subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent the unavailability of supplemental oxygen to the flight attendant in the event of cabin decompression, which could result in loss of consciousness of the flight attendant, accomplish the following:

(a) Within 100 flight hours after the effective date of this AD, accomplish either paragraph (a)(1) or (a)(2) of this AD.

Airplane Flight Manual (AFM) Revision

(1) Revise the Limitations Section of EMBRAER EMB120 Brasilia Airplane Flight Manual AFM–120/794 to include the following information, and operate the airplane per those limitations (this may be accomplished by inserting a copy of this AD into the AFM):

''Maximum operating altitude is limited to 25,000 feet.''

(2) Accomplish either paragraph (a)(2)(i) or (a)(2)(ii) of this AD, as applicable.

Modification

(i) For airplanes listed in paragraph 1.1.1., Part I, of the effectivity of EMBRAER Service Bulletin 120–25–0264, Change 01, dated July 22, 2002: Replace the shock absorber of the flight attendant's seat with a new part, and install an oxygen bottle kit under the seat (including installing placards); per paragraph 2.1 of the Accomplishment Instructions of that service bulletin.

Rework

(ii) For airplanes listed in paragraph 1.1.2., Part II, of the effectivity of EMBRAER Service Bulletin 120–25–0264, Change 01, dated July 22, 2002: Rework the oxygen bottle kit (including installing placards and attaching the oxygen mask hose to the oxygen bottle), per paragraph 2.2 of the Accomplishment Instructions of that service bulletin.

AFM Revision

(b) Before further flight following the accomplishment of paragraph (a)(2) of this AD: Revise the Limitations Section of EMBRAER EMB120 Brasilia Airplane Flight Manual AFM–120/794 to include the following information, and operate the airplane per those limitations (this may be accomplished by inserting a copy of this AD into the AFM):

''Maximum operating altitude is limited to 30,000 feet.''

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) Unless otherwise specified in this AD, the actions shall be done in accordance with EMBRAER Service Bulletin 120–25–0264, Change 01, dated July 22, 2002. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in Brazilian airworthiness directive 2001–11–03 R1, dated September 13, 2002.

Effective Date

(f) This amendment becomes effective on July 28, 2003.

Issued in Renton, Washington, on June 11, 2003.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–15323 Filed 6–20–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 3

[Docket No. 2003N–0235]

Assignment of Agency Component for Review of Premarket Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its regulations concerning FDA's procedures for determining which component within FDA will have primary jurisdiction for the premarket review and regulation of a product composed of a combination of a drug, device, or biological product; or any drug, device, or biological product where the agency component with jurisdiction is unclear or in dispute. FDA is taking this action to implement the requirement of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) that FDA establish an office within FDA's Office of the Commissioner to ensure the prompt assignment of combination products to agency centers.

DATES: This rule is effective June 23, 2003.

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, 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.*

SUPPLEMENTARY INFORMATION:

I. Background

A combination product is a product containing a combination of a drug, a device, or a biological product. The Safe Medical Devices Act of 1990 (Public Law 101–629) added new section 503(g) (21 U.S.C. 353(g)) to the Federal Food, Drug, and Cosmetic Act (the act)), relating to combination products. This section requires that the agency assign a component of FDA to have primary jurisdiction for the premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product. It further requires FDA to make this assignment based upon a determination of the primary mode of action of the combination product. In the **Federal Register** of November 21, 1991 (56 FR 58754), FDA issued a final rule establishing the procedures for implementing section 503(g) in part 3 (21 CFR part 3).

