

§95.8003 VOR FEDERAL AIRWAYS CHANGEOVER POINTS

AIRWAY SEGMENT		CHANGEOVER POINTS	
FROM	TO	DISTANCE	FROM
V-23			
IS AMENDED TO DELETE			
PAINE, WA VOR/DME	BELLINGHAM, WA VORTAC	24	PAINE
V-229			
IS AMENDED BY ADDING			
BRIDGEPORT, CT VOR	HARTFORD, CT VORTAC	19	BRIDGEPORT
V-440			
IS AMENDED TO READ IN PART			
MIDDLETON ISLAND, AK VOR/DME	ANCHORAGE, AK VOR/DME	95	MIDDLETON ISLAND

TENNESSEE VALLEY AUTHORITY**18 CFR Part 1301****Revisions to Government in the Sunshine Act Regulations****AGENCY:** Tennessee Valley Authority (TVA).**ACTION:** Final rule.

SUMMARY: This rule redesignates the positions responsible for handling and determining initial requests and administrative appeals under the Government in the Sunshine Act to reflect TVA organizational changes. This rule was not published in proposed form since it relates to agency organization, procedure, and practice. Since this rule is nonsubstantive, it is being made effective immediately.

EFFECTIVE DATE: October 28, 1991.**FOR FURTHER INFORMATION CONTACT:** John Doty (615) 632-3570.**List of Subjects in 18 CFR Part 1301**

Administrative practice and procedure, Freedom of Information, Privacy, and Sunshine Act.

For the reasons set forth in the preamble, title 18, chapter XIII, part 1301, of the Code of Federal Regulations is amended as follows:

PART 1301—PROCEDURES

1. The authority citation for part 1301 continues to read as follows:

Authority: 48 Stat. 58, as amended; 16 U.S.C. 831-831dd, unless otherwise noted.

2. Section 1301.48 is amended by revising paragraph (a), the second sentence of paragraph (b), paragraph (c), and paragraph (d), as follows:

§ 1301.48 Public availability of transcripts and other documents.

(a) Public announcements of meetings pursuant to § 1301.44, written copies of votes to change the subject matter of meetings made pursuant to § 1301.44(c), written copies of votes to close meetings and explanations of such closings made pursuant to § 1301.45(c) and certifications of the General Counsel made pursuant to § 1301.45(d) shall be available for public inspection during regular business hours in the TVA Corporate Library, room WT 2F, 400 West Summit Hill Drive, Knoxville, Tennessee 37902-1499.

(b) * * * Each request for such material shall be made to the Manager, Media Relations, Tennessee Valley Authority, Knoxville, Tennessee 37902-1499; state that it is a request for records pursuant to the Government in the Sunshine Act and this subpart; and

reasonably describe the discussion or item of testimony, and the date of the meeting, with sufficient specificity to permit TVA to identify the item requested.

(c) In the event the person making a request under paragraph (b) of this section has reason to believe that all transcripts, electronic recordings, or minutes or portions thereof requested by that person and required to be made available under paragraph (b) of this section were not made available, the person shall make a written request to the Manager, Media Relations for such additional transcripts, electronic recordings, or minutes or portions thereof as that person believes should have been made available under paragraph (b) of this section and shall set forth in the request the reasons why such additional material is required to be made available with sufficient particularity for the Manager, Media Relations to determine the validity of such request. Promptly after a request pursuant to this paragraph is received, the Manager, Media Relations or his/her designee shall make a determination as to whether to comply with the request, and shall immediately give written notice of the determination to the person making the request. If the determination is to deny the request, the notice to the person making the request shall include a statement of the reasons for the denial, a notice of the right of the person making the request to appeal the denial to TVA's Senior Vice President, Communications and Employee Development, and the time limits thereof.

(d) If the determination pursuant to paragraph (c) of this section is to deny the request, the person making the request may appeal such denial to TVA's Senior Vice President, Communications and Employee Development. Such an appeal must be taken within 30 days after the person's receipt of the determination by the Manager, Media Relations and is taken by delivering a written notice of appeal to the Senior Vice President, Communications and Employee Development, Tennessee Valley Authority, Knoxville, Tennessee 37902-1499. Such notice shall include a statement that it is an appeal, from a denial of a request under § 1301.48(c) and the Government in the Sunshine Act and shall indicate the date on which the denial was issued and the date on which the denial was received by the person making the request. Promptly after such an appeal is received, TVA's Senior Vice President, Communications and Employee Development or the Senior Vice President's designee shall make a

final determination on the appeal. In making such a determination, TVA will consider whether or not to waive the provisions of any exemption contained in § 1301.46. TVA shall immediately give written notice of the final determination to the person making the request. If the final determination on the appeal is to deny the request, the notice to the person making the request shall include a statement of the reasons for the denial and a notice of the person's right to judicial review of the denial.

* * *

Mary Cartwright,

Senior Vice President, Communications and Employee Development.

