Background

The final regulations published March 29, 2007, changed cross-references in 20 CFR 402.35(b)(2) from §§ 404.984(b), 410.610c(b) and 416.1484(b) to §§ 404.985(c), 410.670c(b) and 416.1485(c), respectively. However, two of the new cross-references, §§ 404.985(c) and 416.1485(c) should have been §§ 404.985(b) and 416.1485(b). In addition, we omitted another set of corrections in the same CFR section. The next-to-last sentence incorrectly cites 20 CFR 404.984, 410.610, and 416.1484, which should correctly read as 20 CFR 404.985(c), 410.670c, and 416.1485(c), respectively.

Need for Correction

As published, the final regulations contained errors at 20 CFR 402.35(b)(2). Therefore, we are changing the last two sentences of that section to reflect correct CFR citations and cross-references.

(Catalog of Federal Domestic Assistance Programs Nos. 96.001 Social Security—Disability Insurance; 96.002 Social Security—Retirement Insurance; 96.004 Social Security—Survivors Insurance and 96.006 Supplemental Security Income.)

List of Subjects in 20 CFR Part 402

Administrative practice and procedure; Freedom of information.

Dated: June 27, 2007.

Paul Kryglik,

Acting SSA Regulations Officer.

■ Accordingly, part 402 of chapter III of title 20 of the Code of Federal Regulations is corrected by making the following correcting amendments:

PART 402—AVAILABILITY OF INFORMATION AND RECORDS TO THE PUBLIC

■ 1. The authority citation for part 402 continues to read as follows:

Authority: Secs. 205, 702(a)(5), and 1106 of the Social Security Act; (42 U.S.C. 405, 902(a)(5), and 1306); 5 U.S.C. 552 and 552a; 8 U.S.C. 1360; 18 U.S.C. 1905; 26 U.S.C. 6103; 30 U.S.C. 923(b); 31 U.S.C. 9701; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

■ 2. Section 402.35 is being corrected by revising the second and third sentences of paragraph (b)(2) to read as follows:

§ 402.35 Publication.

* * * * *

(b) * * *

(2) * * * They are binding on all components of the Social Security Administration, except with respect to claims subject to the relitigation procedures established in 20 CFR 404.985(c), 410.670c, and 416.1485(c). For a description of Social Security Acquiescence Rulings, see 20 CFR 404.985(b), 410.670c(b), and 416.1485(b) of this title.

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[FR Doc. E7–12828 Filed 7–2–07; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 2007N–0198]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the filtering facepiece respirator for use by the general public in public health medical emergencies into class II (special controls). The agency is classifying these devices into class II (special controls) in order to provide a reasonable assurance of the safety and effectiveness of these devices and is specifying what those special controls are.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document entitled, ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies.'' This guidance document will serve as one of the special controls, along with certification of the respirator by the National Institute for Occupational Safety and Health (NIOSH) in accordance with its regulations for non-powered air-purifying particulate respirators, found in 42 CFR part 84, as specified in the classification regulation.

DATES: This rule is effective August 2, 2007. The classification was effective May 8, 2007.

FOR FURTHER INFORMATION CONTACT: Sheila A. Murphey, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3700.

SUPPLEMENTARY INFORMATION:

I. What is the Background of this Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless the device is classified or reclassified into class I or class II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on August 30, 2006, classifying the two 3M filtering facepiece respirators intended for use by the general public in public health medical emergencies (designated at that time as the 3M™ N95 Home Respirator with Fluid Resistance and 3M™ N95 Home Respirator) in class III, because each device was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On October 3, 2006, 3M Inc. submitted a petition requesting initial classification of these devices under section 513(f) (2) of the act. The manufacturer recommended that the

devices be classified into class II (Ref. 1). In response to FDA requests for additional information, 3M supplemented its petition on March 22, 2007.

