PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.1128 is added to subpart B to read as follows:

§ 73.1128 Mica-based pearlescent pigments.

(a) *Identity.* (1) The color additive is formed by depositing titanium and/or iron salts onto mica, followed by heating to produce one of the following combinations: Titanium dioxide on mica; iron oxide on mica; titanium dioxide and iron oxide on mica. Mica used to manufacture the color additive shall conform in identity to the requirements of § 73.1496(a)(1).

(2) Color additive mixtures for drug use made with mica-based pearlescent pigments may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring ingested drugs.

(b) *Specifications.* Mica-based pearlescent pigments shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practice:

(1) Lead (as Pb), not more than 4 parts per million (ppm).

(2) Arsenic (as As), not more than 3 ppm.

(3) Mercury (as Hg), not more than 1 ppm.

(c) *Uses and restrictions.* Mica-based pearlescent pigments may be safely used to color ingested drugs in amounts up to 3 percent, by weight, of the final drug product. The maximum amount of iron oxide to be used in producing said pigments is not to exceed 55 percent, by weight, in the finished pigment.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: July 13, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14457 Filed 7–21–05; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7942–9]

Idaho: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Idaho applied to the United States Environmental Protection Agency (EPA) for final authorization of changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). On May 16, 2005, EPA published a proposed rule to authorize the changes and opened a public comment period. The comment period closed on June 15, 2005. EPA has decided that these revisions to the Idaho hazardous waste management program satisfy all of the requirements necessary to qualify for final authorization and is authorizing these revisions to Idaho's authorized hazardous waste management program in today's final rule.

DATES: Final authorization for the revisions to the hazardous waste program in Idaho shall be effective at 1 p.m. E.S.T. on July 22, 2005.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, Mail Stop AWT–122, U.S. EPA Region 10, Office of Air, Waste, and Toxics, 1200 Sixth Avenue, Seattle, Washington 98101, phone (206) 553–0256. E-mail: *hunt.jeff@epa.gov.*

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to and consistent with the Federal program. States are required to have enforcement authority which is adequate to enforce compliance with the requirements of the hazardous waste program. Under RCRA Section 3009, States are not allowed to impose any requirements which are less stringent than the Federal program. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to EPA's regulations in title 40 of the Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273 and 279.

Idaho's hazardous waste management program received final authorization effective on April 9, 1990 (55 FR 11015, March 29, 1990). EPA also granted authorization for revisions to Idaho's program effective on June 5, 1992 (57 FR 11580, April 6, 1992), on August 10, 1992 (57 FR 24757, June 11, 1992), on June 11, 1995 (60 FR 18549, April 12, 1995), on January 19, 1999 (63 FR 56086, October 21, 1998), on July 1, 2002 (67 FR 44069, July 1, 2002), and on March 10, 2004 (69 FR 11322).

Today's final rule addresses a program revision application that Idaho submitted to EPA in September 2004, in accordance with 40 CFR 271.21, seeking authorization of changes to the State program. On May 16, 2005, EPA published a proposed rule announcing its intent to grant Idaho final authorization for revisions to Idaho's hazardous waste program and provided a period of time for the receipt of public comments. The proposed rule can be found at 70 FR 25798.

B. What Were the Comments to EPA's Proposed Rule?

EPA received two letters during the public comment period. One letter was dated June 3, 2005, from Mr. Chuck Broscious on behalf of the Environmental Defense Institute and a second letter was dated June 14, 2005, from Mr. Chuck Broscious on behalf of the Environmental Defense Institute, Keep Yellowstone Nuclear Free, and David B. McCoy, collectively the commenters.

The comment letters focused on issues originally raised in petitions submitted to EPA on August 8, 2000, and September 13, 2001, and on numerous follow up letters and correspondence related to those petitions. The petitions themselves centered on issues related to specific units located at the Idaho National Laboratory (INL) in Idaho Falls, Idaho. The comment letters also raised a concern about nuclear defense activities at the same INL facility. In response to this aspect of the commenters' letter EPA observes that defense activities related to nuclear production and propulsion programs will generally not meet the definition of solid waste under the RCRA regulations and may be regulated by other federal authorities. With respect to mixed waste, Idaho's hazardous waste program is authorized for mixed waste.

In the September 13, 2001, petition which commenters refer to in their current comments, the commenters as petitioners sought EPA's withdrawal of Idaho's authorization to implement the hazardous waste program under RCRA

because of petitioners' concerns with hazardous waste issues at the INL facility. EPA in response to that withdrawal petition request conducted an informal investigation and determined that sufficient evidence did not exist to initiate formal withdrawal proceedings. The investigation findings were issued on March 20, 2002, with a follow up response on June 20, 2002. The supporting documentation was provided to the commenters and the documentation is currently available to the public under the Freedom of Information Act.

