

information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4141, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Peter Fox, Office of Regulatory Affairs, Office of Strategic Planning and Operational Policy, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rm. 4146, Rockville, MD 20857, 240-402-1857, Peter.Fox@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry and FDA staff entitled “Initiation of Voluntary Recalls Under 21 CFR part 7, subpart C.” The guidance for industry and FDA staff provides guidance on timely initiation of voluntary recalls of FDA-regulated products. The guidance discusses what preparations firms in a distribution chain, including manufacturers and distributors, should consider making to establish recall initiation procedures; to ensure timely identification of, and response to, product problems that might lead to a recall; and to promptly issue recall communications and press releases or other public notices. It also discusses preparations that firms in a distribution chain should consider

making to ensure timely responses to recall communications. In addition, the guidance discusses how FDA assists firms with carrying out their recall responsibilities to protect the public health from distributed products in violation of the FD&C Act and other laws administered by FDA.

This guidance finalizes the draft guidance of the same title issued on April 24, 2019 (84 FR 17112). FDA considered comments received on the draft guidance as the guidance was finalized. In addition to editorial changes made to improve clarity, changes from the draft to the final guidance include the addition of the terms *correction* and *market withdrawal* to the terminology section, the addition of language encouraging the use of electronic communications for conveying voluntary recall communications about FDA-regulated products, and the deletion of section IV (“References”).

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 7.46, 7.49, and 7.59 have been approved under OMB control number 0910-0249; section 417 of the FD&C Act (21 U.S.C. 350f) has been approved under OMB control number 0910-0643; section 761 of the FD&C Act (21 U.S.C. 379aa-1) has been approved under OMB control number 0910-0291; 21 CFR 107.240 has been approved under OMB control number 0910-0188; 21 CFR part 117 has been approved under OMB control number 0910-0751; and 21 CFR part 507 has been approved under OMB control number 0910-0751.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance->

[documents](https://www.regulations.gov) or <https://www.regulations.gov>.

Dated: February 28, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-04704 Filed 3-3-22; 8:45 am]

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DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 0

[Docket No. OAG 175; AG Order No. 5536-2022]

Revisions to Approval of Civil Consent Decrees With State and Local Governmental Entities

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule revises the regulations of the Department of Justice (“Department”) to restore the traditional process regarding the approval procedures to be used when a civil action against a State or local governmental entity is to be resolved by consent decree.

DATES: This rule is effective March 4, 2022.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530, telephone (202) 514-8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Discussion

A. Overview

This rule implements the April 16, 2021 Memorandum of Attorney General Merrick B. Garland titled “Civil Settlement Agreements and Consent Decrees with State and Local Governmental Entities” (the “April 2021 Memorandum”), available at <https://www.justice.gov/ag/page/file/1387481/download>. Specifically, this rule withdraws the changes made to the Department’s regulations by the rule “Approval of Civil Consent Decrees With State and Local Governmental Entities” published on December 28, 2020 (85 FR 84229).

The April 2021 Memorandum also specifically rescinded the Memorandum issued by former Attorney General Jefferson B. Sessions III, entitled “Principles and Procedures for Civil Consent Decrees and Settlement

Agreements with State and Local Governmental Entities” (November 7, 2018) (the “November 2018 Memorandum”).

In addition, for consistency with the April 2021 Memorandum, the Department will revise the changes made to the *Justice Manual* in 2020 in response to the November 2018 Memorandum.

B. Background—Previous Administration

The November 2018 Memorandum set forth principles to guide the development of consent decrees with State or local governmental entities, including limitations on the circumstances in which a consent decree with a State or local governmental entity may be appropriate, the substantive requirements for such consent decrees, internal notification requirements regarding the initiation of negotiations for consent decrees, and a requirement of review and approval of senior leadership of the Department before a consent decree is agreed to by the United States or submitted to the court for entry. Subsequently, conforming changes were made to the *Justice Manual* and to the Department’s regulations at 28 CFR 0.160. The revisions to § 0.160, codified at paragraphs (d)(6) and (e), were limited to amending the Department’s settlement authority regulations to require approval of the specified consent decrees by the Deputy Attorney General or the Associate Attorney General. See 85 FR 84229 (Dec. 28, 2020).

C. Current Administration

Upon further consideration, the Attorney General has determined to restore longstanding regulations, protocols, and practices by authorizing the Assistant Attorneys General of the litigating components generally to handle such approvals because they are the Department officials most familiar with and best able to assess each particular case.

Accordingly, this rule restores the regulatory provisions at 28 CFR 0.160 as they existed prior to the revisions adopted on December 28, 2020.¹

The April 2021 Memorandum also noted that, pursuant to longstanding Department settlement authority regulations predating the changes discussed above, and still in effect, a

settlement agreement or consent decree with a State or local governmental entity must be referred to the Deputy Attorney General or the Associate Attorney General for approval if the component head “is of the opinion that[,] because of a question of law or policy presented . . . or for any other reason, the proposed settlement should receive the personal attention of the Deputy Attorney General or the Associate Attorney General, as appropriate.” 28 CFR 0.160(d)(2).

II. Regulatory Certifications

A. Administrative Procedure Act

This rule relates to a matter of agency management or personnel and is a rule of agency organization, procedure, or practice. As such, this rule is exempt from the usual requirements of prior notice and comment and a 30-day delay in effective date. See 5 U.S.C. 553(a)(2), (b)(A), (d).

B. Regulatory Flexibility Act

A Regulatory Flexibility Analysis was not required for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter. See 5 U.S.C. 601(2), 604(a).

C. Executive Orders 12866 and 13563—Regulatory Review

This rule has been drafted and reviewed in accordance with Executive Order 12866, “Regulatory Planning and Review,” section 1(b), The Principles of Regulation, and Executive Order 13563, “Improving Regulation and Regulatory Review,” section 1, General Principles of Regulation.

