application is deemed by the Bank to be complete, and shall maintain a copy of such letter in the applicant's membership file. The Bank shall notify an applicant if the 60-day clock is stopped, and when the clock is resumed, and shall maintain a written record of such notifications in the applicant's membership file. * * *

* * * * *

8. Section 933.4 is amended by adding paragraph (d) to read as follows:

§ 933.4 Automatic membership.

* * * * *

(d) *Automatic membership, in the Bank's discretion, for certain consolidations.* (1) If a member institution (or institutions) and a nonmember institution are consolidated and the consolidated institution has its principal place of business in a state in the same Bank district as the disappearing institution (or institutions), and the consolidated institution will operate under the charter of the nonmember institution, on the effective date of the consolidation, the consolidated institution may, in the discretion of the Bank of which the disappearing institution (or institutions) was a member immediately prior to the effective date of the consolidation, automatically become a member of such Bank upon the purchase of stock in that Bank pursuant to § 933.20, provided that:

(i) 90 percent or more of the total assets of the consolidated institution are derived from the total assets of the disappearing member institution (or institutions); and

(ii) The consolidated institution provides written notice to such Bank, within 60 calendar days after the effective date of the consolidation, that it desires to be a member of the Bank.

(2) The provisions of § 933.25(d)(1)(i) shall apply, and upon approval of automatic membership by the Bank, the provisions of §§ 933.25(d)(2)(i), (e) and (f) shall apply.

9. Section 933.11 is amended by revising paragraphs (b)(3)(i)(B) and (b)(3)(i)(C) to read as follows:

§ 933.11 Financial condition requirement for applicants other than insurance companies.

* * * * *

(b) * * *

(3) * * *

(i) * * *

(B) *Nonperforming assets.* The applicant's nonperforming loans and leases plus other real estate owned, did not exceed 10 percent of its total loans and leases plus other real estate owned, in the most recent calendar quarter; and

(C) *Allowance for loan and lease losses.* The applicant's ratio of its allowance for loan and lease losses plus the allocated transfer risk reserve to nonperforming loans and leases was 60 percent or greater during 4 of the 6 most recent calendar quarters.

* * * * *

10. Section 933.14 is amended by removing the heading for paragraph (a), revising paragraph (a)(1), and removing and reserving paragraph (b), as follows:

§ 933.14 De novo insured depository institution applicants.

(a)(1) *Duly organized, subject to inspection and regulation, financial condition and character of management requirements.* An insured depository institution applicant whose date of charter approval is within three years prior to the date the Bank receives the applicant's application for membership in the Bank, is deemed to meet the requirements of §§ 933.7, 933.8, 933.11 and 933.12.

* * * * *

11. Section 933.15 is amended by adding new paragraph (c) to read as follows:

§ 933.15 Recent merger or acquisition applicants.

* * * * *

(c) *Makes long-term home mortgage loans requirement; 10 percent requirement.* For purposes of determining compliance with §§ 933.9 and 933.10, a Bank may, in its discretion, permit an applicant that, as a result of a merger or acquisition preceding the date the Bank receives its application for membership, has not yet filed a consolidated regulatory financial report as a combined entity with its appropriate regulator, to provide the combined pro forma financial statement for the combined entity filed with the regulator that approved the merger or acquisition.

* * * * *

§ 933.20 [Amended]

12. Section 933.20 is amended by removing the citation ''§ 933.4(a)'' in paragraphs (b)(1) and (b)(2) and adding the citation ''§ 933.4(a) or (d)'' in its place.

Dated: June 24, 1998.

By the Board of Directors of the Federal Housing Finance Board.

Bruce A. Morrison,

Chairman.

[FR Doc. 98–19912 Filed 7–24–98; 8:45 am]

BILLING CODE 6725–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98N–0274]

Food Labeling; Petitions for Nutrient Content and Health Claims, General Provisions; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of May 14, 1998 (63 FR 26717). The document amended FDA's regulations to define the conditions under which certain petitions for nutrient content and health claims shall be deemed to be denied and to codify the statutory timeframe within which the agency will complete rulemakings on such petitions. The document was published with some errors. This document corrects those errors.

DATES: Effective July 27, 1998.

FOR FURTHER INFORMATION CONTACT: Hilario R. Duncan, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8281.

In FR Doc. 98–12832, appearing on page 26717 in the **Federal Register** of Thursday, May 14, 1998, the following corrections are made:

1. On page 26718, in the first column, in the first paragraph under **Supplementary Information**, beginning in the thirtieth line, the phrase ''to include the statutory language, i.e., 'Secretary' is replaced with 'FDA'" is corrected to read ''by inserting the statutory language (with 'Secretary' replaced by 'FDA')''.

§ 101.69 [Corrected]

3. On page 26719, in the first column, in paragraph (m)(3), in the fifteenth line, the phrase ''denied without filing,'' is corrected to read ''denied, without filing''.

4. On page 26719, in the first column, in paragraph (m)(4)(iii), in the second line, the phrase ''of the filing date'' is corrected to read ''of the date of filing''.

§ 101.70 [Corrected]

5. On page 26719, in the second column, in paragraph (j)(3)(iii), in the second line, the phrase ''of the filing date'' is corrected to read ''of the date of filing''.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19895 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 95N–0176]

RIN 0910–ZA12

Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying certain previously unclassified preamendments pedicle screw spinal systems into class II (special controls) and reclassifying certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. FDA is taking this action because it believes that special controls would provide reasonable assurance of safety and effectiveness. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: August 26, 1998.

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

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I. Background

The act (21 U.S.C. 331 *et seq.*), as amended by the 1976 amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 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).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) 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 previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA promulgates a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).) FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of