though there have been at least 37 deaths from accidental iron ingestion, strongly suggests that many adults are not aware of the potential for serious harm or death in young children from accidental ingestion of iron-containing products. Support for this finding is provided by statements made by the parents of the victims in several of the poisoning incidents, described in the case reports obtained from the U.S. Consumer Product Safety Commission (CPSC). FDA proposed that this requirement apply to iron-containing drugs and dietary supplements based on its authority under sections 201(n), 403(a)(1), 502(a), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n), 343(a)(1), 352(a), and 371(a)). Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 502(a) of the act establishes the same rule for drugs. Section 201(n) of the act states:

> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

These statutory provisions, combined with section 701(a) of the act, which grants the agency authority to issue regulations for the efficient enforcement of the act, clearly authorize FDA to issue a regulation designed to ensure that persons using iron-containing drugs and dietary supplements will receive information that is material with respect to consequences that may result from the use of the product.

The circumstances involved with the iron poisonings parallel in many significant respects those that led the agency to require a warning on protein products. The use of iron-containing products in households where children are present is in no way an unusual practice. Multi-vitamin/mineral supplements with iron are taken routinely by children, and products of this type specifically intended for use by children are widely available and commonly sold. Iron supplements and iron-containing drug products are frequently recommended by physicians for pregnant women (often with a prescription) and other women of child-bearing age to meet their dietary requirement (these groups require more iron than other adults). Yet, the evidence on poisonings and deaths shows that the presence of iron-containing products in households with young children can lead to accidental injury or death if the children gain access to the products. Thus, FDA tentatively concluded that a warning about the risk of accidental pediatric poisoning from iron-containing products in solid oral dosage form is necessary in the labeling of all iron-containing products.

Second, FDA proposed to require that all iron-containing drugs and dietary supplements in solid oral dosage form that contain 30 mg or more iron per dosage unit be packaged in unit-dose packaging. In the proposal, FDA tentatively concluded that full compliance with CPSC's child resistant packaging requirements, even if there are warning statements in labeling of iron-containing products and appropriate educational programs, is not adequate to ensure the safe use of certain iron-containing drugs and dietary supplements if bottle and closure packaging were to continue as the predominant means of packaging such products. FDA recognizes that each of these measures either has been successful in limiting the number of poisonings or can be reasonably expected to be effective in reducing the number of poisonings. However, given the potentially fatal outcome that can result from pediatric iron poisoning, FDA stated that it is not persuaded that these measures are adequate to ensure the safety of the use of certain iron-containing drugs and dietary supplements. To reduce the incidence of pediatric iron poisonings to a level that would permit the agency to conclude that the use of these products is safe, or generally recognized as safe (GRAS), FDA tentatively concluded that it was necessary to require a specific type of physical barrier to access dietary supplements that contain 30 mg or more of iron. Therefore, FDA tentatively concluded that an additional packaging requirement was necessary.

FDA proposed this packaging requirement for iron-containing dietary supplements based on its authority under the act, with the provisions available at that time, to ensure that food ingredients are safe. In particular, the act requires, in sections 402 and 409 (21 U.S.C. 342 and 348), that the safety of each food ingredient be established, either because the ingredient is GRAS, or because it is listed under the food additive or other relevant provisions, before it is added to food.

Section 409(a) of the act deems a food additive to be unsafe unless its use conforms to the conditions specified in the listing regulation. These conditions include, but are not limited to, specifications as to the particular food or classes of food to which the additive may be added, the manner in which the additive may be added to such food, and any directions or other labeling or packaging requirements for such additive deemed necessary to assure the safety of such use (section 409(c)(1)(A) of the act). Thus, under the act, the agency is authorized to specify packaging requirements for a food additive when it finds that use of such packaging is necessary to ensure the safe use of the additive.