In accordance with section 513(f) (2) of the act, FDA reviewed the petition in order to classify the devices under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition and its supplements, FDA determined that the 3M™ filtering facepiece respirator devices, now known as the 3M™ 8612F Respirator for Use by the General Public in Public Health Medical Emergencies and 3M™ 8670F Respirator for Use by the General Public in Public Health Medical Emergencies can be classified into class II with the establishment of special controls. FDA believes that special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish special controls to provide such assurance.

The device is assigned the generic name ''Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies'' and is identified as a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

FDA believes that special controls are needed to help address the following issues affecting the safety and effectiveness of the filtering facepiece respirator for use by the general public in public health medical emergencies.

A. Assuring Filtration and Breathability

For this type of respirator to reduce wearer exposure to pathogenic biological airborne particulates, it must be made of filter material that is highly efficient in filtering such particles. At the same time, because this type of device depends on the wearer's normal respiration to draw ambient air through the respirator materials and into the lungs, the respirator material must also permit adequate respiration.

B. Assuring Proper Fit

The device must fit closely to the wearer's face without any gaps that would allow air to reach the wearer's respiratory tract without passing through the filter material. Otherwise, improper fit of the respirator could result in inhalation of pathogenic biological airborne particulates carried in air that passes around the sides of the device.

C. Avoiding Adverse Skin Reaction

Reducing wearer exposure to pathogenic biological airborne particulates requires that the device be properly fitted to the face. If the respirator material in contact with the skin is not biocompatible, it may cause adverse reactions such as redness, pruritus, and skin irritation.

D. Assuring Proper Use

While a filtering facepiece respirator for use by the general public in public health medical emergencies can help to reduce wearer exposure to pathogenic biological airborne particulates in a public health medical emergency where there is a serious risk from such exposure, these devices do not provide complete protection against infection. Even when used correctly and consistently, a filtering facepiece respirator does not eliminate all respiratory exposure, and for many pathogens that may be transmitted through airborne particulates, transmission via other routes is also possible. (Because filtering facepiece respirators for use by the general public in public health medical emergencies have not been tested against specific microorganisms, the extent of protection to be expected against specific pathogens is not known and would vary with particular conditions in any event.)

The respirator should always be used in conjunction with other infection control and respiratory protection measures. In addition, because the outside of the respirator may be contaminated with infectious materials during normal use, proper handling and disposal is important to avoid the respirator itself becoming a vector of transmission of infectious agents.

Further, failure of the user to assure proper fit of the respirator could result in exposure to pathogenic biological airborne particles. Certain populations such as children will be unlikely to achieve a proper fit because respirators are designed and sized for adults.

For users with certain underlying cardiac, pulmonary or related medical conditions, achieving the fit necessary to help reduce their exposure to pathogenic biological airborne particulates may exacerbate their underlying medical conditions raising a concern about their safe use for these populations.

Finally, these respirators have not been established to be safe or effective if reused, and use of a single respirator by multiple users may result in the respirator itself becoming a vector of transmission.

To address these issues, the class II special controls guidance document provides recommendations for labeling and for information to be provided to meet premarket notification (510(k)) submission requirements for the device, including recommendations for fit testing and biocompatibility testing. In addition, this classification regulation specifies another special control, certification of the respirator by NIOSH as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84. The respirators that were the subject of the initial classification order described in this document and that are the initial legal predicate devices for this new device classification were certified by NIOSH under these requirements, as revised as of October 1, 2006. FDA's determination that NIOSH certification is an appropriate special control to help assure the safety and effectiveness of the respirator for its intended use under this classification rests on the assurance of filtration efficiency and breathability provided by NIOSH certification under these requirements, as effective on May 8, 2007, the date of FDA's classification order. Should NIOSH revise the requirements for certification in the future, FDA will evaluate whether certification under such revised NIOSH regulations is an appropriate special control for devices within this classification and may revise FDA's regulation using appropriate procedures.

