

**V. 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.

**VI. Paperwork Reduction Act of 1995**

FDA concludes that 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.

**VII. Federalism**

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this 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.

**VIII. References**

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <http://www.regulations.gov>. FDA has verified the Web site address as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Bryan Corporation (<http://listings.findthecompany.com/l/12165972/Bryan-Corporation-in-Woburn-MA>, accessed on February 24, 2016).

**List of Subjects in 21 CFR Part 2**

Administrative practice and procedure, Cosmetics, Drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 2 is amended as follows:

**PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS**

- 1. The authority citation for part 2 continues to read as follows:

**Authority:** 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

**§ 2.125 [Amended]**

- 2. In § 2.125, remove and reserve paragraphs (e)(4)(vi) and (ix).

Dated: October 20, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–25851 Filed 10–25–16; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF THE INTERIOR****Office of Surface Mining Reclamation and Enforcement****30 CFR Part 901**

**[SATS No. AL–079–FOR; Docket ID: OSMRE–2016–0005; S1D1S SS08011000 SX064A000 178S180110; S2D2S SS08011000 SX064A000 17XS501520]**

**Alabama Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are approving an amendment to the Alabama regulatory program (Alabama program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Alabama proposed revisions to its Program to closely follow the Federal regulations regarding awarding of appropriate costs and expenses including attorneys' fees. Alabama is revising its program to be no less effective than the Federal regulations.

**DATES:** *Effective Date:* October 26, 2016.

**FOR FURTHER INFORMATION CONTACT:**

Sherry Wilson, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, AL 35209. Telephone: (205) 290–7282. Email: [swilson@osmre.gov](mailto:swilson@osmre.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Alabama Program
- II. Submission of the Amendment
- III. OSMRE's Findings
- IV. Summary and Disposition of Comments
- V. OSMRE's Decision
- VI. Procedural Determinations

**I. Background on the Alabama Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders

by demonstrating that its program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Alabama program effective May 20, 1982. You can find background information on the Alabama program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Alabama program in the May 20, 1982, **Federal Register** (47 FR 22030). You can also find later actions concerning the Alabama program and program amendments at 30 CFR 901.10 and 901.15.

**II. Submission of the Amendment**

By letter dated March 18, 2016 (Administrative Record No. AL–0669), Alabama sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) at its own initiative.

We announced receipt of the proposed amendment in the May 20, 2016, **Federal Register** (81 FR 31881). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on June 20, 2016. We received one public comment (Administrative Record No. AL–0669–04) that is addressed in the "Public Comments" section of part IV. Summary and Disposition of Comments.

**III. OSMRE's Findings**

We are approving the amendment as described below. The following are the findings we made concerning Alabama's amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. Any revisions that we do not specifically discuss below concerning non-substantive wording or editorial changes can be found in the full text of the program amendment available at [www.regulations.gov](http://www.regulations.gov).

**1. Alabama Code 880–X–5A–.35—Assessment of Costs**

Alabama revised this section to allow any party the opportunity to be awarded costs and expenses by a final appellate body. Additionally, language was added to protect the public by including a "bad faith" clause so that expenses may only be assessed against any person in favor of the permittee or the regulatory authority upon demonstration that the

person initiated or participated in the proceedings in bad faith for the purpose of harassing or embarrassing the permittee or the regulatory authority.

We find that Alabama's revision regarding awarding of expenses protects the public in a manner that is no less effective than the counterpart Federal regulations at 43 CFR 4.1294. Therefore, we are approving Alabama's revision.

#### IV. Summary and Disposition of Comments

##### Public Comments

We asked for public comments on the amendment and received one (Administrative Record No. AL-0669-04), which is discussed below.

A comment was received supporting the approval of the proposed amendment in order to bring the Alabama program into compliance with SMCRA and correcting deficiencies in Alabama's program which created hardship for citizens, citizen-based groups, and others, by putting them at risk of potentially having to pay substantial fees if they challenged a permit or other decision covered by Alabama's regulations.

We agree with this comment and are approving the amendment.

##### Federal Agency Comments

On April 7, 2016, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Alabama program (Administrative Record No. AL-0669-03). We did not receive any comments.

##### Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to get a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Alabama proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment. However, on April 7, 2016, under 30 CFR 732.17(h)(11)(i), we requested comments from the EPA on the amendment (Administrative Record No. AL-0669-03). The EPA did not respond to our request.