Section 201(s) of the act provides an exemption to the ''food additive'' definition for substances that are GRAS under the conditions of their intended use. FDA has issued regulations delineating conditions under which the use of certain substances is GRAS. In the proposal, FDA tentatively concluded that those conditions could include packaging. Thus if a dietary supplement contained an iron salt whose use would be GRAS except for the fact that its packaging would not ensure that its use would be safe, the product would be considered to contain an unsafe food additive and thus to be adulterated.

FDA proposed the packaging requirement for iron-containing drugs based on its authority under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)). This section states that a drug shall be deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice (CGMP) to assure that such drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

Under section 501(a)(2)(B) of the act, manufacturers are responsible for preventing intentional misuse of a drug product. For example, in 1982, in response to a series of capsule tamperings, FDA issued a regulation (§ 211.132), under the authority of this section, that requires tamper-resistant packaging for all over-the-counter (OTC) human drug products except dermatologics, dentifrices, and insulin (47 FR 50442, November 5, 1982). The agency's action assured greater package integrity and product security beyond the point of manufacture.

The recent data available to FDA demonstrate that the current manner of holding iron-containing drug products until their use by the intended consumer fails to ensure that the drug products will be safe because large numbers of children are ingesting such products and suffering serious injuries or death. Existing technology permits additional safeguards, such as child-resistant blister packs, to be used for holding iron-containing drug products. Given the known dangers and the ability to minimize or eliminate such dangers through the use of existing technology, FDA tentatively concluded that CGMP dictates that unit-dose packaging be used.

II. The Dietary Supplement Health and Education Act

On October 25, 1994, President Clinton signed into law the DSHEA (Pub. L. 103–417). The DSHEA contains two provisions that bear on FDA's packaging proposal with respect to dietary supplements. First, section 3(b) of the DSHEA added section 201(s)(6) to the act. This provision excludes minerals, such as iron, that are used in dietary supplements from the definition of a ''food additive.'' Second, section 9 of the DSHEA added section 402(g) to the act. Under this provision, a dietary supplement is adulterated unless it has been prepared, packed, and held under conditions that comply with the CGMP (section 402(g)(1) of the act). Under section 402(g)(2), the Secretary (and, by delegation, FDA) is authorized to prescribe CGMP's for dietary supplements by regulation.

The DSHEA does not bear on any aspect of this rulemaking other than the proposed packaging requirement for dietary supplements. Dietary supplements are deemed to be food and thus are subject to sections 201(n), 403(a), and 701(a) of the act (see section 201(ff) of the act). Thus, the proposed labeling requirement for iron-containing dietary supplements is not affected by

the DSHEA. Moreover, the DSHEA does not bear on how drugs are regulated. Thus, the proposed requirements for iron-containing drugs are also unaffected by the new law. Even with the DSHEA, however, FDA continues to have authority to require that dietary supplements that contain 30 mg or more of iron per dosage unit be unit-dose packed.

III. Discussion

A. Effect of Section 201(s)(6) of the Act

In the proposal, FDA explained the basis for its tentative conclusion that it had authority to impose packaging requirements on iron-containing dietary supplements, FDA stated:

> Should FDA determine that a particular type of packaging is necessary to ensure the safe use of iron substances in dietary supplements, either as GRAS substances or as listed food additives, then any use of iron substances in dietary supplements that does not involve use of that type of packaging would constitute a use of an unapproved food additive and render the dietary supplements adulterated under the act.

See 59 FR 51047.

This argument is deprived of its legal validity by new section 201(s)(6) of the act. The use of iron ingredients in dietary supplements is not subject to section 409 of the act, even if the conditions of use of the iron ingredients are not those that are GRAS. Thus, FDA cannot rely on section 409 of the act for authority to require unit-dose packaging of dietary supplements.

B. Effect of Section 402(g) of the Act

While, on the one hand, the DSHEA deprives the agency of the authority that it relied on in the proposal to require unit-dose packaging, on the other it added a new provision to the act that gives the agency authority to establish such a requirement.

