

(D) The name of each exchange, if any, with which the statement, report, or document is filed;

(iii) The copies of the confidential portion and the application filed in accordance with this paragraph shall be enclosed in a separate envelope marked "Confidential Treatment" and addressed to Executive Secretary, Federal Deposit Insurance Corporation, Washington, DC 20429.

(3) Pending the determination by the FDIC as to the objection filed in accordance with paragraph (c)(2)(ii) of this section, the confidential portion will not be disclosed by the FDIC.

(4) If the FDIC determines that the objection shall be sustained, a notation to that effect will be made at the appropriate place in the statement, report, or document.

(5) If the FDIC determines that disclosure of the confidential portion is in the public interest, a finding and determination to that effect will be entered and notice of the finding and determination will be sent by registered or certified mail to the person.

(6) The confidential portion shall be made available to the public:

(i) Upon the lapse of 15 days after the dispatch of notice by registered or certified mail of the finding and determination of the FDIC described in paragraph (c)(5) of this section, or the date of the electronic filing, if prior to the lapse of such 15 days the person shall not have filed a written statement that he intends in good faith to seek judicial review of the finding and determination;

(ii) Upon the lapse of 60 days after the dispatch of notice by registered or certified mail, or the date of the electronic filing, of the finding and determination of the FDIC, if the statement described in paragraph (c)(6)(i) of this section shall have been filed and if a petition for judicial review shall not have been filed within such 60 days; or

(iii) If such petition for judicial review shall have been filed within such 60 days upon final disposition, adverse to the person, of the judicial proceedings.

(7) If the confidential portion is made available to the public, a copy thereof shall be attached to each copy of the statement, report, or document filed with the FDIC and with each exchange concerned.

■ 22. Amend Section 335.801 by revising paragraphs (b)(1), (b)(2), (b)(6)(iv), and (b)(6)(v) to read as follows:

**§ 335.801 Inapplicable SEC regulations; FDIC substituted regulations; additional information.**

\* \* \* \* \*

(b) *Electronic filings.* (1) The FDIC does not participate in the SEC's EDGAR (Electronic Data Gathering Analysis and Retrieval) electronic filing program (17 CFR part 232). The FDIC permits voluntary electronically transmitted filings and submissions of correspondence and other materials in electronic format to the FDIC, with the exception of Beneficial Ownership Reports (Forms 3, 4, and 5) for which electronic filing is mandatory. Beneficial Ownership Report filing requirements are provided in paragraph (b)(2) of this section.

(2) All reporting persons must electronically file Beneficial Ownership Reports (FDIC Forms 3, 4, and 5), including amendments and exhibits thereto, using the Internet-based interagency Beneficial Ownership Filings System, except that a reporting person that has obtained a continuing hardship exemption under these rules may file the forms with the FDIC in paper format. For electronic filing purposes, FDIC Forms 3, 4, and 5 are accessible at the Internet-based interagency Web site for Beneficial Ownership Filings at <https://www2.fdicconnect.gov/index.asp>. These forms and the instructions thereto are available for printing and downloading at <http://www.fdic.gov/regulations/laws/forms>. A reporting person that has obtained a continuing hardship exemption under these rules may file the appropriate forms with the FDIC in paper format. Instructions for continuing hardship exemptions are provided in paragraph (b)(6) of this section.

\* \* \* \* \*

(6) \* \* \* (iv) Where a continuing hardship exemption is granted with respect to an exhibit only, the paper format exhibit shall be filed with the FDIC under Form SE (17 CFR part 249). The name of the FDIC shall be substituted for the name of the SEC on the form. Form SE shall be filed as a paper cover sheet to all exhibits to Beneficial Ownership Reports submitted to the FDIC in paper form pursuant to a hardship exemption.

(v) Form SE may be filed with the FDIC up to six business days prior to, or on the date of filing of, the electronic form to which it relates but shall not be filed after such filing date. If a paper exhibit is submitted in this manner, requirements that the exhibit be filed with, provided with, or accompany the electronic filing shall be satisfied. Any requirements as to delivery or

furnishing the information to persons other than the FDIC shall not be affected by this section.

