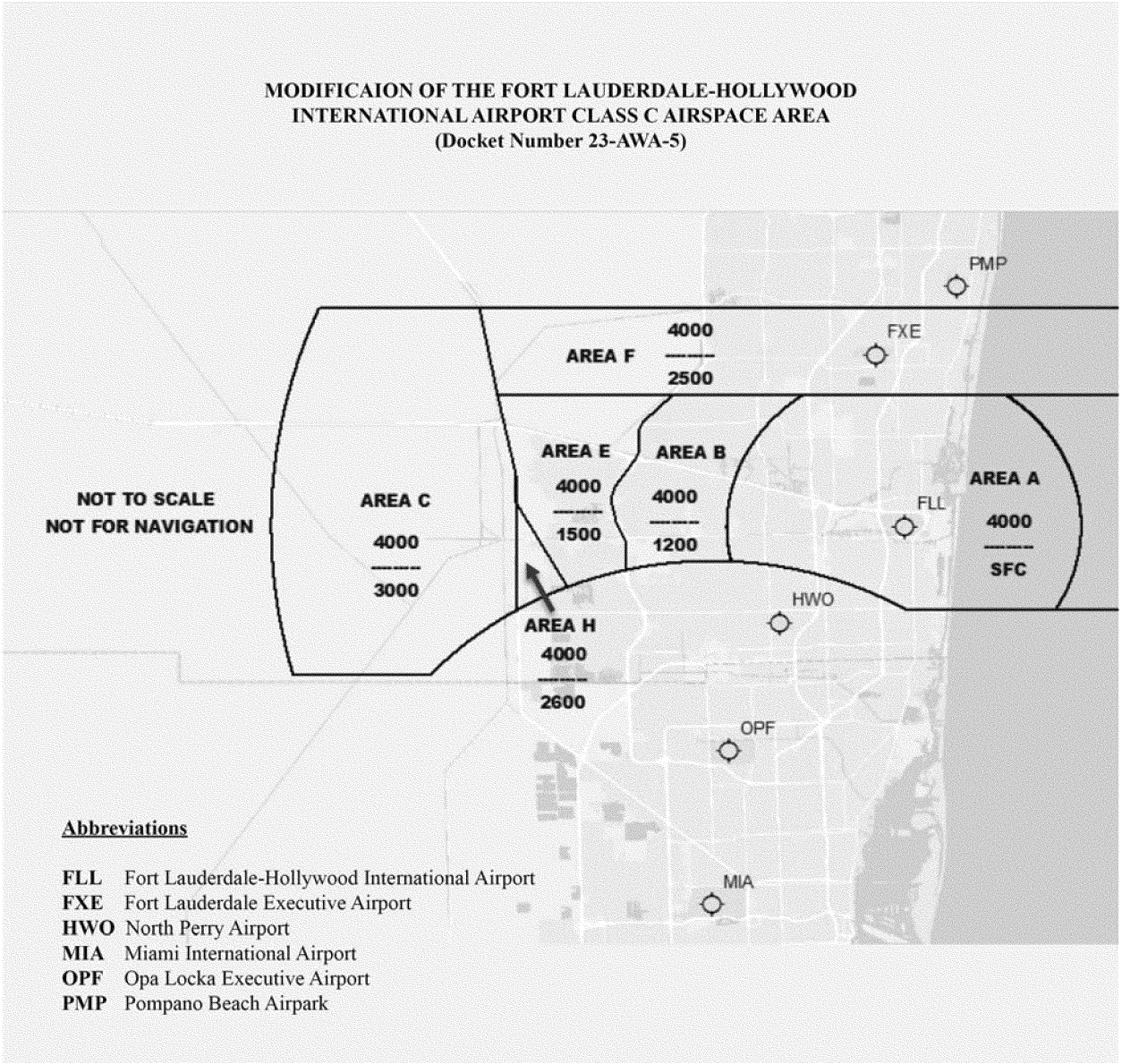

Issued in Washington, DC, on September 16, 2024.

Frank Lias,

Manager, Rules and Regulations Group.

[FR Doc. 2024–21465 Filed 9–19–24; 8:45 am]

BILLING CODE 4910–13–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 16

[Docket No. FDA–2024–N–3654]

RIN 0910–AI97

Regulatory Hearing Before the Food and Drug Administration; General Provisions; Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a direct final rule amending the Scope section of our regulation that provides for a regulatory hearing before the Agency in order to clarify when such hearings are available. We are revising the list of statutory provisions enumerated in the Scope section of the regulation by adding one statutory reference and removing a different statutory reference. The Agency is issuing these amendments directly as a final rule because we believe they are noncontroversial and FDA anticipates no significant adverse comments.

