this document would be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments re specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitting in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2004–18012/Airspace Docket No. 04–ACE–41.'' The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ACE NE E2 Chadron, NE

Chadron Municipal Airport, NE
(Lat. 42°50′15″ N., long. 103°05′44″ W.)
Whitney NDB
(Lat. 42°49′44″ N., long. 103°05′37″ W.)

Within a 5.7-mile radius of Chadron Municipal Airport and within 2.5 miles each side of the 021° bearing from Whitney NDB extending from the 5.7-mile radius of the airport to 7 miles northeast of the NDB. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE NE E5 Chadron, NE

Chadron Municipal Airport, NE
(Lat. 42°50′15″ N., long. 103°05′44″ W.)

That airspace extending upward from 700 feet above the surface within a 10.7-mile radius of Chadron Municipal Airport.

* * * * *

Issued in Kansas City, MO, on June 10, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–14202 Filed 6–22–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 870, and 882

[Docket No. 2003N–0468]

Medical Devices; Effective Date of Requirement for Premarket Approval for Three Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is requiring the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following three class III preamendments devices: Indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, and the ocular plethysmograph. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.

DATES: This rule is effective June 23, 2004. Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before September 21, 2004, for any indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, or ocular plethysmograph that was in commercial

distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before September 21, 2004.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295) and the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

When a rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III devices that are the subjects of this regulation.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the 1976 amendments states that:

> [t]he thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).

In the **Federal Register** of November 18, 2003 (68 FR 65014) (the November 18, 2003, proposed rule), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the indwelling blood oxyhemoglobin concentration analyzer, the cardiopulmonary bypass pulsatile flow generator, and the ocular plethysmograph. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposed rule the agency's proposed findings regarding the degree of risk of illness or injury intended to be eliminated or reduced by requiring the device to meet the statute's approval requirements as well as the benefits to the public from use of the device.

The November 18, 2003, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. In accordance with section 515(b)(2)(A) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of these devices was required to be submitted by December 3, 2003. The comment period closed February 17, 2004.

FDA received no petitions requesting a change in the classification of any of the three devices. One comment was addressed to the docket of the proposed rule. This comment inquired as to when FDA would approve a certain device that was not one of the devices that were the subject of the November 18, 2003, proposed rule. The comment was irrelevant and FDA addressed it outside of the rulemaking process.

II. Devices Subject to This Proposal

A. Indwelling Blood Oxyhemoglobin Concentration Analyzer (21 CFR 868.1120)

An indwelling blood oxyhemoglobin concentration analyzer is a photo electric device used to measure, in vivo, the oxygen carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

B. Cardiopulmonary Bypass Pulsatile Flow Generator (21 CFR 870.4320)

A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

C. Ocular Plethysmograph (21 CFR 882.1790)

An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

III. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the November 18, 2003, proposed rule. As required by section 515(b) of the act, FDA published its findings regarding the following information: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the

advisory committees (panels) for the classification of these devices along with any additional information that FDA has discovered. Additional information can be found in the following proposed and final rules published in the **Federal Register** on these dates: Anesthesiology devices, 21 CFR part 868 (44 FR 63292, November 2, 1979, and 47 FR 31130, July 16, 1982); cardiovascular devices, 21 CFR part 870 (44 FR 13284, March 9, 1979 and 45 FR 7903, February 5, 1980); and neurological devices, 21 CFR part 882 (43 FR 55639, November 28, 1978, and 44 FR 51725, September 4, 1979).

IV. The Final Rule

Under section 515(b)(3) of the act, FDA adopts the findings as published in the preamble of the November 18, 2003, proposed rule and issues this final rule to require premarket approval of the indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, and the ocular plethysmograph. This final rule revises parts 868, 870, and 882 (21 CFR parts 868, 870, and 882).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed within 90 days after date of publication of this rule in the **Federal Register** (see **DATES**), for any indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, or ocular plethysmograph that was in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before that date. If a PMA or notice of completion of a PDP is filed for any such device within this time limit, the applicant will be permitted to continue marketing its device during FDA's review of its submission. Any other indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, or ocular plethysmograph that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for an indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, or ocular plethysmograph is not filed on or before 90 days after date of publication of this rule in the **Federal Register**, that device is deemed adulterated under section 501(f)(1)(A) of the act, and commercial distribution of the device must cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (part 812) are met.

The exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices cease to apply to any indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, or ocular plethysmograph that is: (1) Not legally on the market 90 days after date of publication of this rule in the **Federal Register**; or (2) legally on the market by, but for which a PMA or notice of completion of a PDP is not filed by 90 days after date of publication of this rule in the **Federal Register**, or for which PMA approval has been denied or withdrawn. FDA cautions that manufacturers who are not immediately planning to submit a PMA or notice of completion of a PDP should submit IDE applications to FDA by 60 days after date of publication of this rule in the **Federal Register**, to minimize the possibility of interrupting shipment of the device. At this time, FDA is not aware of any firm that is marketing these devices.

V. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on the following requirements: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence ''obtained from well-controlled clinical studies, with detailed data,'' in order to provide reasonable assurance of the safety and effectiveness of the device for its intended use. (See 21 CFR 860.7(c)(2)).)

Information about the premarket approval process is available from FDA's Center for Devices and Radiological Health (CDRH) on the Internet at *http://www.fda.gov/cdrh/devadvice/pma/.*

VI. PDP Requirements

A PDP for any of these devices may be submitted in lieu of a PMA, and must follow the procedures outlined in section 515(f) of the act. A PDP should provide the following information: (1) A description of the device, (2) preclinical trial information (if any), (3) clinical trial information (if any), (4) a description of the manufacturing and processing of the devices, (5) the labeling of the device, and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought.

Information about the PDP process is also available from CDRH on the on the Internet at *http://www.fda.gov/cdrh/devadvice/pma/app__methods.html#product__dev.*

VII. Environmental Impact

The agency has 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.

VIII. Analysis of Impacts

FDA has examined the impacts of the final rule under 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). 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 not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because there have been no premarket submissions for these devices in the past 5 years, and because FDA is not aware of any firms marketing these devices, the agency has concluded that there is little or no interest in marketing these devices. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and

benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). The burden hours required for § 884.5320(c), included in the collection entitled ''Premarket Approval of Medical Devices—21 CFR Part 814,'' are reported and approved under OMB control number 0910–0231. Therefore, clearance by OMB under the PRA is not required.

List of Subjects in 21 CFR Parts 868, 870, and 882

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 868, 870, and 882 are amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 868.1120 is amended by revising paragraph (c) to read as follows:

§ 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.

* * * * *

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any indwelling blood oxyhemoglobin concentration analyzer that was in commercial distribution before May 28, 1976, or that has, on or before September 21, 2004, been found to be substantially equivalent to an indwelling blood oxyhemoglobin concentration analyzer that was in commercial distribution before May 28, 1976. Any other indwelling blood oxyhemoglobin concentration analyzer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 870—CARDIOVASCULAR DEVICES

■ 3. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 4. Section 870.4320 is amended by revising paragraph (c) to read as follows:

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

* * * * *

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976, or that has, on or before September 21, 2004, been found to be substantially equivalent to any cardiopulmonary bypass pulsatile flow generator that was in commercial distribution before May 28, 1976. Any other cardiopulmonary bypass pulsatile flow generator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 882—NEUROLOGICAL DEVICES

■ 5. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 6. Section 882.1790 is amended by revising paragraph (c) to read as follows:

§ 882.1790 Ocular plethysmograph.

* * * * *

(c) Date PMA or notice of completion of PDP is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 21, 2004, for any ocular plethysmograph that was in commercial distribution before May 28, 1976. Any other ocular plethysmograph shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 14, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14126 Filed 6–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AA60

Health Care Continuation Coverage, Correction

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Final rule, technical corrections.

SUMMARY: The Department published in the **Federal Register** of May 26, 2004, (69 FR 30084) final rules implementing the notice requirements of the health care continuation coverage (COBRA) provisions of part 6 of title I of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). This document makes technical corrections to one of the final rules and to a model notice published in an appendix to one of the final rules.

DATES: *Effective date:* The regulations that are being corrected are effective on July 26, 2004, and these corrections are effective July 26, 2004.

Applicability date: The regulations that are being corrected apply to notice obligations arising under the COBRA provisions of part 6 of title I of ERISA on or after the first day of the first plan year beginning on or after the date that is six months after May 26, 2004.

FOR FURTHER INFORMATION CONTACT: Lisa M. Alexander or Suzanne M. Adelman, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693-8500. this is not a toll-free number.

SUPPLEMENTARY INFORMATION: On May 26, 2004, the Department of Labor published final regulations on the notice provisions of part 6 of title I of ERISA. The regulations comprise four sections. Section 2590.606–1 establishes the time frames within which the general notice of continuation coverage must be provided and describes the specific information that the general notice must contain. Paragraph (d) of § 2590.606–1 permits delivery of a single notice addressed to a covered employee and the covered employee's spouse at their joint residence, provided that the plan's latest information indicates that both reside at that address. paragraph (d) states, on page 30097, that ''nothing in this section shall be construed to create a requirement to provide a separate notice to dependent children who share a residence with a covered employer or a covered employee's spouse to whom notice is provided in accordance with