This final rule is “limited to agency organization, management, or personnel matters” and thus is not a “rule” for purposes of review by the Office of Management and Budget. Executive Order 12866, sec. 3(d)(3).

D. Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988, “Civil Justice Reform.”

E. Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule only pertains to the internal delegation of the Attorney General’s litigation authority, regarding the authority of the Department’s litigation components for

approval of consent decrees entered into by the Department. Therefore, in accordance with Executive Order 13132, “Federalism,” the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

G. Congressional Review Act

This rule is not a major rule as defined by section 804 of the Congressional Review Act (CRA), 5 U.S.C. 804. This action pertains to agency management or personnel, and agency organization, procedure, or practice, and does not substantially affect the rights or obligations of non-agency parties. Accordingly, it is not a “rule” as that term is used in the CRA, 5 U.S.C. 804(3)(B), (C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

H. Paperwork Reduction Act of 1995

This final rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, Organization and functions (Government agencies), Privacy, Reporting and recordkeeping requirements, Whistleblowing.

Accordingly, by virtue of the authority vested in me as Attorney General, including 5 U.S.C. 301 and 28 U.S.C. 509, 510, part 0 of title 28 of the Code of Federal Regulations is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

■ 2. In § 0.160:

■ a. Revise paragraphs (d)(4) and (5); and

¹In addition to other changes made by the December 28, 2020, rule, that rule also corrected an existing drafting error by removing “or” at the end of 28 CFR 0.160(d)(1). That was a non-substantive change, and accordingly this final rule does not undo that technical correction.

- b. Remove paragraphs (d)(6) and (e).
The revisions read as follows:

§ 0.160 Offers that may be accepted by Assistant Attorneys General.

* * * * *

(d) * * *

(4) When the proposed settlement commits a department or agency to expend funds that Congress has not appropriated and that have not been budgeted for the action in question, or commits a department or agency to seek particular appropriation or budget authorization; or

(5) When the proposed settlement otherwise limits the discretion of a department or agency to make policy or managerial decisions committed to the department or agency by Congress or by the Constitution.

Dated: February 18, 2022.

Merrick B. Garland,

Attorney General.

[FR Doc. 2022-04509 Filed 3-3-22; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2021-0482; FRL-9596-02-R3]

Air Plan Approval; Pennsylvania; Revision of the Maximum Allowable Sulfur Content Limit for Number 2 and Lighter Commercial Fuel Oil

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the Commonwealth of Pennsylvania. The revision pertains to the reduction of the maximum allowable sulfur content limit for Number 2 (No. 2) and lighter commercial fuel oil, generally sold and used for residential and commercial furnaces and oil heat burners for home or space heating, water heating or both, from the current limit of 500 parts per million (ppm) to 15 ppm. EPA is approving this revision to the Pennsylvania SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on April 4, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA-R03-OAR-2021-0482. All documents in the docket are listed on

the <https://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov>, or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT:

Mallory Moser, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814-215-814-2030. Ms. Moser can also be reached via electronic mail at moser.mallory@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 15, 2021 (86 FR 71213), EPA published a notice of proposed rulemaking (NPRM) that proposed approval of a SIP revision that incorporates the Commonwealth's updated low-sulfur fuel oil provisions into the Pennsylvania SIP. The SIP revision was submitted by Pennsylvania on September 4, 2020, requesting that EPA incorporate the Pennsylvania Department of Environmental Protection's (PADEP's) revisions to 25 Pennsylvania Code (Pa. Code) Chapters 123 Section 22 into the Pennsylvania SIP. In response to the NPRM, EPA received one comment supporting the proposed action which can be found in the docket. EPA received no adverse comments.

II. Summary of SIP Revision and EPA Analysis

The SIP revision incorporates amendments to 25 Pa. Code Chapter 123 section 22 which set the maximum allowable sulfur content limit for various fuel types into the Pennsylvania SIP. The amendments to 25 Pa. Code Chapter 123.22, reduce the SIP approved maximum allowable sulfur content limit for No. 2 and lighter commercial fuel oil, generally sold for and used in residential and commercial furnaces and oil heat burners for home or space heating, water heating, or both, from a limit of 500 ppm of sulfur to 15 ppm. The amendments to 25 Pa. Code 123.22, became effective on September 1, 2020.

The low-sulfur fuel oil provisions will aid in reducing regional haze and

visibility impairment in Pennsylvania. Additionally, decreased emissions of sulfur dioxide (SO₂) will contribute to the attainment, maintenance, or both, of the SO₂ and fine particulate matter (PM_{2.5}) National Ambient Air Quality Standards (NAAQS) in Pennsylvania and surrounding areas. Other specific requirements of the SIP revision and the rationale for EPA's proposed action are explained in the NPRM and will not be restated here. Relevant support documents for this action are available online at <https://www.regulations.gov>, Docket number EPA-R03-OAR-2021-0482.

III. EPA's Response to Comments Received

EPA received one comment, from the State of New Jersey, supporting our proposed action in the December 15, 2021, NPRM. The comment received is in the docket for this rulemaking action. We received no adverse comments.

IV. Final Action

EPA is approving, as a SIP revision, the Commonwealth of Pennsylvania's September 4, 2020, submittal revising the maximum allowable sulfur content limit for No. 2 and lighter commercial fuel oil.

V. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of Pennsylvania's maximum allowable sulfur content limit for No. 2 and lighter commercial fuel oil regulation described in 25 Pa. Code Chapter 123. EPA has made, and will continue to make, these materials generally available through <https://www.regulations.gov> and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.¹

¹ 62 FR 27968 (May 22, 1997).