DATES: This rule is effective February 3, 2025. Either electronic or written comments on the direct final rule or its companion proposed rule must be submitted by December 4, 2024. If FDA receives no significant adverse comments within the specified comment period, the Agency intends to publish a document confirming the effective date of the final rule in the

Federal Register within 30 days after the comment period on this direct final rule ends. If timely significant adverse comments are received, the Agency will publish a document in the **Federal Register** withdrawing this direct final rule within 30 days after the comment period on this direct final rule ends.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 4, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3654 for ''Regulatory Hearing Before the Food and Drug Administration; General Provisions; Amendments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this 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.

FOR FURTHER INFORMATION CONTACT: Robert Schwartz, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Direct Final Rule

FDA is issuing this direct final rule to amend § 16.1 (21 CFR 16.1) to revise the list of statutory provisions enumerated in the Scope section of the regulation and thus clarify the circumstances under which the Agency intends to use the procedures in part 16 (21 CFR part 16) for regulatory hearings. This rule revises the list in § 16.1 by removing one statutory reference and adding a different statutory reference under the same section of the same statute. Because we believe the rule contains noncontroversial changes and we do not expect significant adverse comment on the rulemaking, we are using direct final rulemaking procedures, as described in this document.

B. Summary of the Major Provisions of the Direct Final Rule

The direct final rule revises § 16.1, Scope, in order to clarify the circumstances under which the Agency intends to use the procedures in part 16 for regulatory hearings. The rule amends the list of statutory provisions enumerated in § 16.1. Specifically, the rule removes the reference to section 906(e)(1)(B) of the Federal Food, Drug, & Cosmetic Act (FD&C Act) (21 U.S.C. 387f(e)(1)(B)) (the statutory provision that requires FDA to afford an opportunity for an oral hearing prior to promulgating a tobacco product manufacturing practice (TPMP) requirements regulation) and adds a reference to section 906(e)(2)(E) of the FD&C Act (the statutory provision that provides a petitioner an opportunity for an informal hearing on an order issued on the petitioner's request for temporary or permanent exemption or variance from TPMP requirements).

C. Legal Authority

FDA is issuing this rule under provisions of the FD&C Act related to

regulations and hearings (21 U.S.C. 371), and general provisions respecting control of tobacco products, (21 U.S.C. 387f(e)).

D. Costs and Benefits

This direct final rule clarifies the circumstances under which the Agency intends to use the procedures in part 16 for a regulatory hearing. Potentially affected entities would include manufacturers of finished and bulk tobacco products who choose to request an exemption or variance from TPMP requirements and are afforded an opportunity for a hearing on orders regarding such requests. Because this rule merely clarifies which of its existing procedures FDA intends to use when conducting certain types of hearings under the FD&C Act, costs and benefits of this rule are expected to be minimal.

II. Direct Final Rulemaking Procedures

In the document titled ''Guidance for FDA and Industry: Direct Final Rule Procedures,'' announced and provided in the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described its procedures on when and how we will employ direct final rulemaking. The guidance may be accessed at *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.* We have determined that this rule is appropriate for direct final rulemaking because we believe that it includes only noncontroversial amendments and we anticipate no significant adverse comments. Consistent with our procedures on direct final rulemaking, FDA is also publishing elsewhere in this issue of the **Federal Register** a companion proposed rule to clarify when the Agency intends to use the procedures under the regulation for regulatory hearings before the Food and Drug Administration. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event that the direct final rule is withdrawn because of any significant adverse comments. The comment period for the direct final rule runs concurrently with the comment period for the companion proposed rule. Any comments received in response to the companion proposed rule will be considered as comments regarding the direct final rule.

We are providing a comment period on the direct final rule of 75 days after the date of publication in the **Federal Register**. If we receive any significant adverse comments, we intend to withdraw this direct final rule before its effective date by publication of a notice in the **Federal Register**. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. A comment recommending a regulation change in addition to those in this direct final rule would not be considered a significant adverse comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of this rule and that part can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not subject to the significant adverse comment.