\* \* \* \* \*

By order of the Board of Directors.  
Federal Deposit Insurance Corporation.

Dated at Washington, DC, this 9th day of November 2010.

**Robert E. Feldman,**  
*Executive Secretary.*

[FR Doc. 2010-30078 Filed 11-29-10; 8:45 am]

**BILLING CODE 6714-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 1, 14, and 17**

[Docket No. FDA-2010-N-0560]

RIN 0910-AG55

**Amendments to General Regulations of the Food and Drug Administration**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). With these amendments, tobacco products will be subject to the same general requirements that apply to other FDA-regulated products. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA's usual procedures for notice and comment to provide a procedural framework to finalize the rule in the event we receive significant adverse comment and withdraw this direct final rule.

**DATES:** This rule is effective April 14, 2011. Submit either electronic or written comments by February 14, 2011. If we receive no significant adverse comments within the specified comment period, we intend 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 we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

**ADDRESSES:** You may submit comments, identified by Docket No. FDA-2010-N-0560 and/or RIN number 0910-AG55, by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301-827-6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., rm. 240G, Rockville, MD 20850, 1-877-CTP-1373, [gerie.voss@fda.hhs.gov](mailto:gerie.voss@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. What is the background of the rule?

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and providing FDA with the authority to regulate tobacco products (Pub. L. 11-31; 123 Stat. 1776). In enacting the Tobacco Control Act, Congress sought to ensure that FDA had authority to provide effective oversight and to impose appropriate regulatory controls on tobacco products. In order to effectuate these purposes, FDA is amending several provisions of its general regulations to reflect the Agency's new authority and mandate regarding tobacco products.

#### II. What does this direct final rulemaking do?

In this direct final rule, FDA is making the following amendments to its existing general regulations, reflecting the Agency's authority over tobacco products under the Tobacco Control Act:

1. Revising 21 CFR 1.1(b) to ensure the applicability of definitions contained in the Tobacco Control Act;
2. Removing the reference to "package" in 21 CFR 1.1(c), as this definition now also is covered by the Tobacco Control Act and is no longer provided solely by the Fair Packaging and Labeling Act;
3. Revising 21 CFR 1.20 to exclude from this definition of "package" the term "package" as defined in section 900(13) of the Tobacco Control Act (21 U.S.C. 387q(13));
4. Adding paragraph (f) to 21 CFR 14.55 to identify the Tobacco Products Scientific Advisory Committee as a permanent statutory advisory committee; and
5. Adding paragraph (j) to 21 CFR 17.1 and revising 21 CFR 17.2 to reflect FDA's authority to impose civil monetary penalties on tobacco-related violations.

#### III. What are the procedures for issuing a direct final rule?

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures" that described when and how FDA will employ direct final rulemaking. We believe that this rule is appropriate for direct final rulemaking because it is intended to make noncontroversial changes to existing regulations. We anticipate no significant adverse comments.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule that is identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this 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 comment, we intend to withdraw this final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. 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 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 in accordance with the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule will 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 a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA. If we receive no significant adverse comment during the specified comment period, we intend to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends.

You can find additional information about FDA's direct final rulemaking procedures in the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures" (62 FR 62466). This guidance document may be accessed at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm>.

#### IV. What is the legal authority for this rule?

FDA is issuing this direct final rule under provisions of the FD&C Act, as amended by the Tobacco Control Act (21 U.S.C. 321, 331, 333, 387, 387a, and 387q).

### V. What is the environmental impact of this rule?

The Agency has determined under 21 CFR 25.30(h) and (i) 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.

### VI. What is the economic impact of this rule?

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits 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). The Agency believes that this direct final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this direct final rule does not impose any new requirements on tobacco product manufacturers, retailers, or distributors, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “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 \$135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

### VII. Paperwork Reduction Act of 1995

FDA concludes that the regulatory revisions and amendments identified in this document are not subject to review by the Office of Management and Budget because they do not constitute a “collection of information” under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

### VIII. What are the federalism impacts of this rule?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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, the Agency has concluded 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.

### IX. How do you submit comments on this rule?

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects

##### 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

##### 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

##### 21 CFR Part 17

Administrative practice and procedure, Penalties.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1, 14, and 17 are amended as follows:

### PART 1—GENERAL ENFORCEMENT REGULATIONS

■ The authority citation for part 1 is revised to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 387, 387a, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. In § 1.1, revise paragraph (b); and in the first sentence of paragraph (c), remove “*package* in § 1.20 and of” to read as follows:

#### § 1.1 General.

\* \* \* \* \*

(b) The definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act.

\* \* \* \* \*

■ 3. Amend § 1.20 by revising the introductory text to read as follows:

#### § 1.20 Presence of mandatory label information.

Except as otherwise provided by section 900(13) of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387(13)) defining “*package*,” the term *package* means any container or wrapping in which any food, drug, device, or cosmetic is enclosed for use in the delivery or display of such commodities to retail purchasers, but does not include:

\* \* \* \* \*

### PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 4. The authority citation for part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155.

■ 5. Amend § 14.55 by adding paragraph (f) to read as follows:

#### § 14.55 Termination of advisory committees.

\* \* \* \* \*

(f) The Tobacco Products Scientific Advisory Committee is a permanent statutory advisory committee established by section 917 of the Family Smoking Prevention and Tobacco Control Act (21 U.S.C. 387q) (Pub. L. 111–31) and is not subject to termination and renewal under paragraph (a) of this section.

### PART 17—CIVIL MONEY PENALTIES HEARINGS

■ 6. The authority citation for part 17 continues to read as follows:

**Authority:** 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

■ 7. Amend § 17.1 by adding paragraph (j) to read as follows:

**§ 17.1 Scope.**

\* \* \* \* \*  
 (j) Section 303(f) of the act authorizing civil money penalties for any person who violates a requirement of the Family Smoking Prevention and

Tobacco Control Act which relates to tobacco products.

■ 8. Revise § 17.2 to read as follows:

**§ 17.2 Maximum penalty amounts.**

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act.

**CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS**

U.S.C. Section	Former maximum penalty amount (in dollars) <sup>1</sup>	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
<b>21 U.S.C.</b>				
333(b)(2)(A) .....	55,000	For each of the first two violations in any 10-year period	2008	60,000.
333(b)(2)(B) .....	1,100,000	For each violation after the second conviction in any 10-year period.	2008	1,200,000.
333(b)(3) .....	110,000	Per violation .....	2008	120,000.
333(f)(1)(A) .....	16,500	Per violation .....	2008	16,500 (not adjusted).
333(f)(1)(A) .....	1,100,000	For the aggregate of violations .....	2008	1,200,000.
333(f)(2)(A) .....	55,000	Per individual .....	2008	60,000.
333(f)(2)(A) .....	275,000	Per "any other person" .....	2008	300,000.
333(f)(2)(A) .....	550,000	For all violations adjudicated in a single proceeding .....	2008	600,000.
333(f)(3)(A) .....	10,000	For all violations adjudicated in a single proceeding .....	2007	10,000 (not adjusted).
333(f)(3)(B) .....	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected.	2007	10,000 (not adjusted).
333(f)(4)(A)(i) .....	250,000	Per violation .....	2007	250,000 (not adjusted).
333(f)(4)(A)(i) .....	1,000,000	For all violations adjudicated in a single proceeding .....	2007	1,000,000 (not adjusted).
333(f)(4)(A)(ii) .....	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification.	2007	250,000 (not adjusted).
333(f)(4)(A)(ii) .....	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day period.	2007	1,000,000 (not adjusted).
333(f)(4)(A)(ii) .....	10,000,000	For all violations adjudicated in a single proceeding .....	2007	10,000,000 (not adjusted).
333(f)(9)(A) .....	<sup>1</sup> N/A	Per violation .....	2009	15,000 (not adjusted).
333(f)(9)(A) .....	N/A	For all violations adjudicated in a single proceeding .....	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(I) .....	N/A	Per violation .....	2009	250,000 (not adjusted).
333(f)(9)(B)(i)(I) .....	N/A	For all violations adjudicated in a single proceeding .....	2009	1,000,000 (not adjusted).
333(f)(9)(B)(i)(II) .....	N/A	For the first 30-day period (or any portion thereof) of continued violation following notification.	2009	250,000 (not adjusted).
333(f)(9)(B)(i)(II) .....	N/A	For any 30-day period, where the amount doubled for every 30-day period of continued violation after the first 30-day period.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(ii)(I) .....	N/A	For all violations adjudicated in a single proceeding .....	2009	10,000,000 (not adjusted).
333(f)(9)(B)(ii)(I) .....	N/A	Per violation .....	2009	250,000 (not adjusted).
333(f)(9)(B)(ii)(I) .....	N/A	For all violations adjudicated in a single proceeding .....	2009	1,000,000 (not adjusted).
333(f)(9)(B)(ii)(II) .....	N/A	For the first 30-day period (or any portion thereof) of continued violation following notification.	2009	250,000 (not adjusted).
333(f)(9)(B)(ii)(II) .....	N/A	For any 30-day period, where the amount doubled for every 30-day period of continued violation after the first 30-day period.	2009	1,000,000 (not adjusted).
333(f)(9)(B)(ii)(II) .....	N/A	For all violations adjudicated in a single proceeding .....	2009	10,000,000 (not adjusted).
333(g)(1) .....	250,000	For the first violation in any 3-year period .....	2007	250,000 (not adjusted).
333(g)(1) .....	500,000	For each subsequent violation in any 3-year period .....	2007	500,000 (not adjusted).
333 note .....	N/A	For the second violation (following a first violation with warning) within a 12-month period by a retailer with an approved training program.	2009	250 (not adjusted).
333 note .....	N/A	For the third violation within a 24-month period by a retailer with an approved training program.	2009	500 (not adjusted).
333 note .....	N/A	For the fourth violation within a 24-month period by a retailer with an approved training program.	2009	2,000 (not adjusted).
333 note .....	N/A	For the fifth violation within a 36-month period by a retailer with an approved training program.	2009	5,000 (not adjusted).
333 note .....	N/A	For the six or subsequent violation within a 48-month period by a retailer with an approved training program.	2009	10,000 (not adjusted).
333 note .....	N/A	For the first violation by a retailer without an approved training program.	2009	250 (not adjusted).
333 note .....	N/A	For the second violation within a 12-month period by a retailer without an approved training program.	2009	500 (not adjusted).
333 note .....	N/A	For the third violation within a 24-month period by a retailer without an approved training program.	2009	1,000 (not adjusted).

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—  
Continued

U.S.C. Section	Former maximum penalty amount (in dollars) <sup>1</sup>	Assessment method	Date of last penalty figure or adjustment	Adjusted maximum penalty amount (in dollars)
333 note .....	N/A	For the fourth violation within a 24-month period by a retailer without an approved training program.	2009	2,000 (not adjusted).
333 note .....	N/A	For the fifth violation within a 36-month period by a retailer without an approved training program.	2009	5,000 (not adjusted).
333 note .....	N/A	For the six or subsequent violation within a 48-month period by a retailer without an approved training program.	2009	10,000 (not adjusted).
335b(a) .....	275,000	Per violation for an individual .....	2008	300,000.
335b(a) .....	1,100,000	Per violation for “any other person” .....	2008	1,200,000.
360pp(b)(1) .....	1,100	Per violation per person .....	2008	1,100 (not adjusted).
360pp(b)(1) .....	330,000	For any related series of violations .....	2008	355,000.
<b>42 U.S.C.</b>				
263b(h)(3) .....	11,000	Per violation .....	2008	11,000 (not adjusted).
300aa-28(b)(1) .....	110,000	Per occurrence .....	2008	120,000.

<sup>1</sup> Maximum penalties assessed under The Family Smoking Prevention and Tobacco Control Act do not have a “former maximum penalty.”

Dated: November 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-30039 Filed 11-29-10; 8:45 am]

**BILLING CODE 4160-01-P**

**FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION**

**29 CFR Part 2700**

**Penalty Settlement Procedure**

**AGENCY:** Federal Mine Safety and Health Review Commission.

**ACTION:** Final rule.

**SUMMARY:** The Federal Mine Safety and Health Review Commission (the “Commission”) is an independent adjudicatory agency that provides hearings and appellate review of cases arising under the Federal Mine Safety and Health Act of 1977, or Mine Act. Hearings are held before the Commission’s Administrative Law Judges, and appellate review is provided by a five-member Review Commission appointed by the President and confirmed by the Senate. The Commission is publishing a final rule to streamline the process for settling civil penalties assessed under the Mine Act.

**DATES:** The final rule takes effect on December 30, 2010. The Commission will accept written and electronic comments received on or before December 15, 2010.

**ADDRESSES:** Written comments should be mailed to Michael A. McCord, General Counsel, Office of the General Counsel, Federal Mine Safety and

Health Review Commission, 601 New Jersey Avenue, NW., Suite 9500, Washington, DC 20001, or sent via facsimile to 202-434-9944. Persons mailing written comments shall provide an original and three copies of their comments. Electronic comments should state “Comments on Penalty Settlement Rule” in the subject line and be sent to [mmccord@fmshrc.gov](mailto:mmccord@fmshrc.gov).

**FOR FURTHER INFORMATION CONTACT:**

Michael A. McCord, General Counsel, Office of the General Counsel, 601 New Jersey Avenue, NW., Suite 9500, Washington, DC 20001; telephone 202-434-9935; fax 202-434-9944.

**SUPPLEMENTARY INFORMATION:**

**Background**

On April 27, 2010, the Commission published in the **Federal Register** an interim rule regarding the Commission’s civil penalty settlement procedures. 75 FR 21987. The Commission explained that since 2006, the number of new cases filed with the Commission has dramatically increased, and that in order to deal with that burgeoning caseload, the Commission is considering methods to simplify how it processes civil penalty settlements. The interim rule became effective on May 27, 2010, and the Commission accepted comments on the rule through June 28, 2010. The Commission received comments from the Secretary of Labor (the “Secretary”) through the U.S. Department of Labor’s Office of the Solicitor, individual Conference and Litigation Representatives (“CLRs”), and a few members of the mining community.

Under section 110(k) of the Mine Act, 30 U.S.C. 820(k), a proposed civil penalty that has been contested before the Commission may be settled only with the approval of the Commission. Under the Commission’s practice prior to the effective date of the interim rule, a party submitted to a Commission Administrative Law Judge a motion to approve a penalty settlement that included for each violation the amount of the penalty proposed by the Department of Labor’s Mine Safety and Health Administration (“MSHA”), the amount of the penalty agreed to in settlement, and facts in support of the penalty agreed to by the parties. 29 CFR 2700.31(b) (2009). A Commission Judge considered the motion and evaluated the penalty agreed to by the parties based on the criteria set forth in section 110(i) of the Mine Act, 30 U.S.C. 820(i). If the Judge concluded that the settlement was consistent with the statutory criteria, the Judge issued a decision approving the settlement and setting forth the reasons for approval.

The interim rule changed the current procedure by adding two new requirements. First, in all penalty proceedings, except for discrimination proceedings arising under section 105(c) of the Mine Act, 30 U.S.C. 815(c), or proceedings against individuals pursuant to section 110(c) of the Mine Act, 30 U.S.C. 820(c), the interim rule requires that a party filing a motion to approve a penalty settlement submit a proposed decision approving settlement (“proposed order”) with the motion. Second, it requires the filing party to submit the motion and proposed order electronically. The basic requirements