Section 402(g)(2) of the act provides that CGMP's for dietary supplements shall be modeled after the CGMP's for food. The current food CGMP regulations provide that food is to be packaged in a way that ensures that it is safe and sanitary (§§ 110.5(a)(2) and 110.80(b)(13)). As explained in the preamble to the October 6, 1994, proposal, FDA has tentatively concluded that unit-dose packaging is necessary to ensure the safety of dietary supplements that contain 30 mg or more of iron per dosage unit.

As discussed in the proposal, the recent data available to FDA demonstrate that iron-containing products with 30 mg or more iron per dosage unit are associated with a significant number of pediatric illnesses and deaths. As FDA stated with respect to drugs in the proposal, to ensure that these products are safe, CGMP requires that manufacturers respond to this new information, and take advantage of advances in technology, to alter, adapt, or change their manufacturing processes to ensure that all possible measures have been taken to eliminate known dangers from their products.

Existing technology permits safeguards, specifically unit-dose packaging, to be used for iron-containing products, including dietary supplements. Unit-dose packaging limits a child's ability to gain access to enough dosage units to provide a harmful amount of iron. Given the known dangers posed by dietary supplements that contain 30 mg or more iron per dosage unit, and the ability to minimize or eliminate such dangers through the use of unit-dose packaging, FDA tentatively concludes that the CGMP dictates that unit-dose packaging be used for these products.

Thus, FDA tentatively concludes that, to ensure that dietary supplements that contain 30 mg of iron or more per dosage unit are safe, CGMP requires that they be packaged in unit-dose packaging.

The agency will consider conducting a more complete rulemaking on what CGMP requirements for dietary supplements under section 402(g) of the act are. However, considering the hazard presented to young children by iron-containing products, FDA tentatively concludes that it is appropriate to effect this aspect of its CGMP authority in advance of any broader rulemaking.

To reflect the shift in the agency's authority with respect to packaging of dietary supplements, FDA is codifying the proposed CGMP requirements for iron-containing dietary supplements in new part 111, rather than in part 170 (21 CFR part 170). Proposed § 170.55 is being removed in this supplemental proposal and replaced by § 111.1. The agency is also making conforming amendments to part 101 to reflect new part 111 rather than part 170. For the convenience of the reader, FDA is republishing the amendments to parts 101 and 310 in their entirety. Thus, the codified portion of this document will also reflect the changes proposed in the October 6, 1994, proposed rule and thereby supersedes that codified material.

In proposing the unit-dose packaging requirement under new part 111, the agency is removing the provision from the packaging regulation in the original proposal that also would have required the proposed warning labels as a condition of safe use (i.e., as food additives or GRAS ingredients) for iron and iron salts in iron-containing supplements. The authority for this requirement was also derived from section 409 of the act, which permits the agency to consider any necessary labeling requirements in establishing conditions of safe use for a food additive. New section 201(s)(6) of the act also invalidates the legal authority that FDA relied upon for this proposed provision because the use of iron ingredients in dietary supplements is no longer subject to section 409 of the act.

IV. Comments

Because of the change in the law and issuance of this supplemental proposal, FDA will allow an additional 60 days for comment on the entire proposed action. This additional time will provide an opportunity for the submission of all views on the issues in the rulemaking.

Interested persons may, on or before April 17, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. Environmental Impact

The agency previously considered the environmental effects of its action to require unit-dose packaging for iron-containing products, in the proposed rule that was published in the **Federal Register** of October 6, 1994 (59 FR 51030). The changes in legal authority being proposed in this document will not affect the agency's previously proposed requirement for unit-dose packaging for iron-containing products and, therefore, will not affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Analysis of Impacts

FDA previously examined the impact of the proposed rule as published in the **Federal Register** of October 6, 1994 (59 FR 51030), in accordance with Executive Order 12866 and the Regulatory Flexibility Act, and determined that it is not an economically significant rule. The discussion of the legal authority contained in this supplemental proposed rule does not alter the

agency's conclusions. The rule will result in total costs of approximately $53 million and discounted benefits of between $315 million and $653 million over the next 20 years (discounted at 7 percent).