If any significant adverse comments are received during the comment period, FDA will publish, before the effective date of this direct final rule, a notice of significant adverse comment and withdraw the direct final rule. If we withdraw the direct final rule, any comments received will be applied to the proposed rule and will be considered in developing a final rule using the usual notice-and-comment procedures.

If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a document confirming the effective date within 30 days after the comment period ends.

III. Background

Part 16 provides procedures for regulatory hearings held before FDA. The procedures in part 16 apply, among other circumstances, when a statute or regulation provides a person an opportunity for a hearing on a regulatory action. In 2012, FDA amended part 16 [1] to add several statutory and regulatory provisions throughout 21 CFR parts 1, 7, and 16, to include reference to tobacco products, where appropriate, so that tobacco products would be subject to the same general requirements that apply to other FDA-regulated products. The 2012 amendments revised § 16.1, which governs the scope of part 16, to include references to certain sections of the FD&C Act that provide an opportunity for a hearing. Among other changes, the 2012 amendments added a reference to section 906(e)(1)(B) of the FD&C Act to § 16.1. This rule further amends § 16.1, as described below.

The Agency is amending the list of statutory provisions enumerated in § 16.1(b)(1) by removing the reference to section 906(e)(1)(B) and adding a reference to section 906(e)(2)(E) of the FD&C Act. The list of statutory provisions enumerated in § 16.1(b)(1) included section 906(e)(1)(B) of the FD&C Act, which requires FDA to afford the public an opportunity for an oral hearing before issuing any TPMP requirements regulation. The purpose of an oral hearing under section 906(e)(1)(B) of the FD&C Act is to allow the public to provide viewpoints, opinions, and information on proposed TPMP rules. The procedures under part 16 are not in alignment with the purpose and goals of the oral hearing required under section 906(e)(1)(B) of the FD&C Act. For example, part 16 includes procedures to resolve a ''genuine and substantial issue of fact'' that is in dispute and the right to confront and cross-examine witnesses, which are not well suited for allowing the public to provide viewpoints, opinions, and information to FDA regarding TPMP rules. Accordingly, FDA is removing the reference to section 906(e)(1)(B) of the FD&C Act from part 16 as other available procedures are better suited to achieve its purposes.

The Agency is also adding a reference to section 906(e)(2)(E) of the FD&C Act to § 16.1(b)(1). Section 906(e)(2)(E) of the FD&C Act provides an opportunity for an informal hearing after the issuance of an order related to a petitioner's request for a temporary or permanent exemption or variance from TPMP requirements. The list of statutory provisions in § 16.1(b)(1) that specifies the statutory and regulatory provisions under which regulatory hearings under part 16 are available did not previously include section 906(e)(2)(E) of the FD&C Act. FDA is adding this reference to clarify that it intends to use the procedures in part 16 when conducting such hearings.

FDA is amending § 16.1 to clarify when it intends to use the procedures in part 16 for regulatory hearings. The amended rule is more consistent with the statute as it aligns the purposes of the two hearings referenced above with more appropriate hearing procedures

[1] ''Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products,'' Food and Drug Administration, 77 FR 5171, February 2, 2012.

under FDA's regulations. It also clarifies the availability of hearings under part 16 to tobacco product manufacturers.

IV. Legal Authority

FDA is issuing this rule under provisions of the FD&C Act related to regulations and hearings (21 U.S.C. 371), and general provisions respecting control of tobacco products (21 U.S.C. 387f). Section 701 (21 U.S.C. 371) vests FDA with ''the authority to promulgate regulations for the efficient enforcement of [the FD&C Act].'' Section 906(e) of the FD&C Act includes provisions regarding TPMP requirements regulations and temporary and permanent exemptions and variances from TPMP requirements.

V. Description of the Direct Final Rule

We are revising § 16.1, Scope, to remove a reference to ''Section 906(e)(1)(B) of the FD&C Act relating to the establishment of good manufacturing practice requirements for tobacco products'' and add a reference to ''Section 906(e)(2)(E) of the FD&C Act relating to exemptions or variances from tobacco product manufacturing practice requirements.'' The amended rule clarifies the availability of the procedures in part 16 for regulatory hearings to include situations when a petitioner has requested a temporary or permanent exemption or variance from TPMP requirements.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule merely clarifies which of its existing procedures FDA intends to use when conducting certain types of hearings under the FD&C Act, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

This rule clarifies the procedures FDA intends to use when conducting certain types of hearings under the FD&C Act. When the TPMP rule becomes final and effective, potentially affected entities, including manufacturers of finished and bulk tobacco products, who choose to request an exemption or variance from TPMP requirements would be afforded an opportunity for a hearing on orders regarding such requests.