MDUFMA amended section 503(g) of the act to require that FDA establish within its Office of the Commissioner an office to ensure: (1) The prompt assignment of combination products to agency centers, (2) the timely and effective premarket review of such products, and (3) consistent and appropriate postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law. New section 503(g)(4) further states that, in carrying out its duties, this office shall:

• Promptly assign an agency center with primary jurisdiction for the premarket review of the product. The office, in determining whether a product

is appropriately classified as a combination product, shall consult with the component within the Office of the Commissioner that is responsible for such determinations;

• Ensure timely and effective premarket reviews by overseeing the timeliness of and coordinating reviews involving more than one agency center;

• Ensure the consistency and appropriateness of postmarket regulation of like products subject to the same statutory requirements to the extent permitted by law;

• Address any dispute regarding the timeliness of the premarket review of a combination product, unless the dispute is clearly premature.

New section 503(g)(4)(F) of the act also directs the Secretary of Health and Human Services, through the new office, to review each agreement, guidance, or practice specific to the assignment of combination products to agency centers and to report annually to the appropriate committees of Congress on the activities and impact of the office.

On December 24, 2002, FDA established the Office of Combination Products to carry out the responsibilities under section 503(g) of the act and to perform other activities related to combination products. More information about the office is available at *http://www.fda.gov/oc/combination/.*

To enhance the efficiency of agency operations, the Office of Combination Products is assuming responsibility from the Office of the Ombudsman for designating the component of FDA with primary jurisdiction for the premarket review and regulation of any product requiring a jurisdictional designation under this part. Such decisions may involve determinations of: (1) The regulatory identity of a product as a drug, device, biologic, or combination product; (2) the agency component that will have jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute; and (3) the primary mode of action and assignment of a lead center for a combination product. The act requires the office, in determining whether a product is appropriately classified as a combination product, to consult with the component within the Office of the Commissioner that is responsible for such determinations. Since the Office of the Commissioner has now assigned to the Office of Combination Products the responsibility for such determinations, no separate consultation is necessary.

II. Summary of the Final Rule

FDA is making the following changes to part 3 to establish rules of agency organization, procedure, and practice, that are consistent with new section 503(g)(4) of the act and are otherwise clear and appropriate:

(1) FDA is amending § 3.1 to cite MDUFMA as an additional authority.

(2) FDA is amending § 3.2 to modify the definition of ''agency component'' to be consistent with definition of ''agency center'' provided in MDUFMA.

(3) FDA is amending § 3.6 to identify the Office of Combination Products as the agency's product jurisdiction officer.

(4) FDA is amending § 3.7 to provide information related to the submission of electronic copies of requests for designation concurrent with the submission of the official request.

(5) FDA is amending § 3.9 to reflect that a nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner. This change reflects the current organizational structure of FDA's Office of the Commissioner.

III. Authority for Issuing Final Rule

This rule provides an administrative mechanism to determine which agency component has responsibility for the review of an application. The agency determined that this is ''a matter relating to agency management'' and a rule of ''agency organization, procedure, or practice'' and, as such, is exempt from notice and comment under the Administrative Procedure Act (5 U.S.C. 553(a)(2) and (b)(A)). FDA also finds good cause under 5 U.S.C. 553(b)(B) and § 10.40(e) (21 CFR 10.40(e)) to forego notice and comment as it would be unnecessary and contrary to the public interest to delay implementation of this rule. As provided under FDA's administrative practices and procedures regulation (§ 10.40(e)), FDA is providing an opportunity for public comment on whether the regulation should be modified or revoked.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this rule 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.

V. Analysis of Impacts

Because this is a rule of agency organization, procedure, practice, and management that is issued as a final rule, and not as a proposed rule, the requirements of Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) do not apply. However, FDA has examined the impacts of this final rule under those provisions. 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. When applicable, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This rule is merely procedural in nature and imposes no new burdens on small entities. Indeed, the purpose of the procedures embodied in this rule is to expedite the review of combination products, and this final rule will not have a significant economic impact on a substantial number of small entities. Finally, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is required only for nonprocedural rules that impose costs of $110 million or more on either the private sector or state, local, and tribal governments in the aggregate. This rule imposes no such costs.

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 this final 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.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by

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.

[FR Doc. 03–15698 Filed 6–20–03; 8:45 am]

BILLING CODE 4160–01–S

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