

Costs of Compliance

There are about 1,063 airplanes of the affected design in the worldwide fleet. This AD will affect about 518 airplanes of U.S. registry.

Replacing the bracket will take about 1 work hour per airplane, at an average labor rate of \$65 per work hour. Required parts will cost about \$186 per airplane. Based on these figures, we estimate the cost of the required replacement on U.S. operators to be \$130,018, or \$251 per airplane.

Inspecting the FQIS wire bundle will take approximately 1 work hour per airplane, at an average labor rate of \$65 per work hour. Based on these figures, we estimate the cost of the required inspection on U.S. operators to be \$33,670, or \$65 per airplane.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866;
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2004-24-07 Boeing: Amendment 39-13883.
Docket No. FAA-2004-18562;
Directorate Identifier 2003-NM-147-AD.

Effective Date

(a) This AD becomes effective January 3, 2005.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 737-600, -700, -700C, -800, and -900 series airplanes, as listed in Boeing Special Attention Service Bulletin 737-28-1190, Revision 1, dated March 27, 2003; certificated in any category.

Unsafe Condition

(d) This AD was prompted by a report of an incorrectly installed fuel quantity indicating system (FQIS) wire bundle. We are issuing this AD to prevent chafing of the FQIS wire(s) in the center fuel tank, which, when combined with a lightning strike or a power wire short to the FQIS wire(s), could result in arcing in the center fuel tank and consequent fuel tank explosion.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Replacement and Inspection

(f) Within 24 months after the effective date of this AD, replace the bracket for the FQIS wire bundle with a new, improved bracket, perform a general visual inspection of the FQIS wire bundle for damage, and perform any applicable corrective actions, by accomplishing all of the actions specified in the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737-28-1190, Revision 1, dated March 27, 2003. Do any applicable corrective actions before further flight.

Note 1: For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

Actions Accomplished in Accordance With Previous Issue of Service Bulletin

(g) Actions accomplished before the effective date of this AD in accordance with Boeing Special Attention Service Bulletin

737-28-1190, dated January 16, 2003, are considered acceptable for compliance with the corresponding action specified in this AD.

Parts Installation

(h) As of the effective date of this AD, no person may install a bracket, part number 287A9111-3, for the FQIS wire bundle, on any airplane.

Alternative Methods of Compliance (AMOCs)

(i) The Manager, Seattle Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

Material Incorporated by Reference

(j) You must use Boeing Special Attention Service Bulletin 737-28-1190, Revision 1, dated March 27, 2003, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approves the incorporation by reference of the document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. For copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124-2207. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL-401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on November 17, 2004.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04-26190 Filed 11-26-04; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 201**

[Docket No. 1990N-0309]

RIN 0910-AF50

Drug Labeling; Sodium Labeling for Over-the-Counter Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the regulations for sodium labeling for over-the-counter (OTC) drug products by extending the sodium content labeling requirement to

rectal drug products containing sodium phosphate/sodium biphosphate (sodium phosphates). FDA is taking this action because people with certain medical conditions are at risk for an electrolyte imbalance to occur when using rectal sodium phosphates products. Serious adverse events and deaths have occurred because of the high level of sodium present in these products. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: This rule is effective November 29, 2005.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 24, 2004 (69 FR 13765), FDA issued a proposed rule to amend the regulations for sodium labeling for OTC drug products to require sodium content labeling for rectal drug products containing sodium phosphates. FDA considers it important that consumers be aware of the sodium content of OTC rectal drug products containing sodium phosphates and that this information appear in product labeling so that it will be readily available to consumers, physicians, and other health professionals. Some OTC laxative drug products intended for rectal administration can contain very high levels of sodium from both active and inactive ingredients. Significant amounts of some of these products may be absorbed causing an electrolyte imbalance.

Section 201.64 (21 CFR 201.64) requires orally ingested sodium phosphates products to bear sodium content information. FDA proposed to add paragraph (k) to § 201.64 to require sodium content information to appear in the labeling of rectal drug products containing dibasic sodium phosphate and/or monobasic sodium phosphate.

II. Final Rule Amending Sodium Labeling Regulations

FDA did not receive any comments to its proposed new labeling requirements, its discussion of the statutory authority to require this labeling, or its discussion of this labeling requirement being constitutionally permissible under the first amendment. Accordingly, FDA is not repeating those discussions in this final rule, but is incorporating the discussions regarding statutory authority and the first amendment by reference (see 69 FR 13766 to 13767).

FDA is finalizing its proposal by requiring sodium content information to appear in the labeling of OTC rectal drug products containing dibasic sodium phosphate and/or monobasic sodium phosphate.

III. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

FDA concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. As discussed in this section of the document, the final rule will not be economically significant as defined by the Executive order. With respect to the Regulatory Flexibility Act, FDA concludes that the rule would not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation adjusted statutory threshold is about \$110 million.