We do not know how many manufacturers would pursue petitioning for an exemption or variance from TPMP requirements, once the Agency has published a final TPMP rule to establish such requirements and that rule is in effect, nor do we know how many requirements may be included in each petition. We reason that a manufacturer would petition for an exemption or variance from a TPMP requirement only if compliance with said requirement is not a financially viable choice compared to the cost of a filing a petition. Because this rule merely clarifies which of its existing procedures FDA intends to use when conducting certain types of hearings under the FD&C Act, costs and benefits of this rule are expected to be minimal.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This direct final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this direct final rule does not contain policies that 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. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

List of Subjects in 21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 16 is amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 1. The authority citation for part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 2. Amend § 16.1 by revising paragraph (b)(1) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(1) The statutory provisions are as follows:

TABLE 1 TO PARAGRAPH (b)(1)

Section 304(g) of the Federal Food, Drug, and Cosmetic Act relating to the administrative detention of devices and drugs (see §§ 800.55(g) and 1.980(g) of this chapter).
Section 304(h) of the Federal Food, Drug, and Cosmetic Act relating to the administrative detention of food for human or animal consumption (see part 1, subpart k of this chapter).
Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 (see part 112, subpart P of this chapter).
Section 515(e)(1) of the Federal Food, Drug, and Cosmetic Act relating to the proposed withdrawal of approval of a device premarket approval application.
Section 515(e)(3) of the Federal Food, Drug, and Cosmetic Act relating to the temporary suspension of approval of a premarket approval application.
Section 515(f)(6) of the Federal Food, Drug, and Cosmetic Act relating to a proposed order revoking a device product development protocol or declaring a protocol not completed.
Section 515(f)(7) of the Federal Food, Drug, and Cosmetic Act relating to revocation of a notice of completion of a product development protocol.
Section 516(b) of the Federal Food, Drug, and Cosmetic Act regarding a proposed regulation to ban a medical device with a special effective date.
Section 518(b) of the Federal Food, Drug, and Cosmetic Act relating to a determination that a device is subject to a repair, replacement, or refund order or that a correction plan, or revised correction plan, submitted by a manufacturer, importer, or distributor is inadequate.
Section 518(e) of the Federal Food, Drug, and Cosmetic Act relating to a cease distribution and notification order or mandatory recall order concerning a medical device for human use.
Section 520(f)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to exemptions or variances from device current good manufacturing practice requirements (see § 820.1(d)).
Section 520(g)(4) and (g)(5) of the Federal Food, Drug, and Cosmetic Act relating to disapproval and withdrawal of approval of an application from an investigational device exemption (see §§ 812.19(c), 812.30(c), 813.30(d), and 813.35(c) of this chapter).
Section 903(a)(8)(B)(ii) of the Federal Food, Drug, and Cosmetic Act relating to the misbranding of tobacco products.
Section 906(e)(2)(E) of the Federal Food, Drug, and Cosmetic Act relating to exemptions or variances from tobacco product manufacturing practice requirements.
Section 910(d)(1) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a new tobacco product to be introduced or delivered for introduction into interstate commerce.
Section 911(j) of the Federal Food, Drug, and Cosmetic Act relating to the withdrawal of an order allowing a modified risk tobacco product to be introduced or delivered for introduction into interstate commerce.

* * * * *

§ 16.1 [Amended]

■ 3. Effective December 18, 2025, in § 16.1, amend paragraph (b)(2) by redesignating table 1 to paragraph (b)(2) as table 2 to paragraph (b)(2).

Dated: September 6, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–21231 Filed 9–19–24; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2024–0032; FRL–11685–02–R9]

Air Plan Revisions; California; San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a revision to the San Diego County Air Pollution Control District (SDCAPCD) portion of the California State Implementation Plan (SIP). This revision concerns a rule submitted to address section 185 of the Clean Air Act (CAA or ''Act'').

DATES: This rule is effective October 21, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2024–0032. 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. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Kira Wiesinger, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; phone: (415) 972–3827; email: *wiesinger.kira@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

Table of Contents

I. Proposed Action

On April 2, 2024 (89 FR 22648), the EPA proposed to approve the following rule into the California SIP.