

OMB under Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 3

Administrative practice and procedure, Biologics, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 3 is amended as follows:

PART 3—PRODUCT JURISDICTION

1. The authority citation for 21 CFR part 3 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360gg–360ss, 371(a), 379(e), 381, 394; 42 U.S.C. 216, 262.

■ 2. Section 3.1 is amended by revising the second sentence to read as follows:

§ 3.1 Purpose.

* * * The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Public Law 101–629) and amended by section 204 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug and a device; a device and a biological; a biological and a drug; or a drug, a device and a biological.* * *

■ 3. Section 3.2 is amended by revising paragraph (b) to read as follows:

§ 3.2 Definitions.

(b) *Agency component* means the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, or alternative organizational component of the agency.* * *

■ 4. Section 3.6 is revised to read as follows:

§ 3.6 Product jurisdiction officer.

The Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–827–9229, e-mail: combination@fda.gov, is the designated product jurisdiction officer.

■ 5. Section 3.7 is amended by adding a sentence to the end of paragraph (d) to read as follows:

§ 3.7 Request for designation.

(d) * * * Concurrent submissions of electronic copies of Requests for Designation may be addressed to combination@fda.gov.

■ 6. Section 3.9 is amended by revising the last sentence of paragraph (b) to read as follows:

§ 3.9 Effect of letter of designation.

(b) * * * A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

Dated: June 13, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 18

RIN 1219–AA98 (Phase 10)

Alternate Locking Devices for Plug and Receptacle-Type Connectors on Mobile Battery-Powered Machines

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: MSHA is amending the existing regulation by allowing the optional use of alternative locking devices to secure battery plugs to receptacles. The final rule eliminates the need to file petitions for modification to use this alternative means of securing battery plugs to receptacles.

MSHA initially proposed using direct final rulemaking for this action because the Agency expected that there would be no significant adverse comments on the rule. However, MSHA received four comments, one of which was considered a significant adverse comment, resulting in MSHA withdrawing the direct final rule and proceeding with rulemaking based on the concurrently published proposed rule on this subject.

EFFECTIVE DATE: This regulation is effective August 22, 2003.

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Jr., Director, Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Boulevard, Room 2352, Arlington, Virginia 22209–3939. Mr. Nichols can be reached at nichols-marvin@msha.gov (Internet e-mail), 202–693–9440 (voice),

or 202–693–9441 (fax). You may obtain copies of the final rule in alternative formats by calling this number. The alternative formats available are either a large print version of the final rule or the final rule in an electronic file on computer disk. The final rule also is available on the Internet at <http://www.msha.gov/REGSINFO.HTM>.

SUPPLEMENTARY INFORMATION

I. Background Information

Currently, under § 18.41 of Title 30, Code of Federal Regulations, MSHA sets forth design and construction requirements for plug and receptacle-type connectors used with permissible electric equipment approved under part 18. These technical requirements were last revised in March of 1968, which represented the latest advances in battery connector technology considered appropriate for use on mining equipment at that time.

Over the past thirty years, there have been technological improvements to the methods used for securing battery plugs to receptacles. Since the provisions of existing § 18.41(f) do not reflect the latest state-of-the-art technology, mine operators must file petitions for modification under section 101(c) of the Mine Act to take advantage of the technological advancements. Since 1980, there have been approximately 300 petitions filed and granted under section 101(c) requesting modification to 30 CFR 75.503 (Permissible electric face equipment; maintenance) and 18.41(f) (Plug and receptacle-type connectors) to allow the use of alternate locking devices. The means of securing battery connectors permitted under this final rule allow for the use of padlocks and other equally effective mechanical devices that preclude the inadvertent separation of the battery plug from the receptacle. The alternate locking devices permitted under this final rule also provide for at least the same measure of protection, as set forth in the existing regulation, and do not reduce protection to miners as required by section 101(a)(9) of the Mine Act.

In some operations, mine operators encountered difficulties with padlocks in both normal and emergency situations. The use of padlocks requires the maintenance of keys by authorized personnel. Due to the nature of mining operations, padlocks may become filled with mining debris, rendering them difficult or impossible to open with a key. Padlock keys can be misplaced, broken, or bent and may become unusable. This can go unnoticed by the operator until an emergency occurs, when the key may be unavailable or unusable. The removal of a padlock to