FDA believes that these special controls, designated in this rule, in addition to general controls, address the issues identified previously and provide reasonable assurance of the safety and effectiveness of the device type. Thus, on May 8, 2007, FDA issued an order to the petitioner classifying the device type into class II. FDA is codifying this classification at 21 CFR 880.6260.

Following the effective date of the final classification rule, manufacturers will need to demonstrate NIOSH certification of any filtering facepiece respirator for use by the general public in public health medical emergencies,

as set forth in 21 CFR 880.6260(b)(1), and address the issues covered in the special controls guidance. With respect to the issues addressed only in the special control guidance, however, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For filtering facepiece respirators for use by the general public in public health medical emergencies, however, FDA has determined that premarket review of fit performance data, labeling, and other requirements as outlined in 21 CFR 807.87, is necessary to provide reasonable assurance that acceptable levels of performance for both safety and effectiveness will be addressed before marketing clearance. Thus, persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device type.

II. What is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Thus, neither an environmental assessment nor an environmental impact statement is required.

III. What is the Economic Impact of This Rule?

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 as defined by 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 classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency 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 $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1–year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

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.

V. How Does This Rule Comply with the Paperwork Reduction Act of 1995?

This final rule contains no new information collection provisions but refers to NIOSH regulations in 42 CFR part 84 that contain information collection provisions that have been reviewed and approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), under OMB Control No. 0920–0109. Based on information from NIOSH regarding submissions for respirator certification received in the past 3 years, FDA concludes that specification of NIOSH certification as a special control will not result in the collection of any additional information by NIOSH not already covered by NIOSH's burden estimates. This final rule also designates a guidance document as a special control. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of that guidance document, ''Class II Special Controls Guidance Document: Filtering Facepiece Respirators for Use by the General Public in Public Health Medical Emergencies,'' which contains a Paperwork Reduction Act analysis for that guidance.

VI. What References are on Display?

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from 3M.

2. 42 CFR part 84, as revised as of October 1, 2006.

List of Subjects in 21 CFR part 880

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 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for 21 CFR part 880 continues to read as follows:

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

■ 2. Section 880.6260 is added to subpart G to read as follows:

§ 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies.

(a) *Identification.* A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

(b) *Classification.* Class II (special controls). The special controls are:

(1) Certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-

purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.

(2) The FDA guidance document entitled: ''Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies.'' See § 880.1(e) for information on obtaining a copy of this guidance document.

Dated: June 22, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–12789 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2006–0510; FRL–8334–4]

RIN 2060–AO46

Amendments to National Emission Standards for Hazardous Air Pollutants for Primary Copper Smelting and Secondary Copper Smelting Area Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to amend the national emission standards for primary copper smelting area sources and secondary copper smelting area sources published on January 23, 2007. The amendments to the national emission standards for primary copper smelting area sources clarify when plants must exhaust gases to a control device and what control devices may be used for this requirement; numbering errors are also corrected. The amendments to the national emission standards for secondary copper smelting area sources clarify the date which defines a new copper smelter and correct a cross-referencing error.

DATES: This direct final rule is effective on October 1, 2007 without further notice, unless EPA receives adverse comment by August 2, 2007. If the effective date is delayed, timely notice will be published in the **Federal Register**. If we receive adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that some or all of the amendments in this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2006–0510 by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: a-and-r-docket@epa.gov.*
- *Fax:* (202) 566–1741.
- *Mail:* National Emission Standards for Hazardous Air Pollutants for Four Area Source Categories Docket, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies.
- *Hand Delivery:* EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2006–0510. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or e-mail. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the National Emission Standards for Hazardous Air Pollutants for Four Area Source Categories Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Ms. Sharon Nizich, Sector Policies and Programs Division, Office of Air Quality Planning and Standards (D243–02), Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number: (919) 541–2825; fax number: (919) 541–3207; e-mail address: *nizich.sharon@epa.gov.*

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows: