patients with ingestion or digestion problems but with otherwise ''normal'' nutrient requirements? Would the latter interpretation be consistent with the act?

3. What requirements are necessary to ensure the safe and appropriate use of: (a) Products that meet the statutory definition of a medical food? (b) products that have been marketed as medical foods but that do not meet the statutory definition of a medical food?

Examples might include requirements that address product composition, current good manufacturing practice and quality control procedures, labeling requirements, and standards governing claims about the product and for foods that may be used as a sole item of the diet.

4. To ensure the safety and effectiveness of a medical food, should the agency require that the manufacturer notify FDA before marketing the product, and that it submit evidence that establishes that the product will be safe for its intended use and that any claims made for the product are supported by sound science? What information should be included in such a submission?

5. What standard should be used to determine the safety of a medical food?

6. What quantity and quality of scientific evidence should be required to establish that a disease or condition has distinctive nutritional requirements based on recognized scientific principles?

7. What quantity and quality of scientific evidence should be required to support the validity of claims made for medical foods?

8. What information should be included on the label of a medical food or otherwise disclosed to health care professionals and consumers? Should the amount and detail of the information to be disclosed depend on the types of claims made for the medical food or on other characteristics of the product? What methods would be most effective in communicating information on the intended uses, benefits, and other characteristics of a medical food to enable physicians and consumers to make informed decisions regarding its use (e.g., labels, package inserts, detailed summaries of the science upon which a firm is basing the claims made for its product)?

9. Should the agency develop regulations specifying quality control standards and procedures and current good manufacturing practice requirements for medical foods? What types of requirements are necessary (e.g., expiration dating, analysis of nutrient content, microbiological safety measurements, etc.)?

10. How should FDA monitor the safety and effectiveness of medical foods already on the market? What elements are necessary components of an effective postmarket surveillance system for these products? Should a postmarket surveillance system for medical foods include requirements and procedures for the collection and reporting to FDA of safety- and efficacy-related product defects, adverse reaction reports, and complaints by health care professionals and consumers? Should manufacturers be required to collect information describing the outcomes associated with the use of medical food products in designated patient categories that would be available to FDA, health care providers, and consumers?

VIII. Comments

Interested persons may, on or before February 27, 1997, 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.

IX. References

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

1. Talbot, J. M., ''Guidelines for the Scientific Review of Enteral Food Products for Special Medical Purposes,'' prepared for the Food and Drug Administration under FDA Contract No. 223–88–2124 by the Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD, 1990.

2. Fisher, K. D., J. M. Talbot, and C. J. Carr, ''A Review of Foods for Medical Purposes: Specially Formulated Products for Nutritional Management of Medical Conditions,'' prepared for the Food and Drug Administration under Contract No. FDA 223–75–2090 by the Life Sciences Research Office, Federation of American Societies for Experimental Biology, Bethesda, MD, 1977.

3. Hattan, D. G., and D. R. Mackey, ''A Review of Medical Foods: Enterally Administered Formulations Used in the Treatment of Diseases and Disorders,'' *Food Drug Cosmetic Law Journal,* 44:479–502, 1989.

4. Health Hazard Evaluation No. 1470, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC, April 25, 1986.

5. FDA Enforcement Report, August 23, 1989, Rockville, MD.

6. FDA Enforcement Report, May 19, 1993, Rockville, MD.

7. FDA Enforcement Report, July 28, 1993, Rockville, MD.

8. The United States Pharmacopeial Convention, Inc., *USP DI, Drug Information for the Health Care Professional, Volume I,* Rand McNally, Taunton, MS, 1996.

9. Subcommittee on the Tenth Edition of the RDA's, Food and Nutrition Board, Commission on Life Sciences, National Research Council, ''Recommended Dietary Allowances, 10th ed.,'' National Academy Press, Washington, DC, 1989.

10. H. Rept. 101–538, 101st Cong., 2d sess., 19, ''Nutrition Labeling and Education Act of 1990,'' June 13, 1990.

11. Koretz, R. L., *A Critical Look at the Trials,* Symposium #2, Immunonutrition in the ICU, In: Proceedings of the 19th Clinical Congress, American Society for Parenteral and Enteral Nutrition, Miami, FL, pp. 97–103, 1995.

This document is issued under sections 4, 5, and 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); sections 201, 301, 402, 403, 404, 405, 409, 411, 412, 501, 502, 503, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 344, 345, 348, 350, 350a, 351, 352, 353, 355, 371); and 21 U.S.C. 360ee(b)(3) (section 5(b)(3) of the Orphan Drug Amendments of 1988, as amended by Pub. L. 100–290).

Dated: October 31, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–30441 Filed 11–27–96; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR PART 52

[ND4–1–6459b, UT8–1–6460b, CO20–1–6461b, MT14–1–6462b; FRL–5282–2]

Clean Air Act, Section 507, Small Business Stationary Source Technical and Environmental Compliance Assistance Program for the States of North Dakota, Utah, Colorado and Montana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction.

SUMMARY: EPA approved the State Implementation Plan revisions for the States of North Dakota, Utah, Colorado and Montana (January 11, 1994 in 59 FR 1485, January 11, 1994 in 59 FR 1485, January 28, 1994 in 59 FR 4003, March

4, 1994 in 59 FR 10284, respectively) for the purpose of establishing Small Business Stationary Source Technical and Environmental Compliance Assistance Programs. This document proposes to amend those approvals to incorporate by reference the States' Programs, and deletes the following sections from part 52, chapter I, title 40 of the Code of Federal Regulations: § 52.1833 of subpart JJ—North Dakota, § 52.2348 of subpart TT—Utah, § 52.347 of subpart G—Colorado, and § 52.1389 of subpart BB—Montana.

In the Final Rules Section of this Federal Register, the EPA is approving this action as a direct final rule without prior proposal because the Agency views this as a noncontroversial corrective action and anticipates no adverse comments. 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 action.

DATES: Comments must be submitted by December 30, 1996.

ADDRESSES: Comments must be submitted to Meredith Bond, Mail Code 8P2–A, EPA, Region 8, 999 18th Street, suite 500, Denver, Colorado 80202–2405.

FOR FURTHER INFORMATION CONTACT: Meredith Bond, Mail Code 8P2–A, EPA Region 8, 999 18th Street, suite 500, Denver, Colorado 80202–2405, (303) 312–6438.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Small business assistance program.

Authority: 42 U.S.C. 7401–7671q.

Dated: February 13, 1996.

Editorial Note: This document was received at the Office of the Federal Register on November 22, 1996.

Jack W. McGraw,

Acting Regional Administrator.

[FR Doc. 96–30326 Filed 11–27–96; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 131

[FRL–5656–6]

Withdrawal From Federal Regulations of Arsenic Criteria Applicable to Idaho

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comments.

SUMMARY: In 1992, EPA promulgated federal regulations establishing water quality criteria for toxic pollutants for several states, including Idaho (40 CFR 131.36). Idaho has now adopted, and EPA has approved, human health water quality criteria. In this action, EPA is proposing to withdraw the human health criteria for arsenic applicable to Idaho. EPA is providing an opportunity for public comment on withdrawal of the federal criteria because the State's arsenic criteria differ from the federal criteria. In a related action published in the final rule section of this issue of the Federal Register, EPA is amending the federal regulations to withdraw the human health criteria for those pollutants where Idaho has adopted criteria that are identical to the federal criteria.

DATES: EPA will accept public comments on its proposed withdrawal of the human health criteria for arsenic applicable to Idaho until December 30, 1996. Comments postmarked after this date may not be considered.

ADDRESSES: An original plus 2 copies, and if possible an electronic version of comments either in WordPerfect or ASCII format, should be addressed to Lisa Macchio, U.S. EPA Region 10, Office of Water, 1200 Sixth Avenue, Seattle, Washington, 98101.

The administrative record for the consideration of Idaho's human health criteria for arsenic is available for public inspection at EPA Region 10, Office of Water, 1200 Sixth Avenue, Seattle, Washington, 98101, between 8:00 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Fred Leutner at EPA Headquarters, Office of Water (4305), 401 M Street, SW, Washington, D.C., 20460, (telephone: 202–260–1542) or Lisa Macchio in EPA's Region 10 at 260–553–1834.

SUPPLEMENTARY INFORMATION:

Potentially Affected Entities

Citizens concerned with water quality in Idaho, and with pollution from arsenic in particular, may be interested in this proposed rulemaking. Since criteria are used in determining NPDES permit limits, entities discharging arsenic to waters of the United States in Idaho could be affected by this proposed rulemaking. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Industries discharging arsenic to surface waters in Idaho.
Municipalities	Publicly-owned treatment works discharging arsenic to surface waters in Idaho.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in § 131.36 of title 40 of the Code of Federal Regulations. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Background

In 1992, EPA promulgated a final rule (known as the National Toxics Rule) to establish numeric water quality criteria for 12 States and 2 Territories (hereafter ''States'') that had failed to comply fully with section 303(c)(2)(B) of the Clean Water Act. (57 FR 60848). The criteria, codified at 40 CFR l3l.36, became the applicable water quality standards in those 14 jurisdictions for all purposes and programs under the Clean Water Act effective February 5, 1993.

When a State adopts criteria that meet the requirements of the Clean Water Act, EPA withdraws its criteria. If the State's criteria are no less stringent than the federal regulations, EPA will withdraw its criteria without notice and comment rulemaking since additional comment on the criteria is unnecessary. If a State's criteria are less stringent than the federal regulations, EPA will withdraw its criteria only after notice and opportunity for public comment on that decision. (see 57 FR 60860).

On August 24, 1994, Idaho adopted revisions to its surface water quality standards (Title 1, Chapter 2, section 250 of the Idaho Administrative Code), regarding human health criteria for toxic pollutants. For most pollutants, Idaho adopted by reference EPA's human health criteria. In a separate final action published in this issue of the Federal Register, EPA is withdrawing without public comment those human health criteria applicable to Idaho for which the State has adopted identical criteria.

Idaho adopted human health criteria for arsenic that differ from the federal