The purpose of this final rule is to extend the requirement for sodium content labeling to OTC rectal drug products that contain sodium phosphates so that the information is available to: (1) Health professionals and (2) individuals who need to limit their sodium intake. The final rule would require minor relabeling of OTC rectal drug products containing sodium phosphates. There are fewer than five

major manufacturers of these products in the OTC drug marketplace. One company manufactures a nationally branded product with the others producing private label products. One large manufacturer produces about one-half to two-thirds of the products covered by this final rule. Three small manufacturers account for the remainder of the market. There may be other manufacturers/marketers not identified in sources FDA reviewed, but FDA believes there are a limited number and they would be small manufacturers. FDA concludes that this final rule would not have a significant economic impact on small entities, using the U.S. Small Business Administration designations for this industry (750 employees). Together, fewer than 300 stockkeeping units (SKUs) are marketed. The manufacturer of the nationally branded product and some private label manufacturers of these products already include sodium content information in the labeling of their products. Any necessary relabeling (addition of sodium content labeling) will impose direct one-time costs on some manufacturers. FDA has been informed that the cost to relabel these products ranges from \$500 to \$3,500 per SKU. Using \$3,500 per SKU, and assuming all SKUs would need to be relabeled, the total one-time cost to relabel these products would be \$1,050,000. Actual costs will be lower because most of these products already include the sodium content information in their labeling.

Manufacturers that have not voluntarily included sodium content information may also incur one-time costs to test their products to determine the sodium content. The cost to test for one cation (e.g., sodium) is about \$150 for private label manufacturers. Assuming they repeat the testing, the total one-time costs for an estimated 10 products would be \$3,000.

FDA considered but rejected several labeling alternatives: (1) A longer implementation period and (2) an exemption from coverage for small entities. A longer time period would unnecessarily delay the benefit of the new labeling to consumers who self-medicate with these products. FDA rejected an exemption for small entities because the labeling is also needed by consumers who purchase products marketed by those entities.

For the reasons stated previously and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirement in this document is not subject to review by the Office of Management and Budget because it does not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

V. Environmental Impact

FDA has determined under 21 CFR 25.31(a) 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. Federalism

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.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 201 is amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Section 201.64 is amended by adding paragraph (k) to read as follows:

§ 201.64 Sodium labeling.

* * * * *

(k) The labeling of OTC drug products intended for rectal administration containing dibasic sodium phosphate and/or monobasic sodium phosphate

shall contain the sodium content per delivered dose if the sodium content is 5 milligrams or more. The sodium content shall be expressed in milligrams or grams. If less than 1 gram, milligrams should be used. The sodium content shall be rounded-off to the nearest whole number if expressed in milligrams (or nearest tenth of a gram if expressed in grams). The sodium content per delivered dose shall follow the heading "Other information" as stated in § 201.66(c)(7). Any product subject to this paragraph that contains dibasic sodium phosphate and/or monobasic sodium phosphate as an active ingredient intended for rectal administration and that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after November 29, 2005, is misbranded under sections 201(n) and 502(a) and (f) of the act.

Dated: November 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26269 Filed 11–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[Docket No. IN–141–FOR]

Indiana 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 (OSM), are approving, with an additional requirement, an amendment to the Indiana regulatory program (Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Indiana proposed revisions to and additions of rules about definitions, identification of interests, topsoil, siltation structures, impoundments, refuse piles, prime farmland, lands eligible for re-mining, permitting, performance bond release, surface and ground water monitoring, roads, inspection, and civil penalties. Indiana intends to revise its program to be consistent with the corresponding Federal regulations, clarify ambiguities, and improve operational efficiency.

DATES: Effective: November 29, 2004.

FOR FURTHER INFORMATION CONTACT:

Andrew R. Gilmore, Chief, Alton Field Division. Telephone: (317) 226–6700. E-mail: IFOMAIL@osmre.gov.

SUPPLEMENTARY INFORMATION:

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

I. Background on the Indiana 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 State program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Indiana program effective July 29, 1982. You can find background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval, in the July 26, 1982, **Federal Register** (47 FR 32071). You can also find later actions concerning the Indiana program and program amendments at 30 CFR 914.10, 914.15, 914.16, and 914.17.

II. Submission of the Amendment

By letter dated May 19, 2004 (Administrative Record No. IND–1726), the Indiana Department of Natural Resources, Division of Reclamation (Indiana or IDNR) sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Indiana sent the amendment in response to a June 17, 1997, letter (Administrative Record No. IND–1575) that we sent to Indiana in accordance with 30 CFR 732.17(c) and in response to the required program amendments at 30 CFR 914.16(f), (s), and (hh) through (mm). The amendment also included changes made at Indiana's own initiative.

We announced receipt of the proposed amendment in the July 19, 2004, **Federal Register** (69 FR 42931). 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