List of Subjects

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

21 CFR Part 111

Current good manufacturing practices, Dietary supplements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical Devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the codified text as proposed in the **Federal Register** of October 6, 1994 (59 FR 51030), is republished in its entirety and is thereby superseded by this document. It is further proposed that Title 21, Chapter I be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.17 is amended by adding a new paragraph (e) to read as follows:

§ 101.17 Food labeling warning and notice statements.

* * * * *

(e) *Dietary supplements containing iron or iron salts.* (1) The labeling of any dietary supplement in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an iron source shall bear the following statement:

(i) If the product is packaged in unit-dose packaging as defined in § 111.1 of this chapter:

WARNING—Keep away from children. Keep in original package until each use. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(ii) If the product contains less than 30 milligrams of iron per dosage unit and is packaged by the manufacturer in other than unit-dose packaging as defined in § 111.1 of this chapter, e.g., a container with a child-resistant closure, its label shall bear the following statement:

WARNING—Close tightly and keep away from children. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(2) The statement required by paragraph (e)(1)(i) of this section shall appear prominently and conspicuously on the immediate container labeling in such a way that the warning is intact until all of the dosage units to which it applies are used. The statement required by paragraph (e)(1)(ii) of this section shall appear prominently and conspicuously on the immediate container labeling. In all cases where the immediate container is not the retail package, the warning statement shall also appear prominently and conspicuously on the principal display panel of the retail package. In addition, the warning statement shall appear on any labeling that contains warnings.

3. Part 111 is added to read as follow:

PART 111—CURRENT GOOD MANUFACTURING PRACTICE FOR DIETARY SUPPLEMENTS

Authority: Secs. 201, 402, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 371).

§ 111.1 Iron and iron salts in dietary supplements.

The use of iron and iron salts as iron sources in dietary supplements offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, is safe and in accordance with current good manufacturing practice only when such supplements are packaged in unit-dose packaging. ''Unit-dose packaging'' means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term ''dosage unit'' means the individual physical unit of the product (e.g., tablets or capsules).

PART 170—FOOD ADDITIVES

3. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: Secs. 201, 401, 402, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 346a, 348, 371).

§ 170.55 [Removed]

4. Section 170.55 *Iron and iron salts in dietary supplements not in conventional food form* (as proposed in at 59 FR 51030, October 6, 1994) is removed.

PART 310—NEW DRUGS

5. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 512–516, 520, 601(a), 701, 704, 705, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; secs. 215, 301, 302(a), 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 242(a), 262, 263b–263n).

6. New § 310.518 is added to subpart E to read as follows:

§ 310.518 Drug products containing iron or iron salts.

Drug products containing elemental iron or iron salts as an active ingredient in solid oral dosage form (e.g., capsules or tablets) shall meet the following requirements:

(a) *Packaging.* If the product contains 30 milligrams or more of iron per dosage unit, it shall be packaged in unit-dose packaging. ''Unit-dose packaging'' means a method of packaging a product into a nonreusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term ''dosage-unit'' means the individual physical unit of the product, e.g., tablets or capsules.

(b) *Labeling.* (1) If the product is packaged by the manufacturer in unit-dose packaging, its label shall bear the following statement:

WARNING—Keep away from children. Keep in original package until each use. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(2) If the product contains less than 30 milligrams of iron and is packaged by the manufacturer in other than unit-dose packaging, e.g., a container with a child-resistant closure, its label shall bear the following statement:

WARNING—Close tightly and keep away from children. Contains iron, which can harm or cause death to a child. If a child accidentally swallows this product, call a doctor or poison control center immediately.

(3) The statement required by paragraph (b)(1) of this section shall appear prominently and conspicuously on the immediate container labeling in

such a way that the warning is intact until all of the dosage units to which it applies are used. The statement required by paragraph (b)(2) of this section shall appear prominently and conspicuously on the immediate container labeling. In all cases where the immediate container is not the retail package, the warning statement shall also appear prominently and conspicuously on the principal display panel of the retail package. In addition, the warning statement shall appear on any labeling that contains warnings.