[FR Doc. 91-25632 Filed 10-25-91; 8:45 am]

BILLING CODE 8120-08-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Social Security Administration****20 CFR Part 416**

Supplemental Security Income for the Aged, Blind, and Disabled; Suspension and Termination of Supplemental Security Income Benefit Payments—Increase in Benefit Rate for Individuals in Medical Care Facilities; Technical Corrections

AGENCY: Social Security Administration, HHS.**ACTION:** Final rule.

SUMMARY: We are amending the supplemental security income (SSI) regulations to make a few technical corrections. As a result of a general revision of the SSI eligibility regulations (subpart B), published in the *Federal Register* on January 22, 1982, 47 FR 3099, a number of cross-reference in the regulations became incorrect. All but two of those cross-references have since been corrected. This final rule corrects those two remaining cross-references contained in subpart M at § 416.1321. Also, as a result of errors made in amendatory language published in the *Federal Register* on May 4, 1989, 54 FR 19162, language relating to the basic pass along rules in the SSI program was inadvertently deleted from the Code of Federal Regulations (CFR). This final rule officially returns that language to the CFR. These final rules make no changes in policy.

EFFECTIVE DATE: October 28, 1991.

FOR FURTHER INFORMATION CONTACT: Harry J. Short, Legal Assistant, Office of Regulations, Social Security

Administration, 6401 Security Blvd.,
Baltimore, MD 21235, (301) 965-1753.

SUPPLEMENTARY INFORMATION: In these final regulations, we are making technical changes to correct cross-references and to replace erroneously deleted regulatory text. The rules relating to general eligibility for SSI benefits in subpart B of part 416 were revised and reorganized to make them clearer and easier to understand. These revisions were published as final rules on January 22, 1982, 47 FR 3099. As a result of this general reorganization, a number of cross-references to sections within subpart B appearing in other subparts of the SSI regulations became incorrect. All but two of those references have since been corrected. These final regulations correct those two remaining cross-references in subpart M at § 416.1321.

In addition, these final regulations correct the inadvertent removal of text from subpart T. The interim final rules reflecting sections 9113, 9114, and 9119 of Public Law 100-203, the Omnibus Budget Reconciliation Act of 1987, published on May 4, 1989, at 54 FR 19162, contained technically incorrect amendatory language for a section of the rules. The error in the amendatory language resulted in the inadvertent removal from the CFR of text relating to the basic pass along rules described in 20 CFR 416.2096. The amendments published on May 4, 1989, revised the then existing paragraph (a), the introductory text of (b), and (c), and added a new paragraph (d) to reflect the provisions of section 9119(b) of Public Law 100-203. The correct changes were made to these paragraphs and paragraph (d) was added to the regulations. However, the erroneous amendatory language resulted in the inadvertent removal of the text contained in paragraphs (a)(1) (i), (ii), and (iii) and (a)(2). These final regulations return those paragraphs to the regulations.

Justification for Final Rules

The Department generally follows the notice of proposed rulemaking and public comment procedures specified in the Administrative Procedure Act (APA); 5 U.S.C. 553, in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that,

under 5 U.S.C. 553(b)(3)(B), good cause exists for waiver of notice of proposed rulemaking and public comment procedures with respect to these regulations. Opportunity for public comment is unnecessary since these regulations merely correct two erroneous cross-references and return to the regulations material that was inadvertently removed. These changes are technical and do not involve the setting of policy. Therefore, the use of notice and comment rulemaking is unnecessary and these regulations are being issued as final rules.

Regulatory Procedures

Executive Order 12291

The Secretary has determined that this is not a major rule under Executive Order 12291 because these regulations make no substantive changes and merely correct erroneous cross-references and return to the regulations inadvertently removed material. They therefore do not meet any of the threshold criteria for a major rule and a regulatory impact analysis is not required.

Paperwork Reduction Act

These regulations impose no additional reporting and recordkeeping requirements necessitating clearance by the Office of Management and Budget.

Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals and States. Therefore, a regulatory flexibility analysis as provided in Public Law 96-354, the Regulatory Flexibility Act, is not required.

(Catalog of Federal Domestic Assistance Program No. 93.807, Supplemental Security Income Program)

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income.

Dated: August 5, 1991.

Gwendolyn S. King,

Commissioner of Social Security.

Approved: September 12, 1991.

Louis W. Sullivan,

Secretary of Health and Human Services.

Part 416 of chapter III of title 20 of the Code of Federal Regulations is amended to read as follows:

1. The authority citation for subpart M is revised to read as follows:

Authority: Secs. 1102, 1611-1615, 1619 and 1631 of the Social Security Act; 42 U.S.C. 1302, 1382-1382d, 1382h, 1383.

2. Section 416.1321 is amended by revising the references in paragraph (c)(1) from § 416.230(c) and § 416.230(d) to § 416.210(c) and § 416.210(e)(2) respectively.