On February 6, 2003, the EPA Office of Inspector General (OIG) requested that Region 10 conduct a second investigation to answer a series of follow up questions related to the September 13, 2001, petition. EPA Region 10 conducted a second investigation and issued its findings on April 10, 2003. The investigation results were provided to Mr. David McCoy, one of the current commenters, as part of an October 13, 2004, Freedom of Information Act response. On February 5, 2004, after conducting independent field work, the OIG issued a final evaluation report which concluded, ''Region 10 generally relied on appropriate regulatory requirements and standards in reaching its conclusion that evidence did not exist to commence proceedings to withdraw the State of Idaho's authority to run its RCRA Hazardous Waste program.''

While the evaluation report concluded that evidence did not exist to commence withdrawal proceedings, the OIG did identify areas of concern for further Regional and State follow up. As detailed in the Evaluation Report, the OIG and EPA Region 10 agreed to specific follow up actions. To document resolution of these action items, EPA Region 10 submitted quarterly progress reports to the Region 10 OIG Audit Liaison on January 13, 2004, April 16, 2004, July 15, 2004, October 12, 2004, February 9, 2005, and April 8, 2005. These reports document the steps taken by EPA and the Idaho Department of Environmental Quality to meet the specific actions recommended by the OIG. The first three of these quarterly reports were sent to the commenters and the OIG as part of a July 26, 2004, letter from then Regional Administrator, L. John Iani. Hardcopies of all the quarterly reports were made directly available to the public as part of the authorization docket for the proposed authorization with repositories in Seattle, Washington and the University of Idaho in Moscow. These quarterly reports are also currently available to the public under the Freedom of Information Act.

While the Region will continue its ongoing obligation to conduct state oversight, EPA considers the follow up to the September 13, 2001, withdrawal petition and the February 5, 2004, OIG Evaluation Report complete. The information documenting EPA's follow up to the February 5, 2004, OIG Evaluation Report was contained in the authorization docket available to the public through the Region 10 Library in Seattle, Washington, as well as through the Freedom of Information Act process. In response to a request by Mr. Chuck Broscious, EPA made a hardcopy version of the docket available to the public at the University of Idaho Library in Moscow, Idaho. Furthermore, in response to a request from the Shoshone Bannock Tribe, and Mr. Chuck Broscious, EPA electronically scanned the State of Idaho's authorization application and made this document available on the Region 10 Web site at: *http://yosemite.epa.gov/R10/OWCM.NSF/ed6c817875102d2d8825650f00714a59/2b89088c6ed7351788257014008 1e7f9?OpenDocument.*

Based on the follow up actions that were taken in response to the OIG Evaluation Report, EPA disagrees with comments submitted on June 3 and 14, 2005, alleging that EPA and the Idaho Department of Environmental Quality have not sufficiently responded to the issues raised by the February 5, 2004, OIG Evaluation report. Therefore, EPA has determined that these comments do not constitute basis for continued delay or denial of Idaho's application for program revision.

C. What Decisions Have We Made in This Rule?

EPA has made a final determination that Idaho's revisions to the Idaho authorized hazardous waste program meet all of the statutory and regulatory requirements established by RCRA for authorization. Therefore, EPA is authorizing the revisions to the Idaho hazardous waste program and authorizing the State of Idaho to operate its hazardous waste program as described in the revision authorization application. Idaho's authorized program will be responsible for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of RCRA, including the Hazardous and Solid Waste Amendments of 1984 (HSWA).

New Federal requirements and prohibitions imposed by Federal regulations that EPA promulgates under the authority of HSWA are implemented by EPA and take effect in States with authorized programs before such programs are authorized for the requirements. Thus, EPA will implement those HSWA requirements and prohibitions in Idaho, including issuing permits or portions of permits, until the State is authorized to do so.

D. What Will Be the Effect of Today's Action?

The effect of today's action is that a facility in Idaho subject to RCRA must comply with the authorized State program requirements and with any applicable federally-issued requirement, such as, for example, the federal HSWA provisions for which the State is not authorized, and RCRA requirements that are not supplanted by authorized State-issued requirements, in order to comply with RCRA. Idaho has enforcement responsibilities under its State hazardous waste program for violations of its currently authorized program and will have enforcement responsibilities for the revisions which are the subject of this final rule. EPA continues to have independent enforcement authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

—Conduct inspections; require monitoring, tests, analyses or reports;
—Enforce RCRA requirements, including State program requirements that are authorized by EPA and any applicable Federally-issued statutes and regulations; suspend, modify or revoke permits; and
—Take enforcement actions regardless of whether the State has taken its own actions.

This final action approving these revisions will not impose additional requirements on the regulated community because the regulations for which Idaho's program is being authorized are already effective under State law.

E. What Rules Are We Authorizing With Today's Action?

In September 2004, Idaho submitted a complete program revision application, seeking authorization for all delegable federal hazardous waste regulations codified as of July 1, 2003, as incorporated by reference in IDAPA 58.01.05.(002)–(016) and 58.01.05.997, including previously unauthorized portions of the Post Closure Rule promulgated on October 22, 1998 (63 FR 56710).

F. Who Handles Permits After This Authorization Takes Effect?

Idaho will issue permits for all the provisions for which it is authorized and will administer the permits it

issues. All permits or portions of permits issued by EPA prior to final authorization of this revision will continue to be administered by EPA until the effective date of the issuance, re-issuance after modification, or denial of a State RCRA permit or until the permit otherwise expires or is revoked, and until EPA takes action on its permit or portion of permit. HSWA provisions for which the State is not authorized will continue in effect under the EPA-issued permit or portion of permit. EPA will continue to issue permits or portions of permits for HSWA requirements for which Idaho is not yet authorized.

G. What Is Codification and Is EPA Codifying Idaho's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. EPA does this by referencing the authorized State's authorized rules in 40 CFR part 272. EPA is reserving the amendment of 40 CFR part 272, subpart F for codification of Idaho's program at a later date.

H. How Does Today's Action Affect Indian Country (18 U.S.C. 1151) in Idaho?

EPA's decision to authorize the Idaho hazardous waste program does not include any land that is, or becomes after the date of this authorization, ''Indian Country,'' as defined in 18 U.S.C. 1151. This includes: (1) All lands within the exterior boundaries of Indian reservations within or abutting the State of Idaho; (2) Any land held in trust by the U.S. for an Indian tribe; and (3) Any other land, whether on or off an Indian reservation that qualifies as Indian country. Therefore, this action has no effect on Indian country. EPA retains jurisdiction over ''Indian Country'' as defined in 18 U.S.C. 1151.

I. Statutory and Executive Order Reviews

1. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4,1993), the Agency must determine whether the regulatory action is ''significant'', and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more, 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 or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined that this final rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

2. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, is intended to minimize the reporting and recordkeeping burden on the regulated community, as well as to minimize the cost of Federal information collection and dissemination. In general, the Act requires that information requests and recordkeeping requirements affecting ten or more non-Federal respondents be approved by OPM. Since this final rule does not establish or modify any information or recordkeeping requirements for the regulated community, it is not subject to the provisions of the Paperwork Reduction Act.

3. Regulatory Flexibility

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires federal agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business, as codified in the Small Business Size Regulations at 13 CFR part 121; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. EPA has determined that this action will not have a significant impact on small entities because the final rule will only have the effect of authorizing pre-existing requirements under State law. After considering the economic impacts of today's rule, I certify that this action will not have a significant economic impact on a substantial number of small entities.

4. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why the alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local or tribal governments or the private sector. It imposes no new enforceable duty on any State, local or tribal governments or the private sector. Similarly, EPA has also determined that this rule contains no regulatory

requirements that might significantly or uniquely affect small government entities. Thus, the requirements of section 203 of the UMRA do not apply to this rule.

5. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations 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 various levels of government.''

This rule does not have federalism implications. It 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 various levels of government, as specified in Executive Order 13132. This rule addresses the authorization of pre-existing State rules. Thus, Executive Order 13132 does not apply to this rule.

6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This rule does not have tribal implications, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

7. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 applies to any rule that: (1) Is determined to be ''economically significant'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not a ''significant regulatory action'' as defined under Executive Order 12866.

9. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law 104–113, 12(d) (15 U.S.C. 272) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through the OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rule does not involve ''technical standards'' as defined by the NTTAA. Therefore, EPA is not considering the use of any voluntary consensus standards.

10. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

To the greatest extent practicable and permitted by law, and consistent with the principles set forth in the report on the National Performance Review, each Federal agency must make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health and environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States and its territories and possessions, the District of Columbia, the Commonwealth of Puerto Rico, and the Commonwealth of the Mariana Islands. Because this rule addresses authorizing pre-existing State rules and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898.

11. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5. U.S.C. 804(2). This rule will be effective on the date the rule is published in the **Federal Register**.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: July 14, 2005.

Michelle Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 05–14545 Filed 7–21–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

[CMS–4094–F3]

RIN 0938–AN22

Amendment to the Interim Final Regulation for Mental Health Parity

AGENCY: Centers for Medicare & Medicaid Services (CMS), DHHS.