**List of Subjects in 21 CFR Part 573**

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

## PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 348.

2. Section 573.920 is amended by revising paragraph (h) to read as follows:

**§ 573.920 Selenium.**

* * * * *

(h) The additive selenium yeast is added to complete feed for chickens, turkeys, and swine at a level not to exceed 0.3 part per million. Usage of this additive must conform to the requirements of paragraphs (d)(1), (e), and (f) of this section.

Dated: July 1, 2002.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 02–17959 Filed 7–16–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 868

**[Docket No. 00N–1457]**

## Medical Devices; Apnea Monitor; Special Controls

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule to create a separate classification for the apnea monitor. The device currently is included in the generic type of device called breathing frequency monitors. The apnea monitor will remain in class II, but will be subject to a special control. The special control is an FDA guidance document that identifies minimum performance, testing, and labeling recommendations for the device. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a ''new'' apnea monitor will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control. FDA is taking these actions because it believes that they are necessary to provide reasonable assurance of the safety and effectiveness of the apnea monitor.

**DATES:** This rule is effective October 15, 2002.

**FOR FURTHER INFORMATION CONTACT:** Joanna H. Weithershausen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 164.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of September 22, 2000 (65 FR 57301), FDA published a proposed rule to create a separate classification for the apnea monitor. FDA proposed that the apnea monitor remain in class II, but be subject to a special control. The proposed special control was an FDA guidance document that identified minimum performance, testing, and labeling recommendations for the device.

In the same edition of the **Federal Register**, FDA withdrew its proposed mandatory standard for infant apnea monitors (65 FR 57303) and announced the availability of the draft guidance that FDA intended to serve as the special control for the device (65 FR 57355).

FDA invited interested persons to comment on the proposed rule by December 21, 2000. FDA received no comments. Based on a review of the available information, referenced in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA concludes that special controls, in conjunction with general controls, provide reasonable assurance of the safety and effectiveness of this device. FDA has made some revisions to the identification paragraphs in §§ 868.2375 and 868.2377 for clarity. Otherwise, FDA is finalizing the rule as proposed. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the special control guidance.

### II. Environmental Impact

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. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### III. Analysis of Impacts

FDA has examined the impact of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), 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 consistent with the regulatory philosophy and principles identified in the Executive order. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a ''new'' apnea monitor will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. In the past 10 years, the agency estimates that it has received, on average, approximately four 510(k) submissions per year for breathing frequency monitor devices. FDA estimates that only one or two of these submissions per year pertained to apnea monitor devices.

Based on its review of these 510(k) submissions, FDA believes that presently marketed apnea monitors conform to the guidance and, therefore, the manufacturers of these devices will not have to take further action because of this rule. New manufacturers of apnea monitors will only need to submit 510(k)s, as the statute now requires them to do, and demonstrate that they meet the recommendations of the guidance or in some other way provide equivalent assurances of safety and effectiveness. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action will

not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

**IV. 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.

**V. Paperwork Reduction Act of 1995**

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**List of Subjects in 21 CFR Part 868**

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 868 is amended to read 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 868.2375(a) is revised to read as follows:

**§ 868.2375 Breathing frequency monitor.**

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device intended to measure or monitor a patient's respiratory rate. The device may provide an audible or visible alarm when the respiratory rate, averaged over time, is outside operator settable alarm limits. This device does not include the apnea monitor classified in § 868.2377.

* * * * *

3. Section 868.2377 is added to subpart C to read as follows:

**§ 868.2377 Apnea monitor.**

(a) *Identification.* An apnea monitor is a complete system intended to alarm primarily upon the cessation of breathing timed from the last detected breath. The apnea monitor also includes indirect methods of apnea detection such as monitoring of heart rate and other physiological parameters linked to the presence or absence of adequate respiration.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA.''

Dated: July 5, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02–17957 Filed 7–16–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 888

**[Docket No. 02P–0294]**

## Medical Devices; Reclassification of Polymethylmethacrylate (PMMA) Bone Cement

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it has reclassified the polymethylmethacrylate (PMMA) bone cement intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone from class III to class II (special controls). The agency is also announcing that it has issued an order in the form of a letter to the Orthopedic Surgical Manufacturers Association (OSMA) reclassifying the device. The special control for the device is a guidance document entitled ''Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement.'' The agency is reclassifying this device into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls.

**DATES:** The reclassification was effective October 14, 1999. The revision of § 888.3027 is effective August 16, 2002.

**FOR FURTHER INFORMATION CONTACT:** Hany W. Demian, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Public Law 105–115), 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).

The 1976 amendments broadened the definition of ''device'' in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices, i.e., those devices previously regulated as new drugs, including the PMMA bone cement, into class III. The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 27 (1990)). Congress amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). Accordingly, in the **Federal Register** of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, requiring manufacturers of transitional devices, including the PMMA bone cement (21 CFR 888.3027), to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information which had not been submitted under section 519 of the act