##### State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the

SHPO and ACHP on amendments that may have an effect on historic properties. On April 7, 2016, we requested comments on Alabama's amendment (Administrative Record No. AL-0669-03), but neither the SHPO nor ACHP responded to our request.

#### V. OSMRE's Decision

Based on the above findings, we approve the amendment Alabama sent us on March 18, 2016 (Administrative Record No. AL-0669).

To implement this decision, we are amending the Federal regulations, at 30 CFR part 901, that codify decisions concerning the Alabama program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this rule effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

#### VI. Procedural Determinations

##### Executive Order 12630—Takings

This rulemaking does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

##### Executive Order 12866—Regulatory Planning and Review

This rulemaking is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

##### Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rulemaking meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSMRE. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the

other requirements of 30 CFR parts 730, 731, and 732 have been met.

##### Executive Order 13132—Federalism

This rulemaking does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

##### Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rulemaking on Federally-recognized Indian tribes and have determined that the rulemaking does not 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. The basis for this determination is that our decision is on a State regulatory program and does not involve Federal regulations involving Indian lands.

##### Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rulemaking that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rulemaking is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

##### National Environmental Policy Act

This rulemaking does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency

decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

*Paperwork Reduction Act*

This rulemaking does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

*Regulatory Flexibility Act*

The Department of the Interior certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rulemaking, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rulemaking would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

*Small Business Regulatory Enforcement Fairness Act*

This rulemaking is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rulemaking: (a) Does not have an annual effect on the economy of \$100 million; (b) will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rulemaking, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rulemaking.

*Unfunded Mandates*

This rulemaking will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which

is the subject of this rulemaking, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

**List of Subjects in 30 CFR Part 901**

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 14, 2016.

**Sterling Rideout,**

*Acting Regional Director, Mid-Continent Region.*

For the reasons set out in the preamble, 30 CFR part 901 is amended as set forth below:

**PART 901—ALABAMA**

■ 1. The authority citation for part 901 continues to read as follows:

**Authority:** 30 U.S.C. 1201 *et seq.*

■ 2. Section 901.15 is amended in the table by adding an entry in chronological order by “Date of final publication” to read as follows:

**§ 901.15 Approval of Alabama regulatory program amendments.**

\* \* \* \* \*

Original amendment submission date	Date of final publication	Citation/description
March 18, 2016	October 26, 2016	Alabama Code 880-X-5A-.35.

**Editorial note:** This document was received for publication by the Office of the Federal Register on October 21, 2016.  
[FR Doc. 2016-25869 Filed 10-25-16; 8:45 am]  
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**POSTAL SERVICE**

**39 CFR Part 20**

**International Product and Price Changes**

**AGENCY:** Postal Service™.  
**ACTION:** Final rule.

**SUMMARY:** The Postal Service is revising *Mailing Standards of the United States Postal Service*, International Mail Manual (IMM®), to reflect the prices, product features, and classification changes to Competitive Services, as established by the Governors of the Postal Service.

**DATES:** *Effective date:* January 22, 2017.

**FOR FURTHER INFORMATION CONTACT:** Paula Rabkin at 202-268-2537.

**SUPPLEMENTARY INFORMATION:** New prices will be posted under Docket Number CP2017-20 on the Postal Regulatory Commission’s Web site at <http://www.prc.gov>.

This final rule describes the international price and classification changes and the corresponding mailing standards changes for the following Competitive Services:

- Global Express Guaranteed® (GXG®);
- International Priority Airmail® (IPA®);
- International Surface Air Lift® (ISAL®);
- Direct Sacks of Printed Matter to One Addressee (Airmail M-bag®); and
- International Extra Services:
  - Priority Mail Express International® (PMEI) Insurance and Priority Mail International® (PMI) Insurance,
  - Registered Mail™ Service,
  - International Postal Money Orders, and
  - Pickup on Demand®.

New prices will be located on the Postal Explorer® Web site at <http://pe.usps.com>.

**Global Express Guaranteed**

Global Express Guaranteed (GXG) provides fast international shipping with international transportation and delivery provided by FedEx Express®. The price increase for GXG service averages 4.9 percent.

The Postal Service continues to provide Commercial Base pricing to online customers who prepare and pay for GXG shipments via USPS®-approved payment methods, with variable discounts up to 5 percent off the published retail prices for GXG.

The Postal Service also continues to offer Commercial Plus pricing incentives for large volume customers who commit to tendering \$100,000 in annual postage revenue from GXG, Priority Mail Express International (PMEI), Priority Mail International (PMI), and First-Class Package International Service® (FCPIS®) via