3. The authority citation for subpart T is revised to read as follows:

Authority: Secs. 1102, 1616, 1618, and 1631 of the Social Security Act; 42 U.S.C. 1302, 1382e, 1382g, and 1383; Sec. 212 of Pub. L. 93-66, 87 Stat. 155; sec. 8 of Pub. L. 93-233, 87 Stat. 956; secs. 1 and 2 of Pub. L. 93-335, 88 Stat. 291.

4. Section 416.2096 is amended by adding paragraphs (a)(1) (i), (ii), (iii) and (2) to read as follows:

§ 416.2096 Basic passalong rules.

(a) *State agreements to maintain supplementary payment levels.* (1) * * *

(i) The State must agree to continue to make the supplementary payments;

(ii) For months from July 1977 through March 1983, the State must agree to maintain the supplementary payments at levels at least equal to the December 1976 levels (or, if a State first makes supplementary payments after December 1976, the levels for the first month the State makes supplementary payments). For months in the period July 1, 1982 through March 31, 1983, a State may elect to maintain the levels described in paragraph (b)(2) of this section; and

(iii) For months after March 1983, the State must agree to maintain supplementary payments at least sufficient to maintain the combined supplementary/SSI payment levels in effect in March 1983, increased by any subsequent SSI benefit increases, except as provided in § 416.2097(b) and § 416.2097(c).

(2) We will find that the State has met the requirements of paragraph (a)(1) of this section if the State has the appropriate agreement in effect and complies with the conditions in either paragraph (b) or (c) of this section. We will consider a State to have made supplementary payments on or after June 30, 1977, unless the State furnishes us satisfactory evidence to the contrary.

[FR Doc. 91-25853 Filed 10-25-91; 8:45 am]

BILLING CODE 4190-29-M

Food and Drug Administration**21 CFR Part 5****Delegations of Authority and Organization; Center for Drug Evaluation and Research**

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to approval of new drug applications and their supplements. The amendment delegates authority to the director, Division of Oncology and Pulmonary Drug Products, Center for Drug Evaluation and Research (CDER), to approve new drug applications (NDA's) and their supplements for oncologic drug products.

EFFECTIVE DATE: October 28, 1991.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: FDA is amending § 5.80 *Approval of new drug applications and their supplements* (21 CFR 5.80) to redelegate authority to the Director, Division of Oncology and Pulmonary Drug Products, CDER, to approve NDA's and their supplements for oncologic drug products. This amendment adds new paragraph (a)(1)(iv) to § 5.80.

Further redelegation of the authority delegated is not authorized.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organizations and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

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

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; secs. 2-12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451-1461); 21 U.S.C. 41-50; 61-63, 141-149, 467f, 679(b), 801-886, 1031-1309; secs. 201-903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321-394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 354-360F, 361, 362, 1701-1706, 2101-2672 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b-263n

264, 265, 300u-300u-5, 300aa-1-300ff); 42 U.S.C. 1395h, 3246b, 4332, 4831(a), 10007-10008; E.O. 11490, 11921, and 12591.

2. Section 5.80 is amended by adding new paragraph (a)(1)(iv) to read as follows:

§ 5.80 Approval of new drug applications and their supplements.

(a) (1) * * *

(iv) The director, Division of Oncology and Pulmonary Drug Products, CDER, for oncologic drug products. This authority may not be redelegated.

* * *

Dated: October 21, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-25896 Filed 10-25-91; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 89F-0215]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of α -butyl- Ω -hydroxypoly (oxypropylene), minimum molecular weight 1000, as a surface lubricant in the manufacture of metallic articles that contact food. This action is in response to a petition filed by Union Carbide Corp.

DATES: Effective October 28, 1991; written objections and requests for a hearing by November 27, 1991.

ADDRESSES: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street, SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of August 7, 1989 (54 FR 32395), FDA announced that a food additive petition (FAP 9B4151) had been filed by Union Carbide Corp., Old Saw Mill River Rd., Tarrytown, NY 10591, proposing that § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) be amended to provide for the safe use of α -butyl- Ω -hydroxypoly (oxypropylene), minimum molecular

weight 1000, as a surface lubricant in the manufacture of metallic articles that contact food.

FDA, in its evaluation of the safety of this additive, reviewed the safety of both the additive and the starting materials used to manufacture the additive. This additive has not been found to cause cancer. However, propylene oxide, which could be present as an impurity in the additive, has been shown to cause cancer in test animals. Residual amounts of reactants and byproducts, such as propylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the provision: "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." (H. Rept. 2284, 85th Cong., 2d Sess. 4 (1958).) This definition of safety has been incorporated into FDA's food additive regulations (§ 170.3(i)). The anticancer or Delaney clause of the Food Additives Amendment (section 409(c)(3)(A) of the act) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA to establish the safety of additives that contain carcinogenic impurities but that have not themselves been shown to cause cancer.

In the preamble to the final rule permanently listing D&C Green No. 6, published in the *Federal Register* of April 2, 1982 (47 FR 14138), FDA explained the basis for approving the use of a color additive that had not been shown to cause cancer, even though the additive contains a carcinogenic