Dated: February 10, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–3970 Filed 2–15–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Chapter I

[CGD 95–009]

Chemical Transportation Advisory Committee (CTAC) Subcommittee on Hazardous Substances Response Plan Meeting

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

SUMMARY: The Hazardous Substances Response Plan Subcommittee of CTAC will meet to develop response plan criteria for hazardous substances to be considered under proposed requirements for tank vessels and marine transportation related facilities under the Oil Pollution Act of 1990 (OPA 90). The meeting will be open to the public.

DATES: The meeting will be held on March 13, 1995, from 9 a.m. to 4 p.m. Written material should be submitted no later than March 3, 1995.

ADDRESSES: The meeting will be held in Room 2415, U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001. Written material should be submitted to Ms. Margaret K. Doyle, Chemical Carriers' Association, 1700 North Moore Street, Suite 1805, Arlington, VA 22209.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret K. Doyle, Chemical Carriers' Association, 1700 North Moore Street, Suite 1805, Arlington, VA 22209, telephone (703) 528–6900, or Lieutenant Rick Raksnis, Commandant (G–MTH–1), U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593–0001, telephone (202) 267–1217.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2, section 1 *et seq.* OPA 90 requires owners or operators of tank vessels and marine transportation related onshore facilities to prepare and submit response plans for a worst case discharge or release of oil or a hazardous substance. The Coast Guard has begun preliminary work to develop vessel and facility response plan regulations for hazardous substances. This Subcommittee was recently established to evaluate the regulatory approach to assess the appropriateness of the planned requirements for this rulemaking. Attendance is open to the public. With advance notice, and at the Chairman's discretion, members of the public may make oral presentations during the meeting. Persons wishing to make oral presentations should notify Ms. Doyle, listed above under **ADDRESSES,** no later than three days before the meeting. Written material may be submitted at any time for presentation to the Subcommittee. However, to ensure advance distribution to each Subcommittee member, persons submitting written material are asked to provide 30 copies of Ms. Doyle no later than March 3, 1995.

Dated: February 7, 1995.

N.W. Lemley,

Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 95–3834 Filed 2–15–95; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AK6–1–6887b, AK5–1–6437b, AK3–1–5851b; FRL–5147–9]

Approval and Promulgation of State Implementation Plans: Alaska

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve regulations from three submittals received from the Alaska Department of Environmental Conservation (ADEC): submittal dated July 17, 1990 requesting our action to address out-of-date sections found in 40 CFR 52.73–5296 relating to Alaska state implementation plan (SIP) deficiencies, and including the applicable Alaska statutes to support their request; submittal dated October 15, 1991 requesting approval of amendments to regulations dealing with Air Quality Control, 18 AAC 50, for inclusion into Alaska's SIP to assure compliance with Federal ambient air quality standards for airborne particulate matter, and submittal dated March 24, 1994 requesting approval of additional amendments to 18 AAC 50, Air Quality Control, for inclusion into Alaska's SIP to assure compliance with new source review permitting requirements, the 1990 Clean Air Act Amendments (the Act), for sources located in nonattainment areas for either carbon monoxide or particulate matter. In the Final Rules Section of this **Federal Register**, the EPA is approving these SIP revisions as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document.

DATES: Comments on this proposed rule must be received in writing by March 20, 1995.

ADDRESSES: Written comments should be addressed to Montel Livingston, Environmental Protection Specialist (AT–082), Air Programs Section, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

U.S. Environmental Protection Agency, Region 10, Air Programs Section, 1200 6th Avenue, Seattle, WA 98101.

The Alaska Department of Environmental Conservation, 410 Willoughby, Suite 105, Juneau, Alaska 99801–1795.

FOR FURTHER INFORMATION CONTACT: Montel Livingston, Air Programs Branch (AT–082), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553–0180.

SUPPLEMENTARY INFORMATION: See the information provided in the Direct Final action which is located in the Rules Section of this **Federal Register**.