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E.O. 12866. It has been determined that the proposed rulemaking is not significant for purposes of Executive Order 12866.

List of Subjects in 15 CFR Part 303

Administrative practice and procedure, American Samoa, Customs duties and inspection, Guam, Imports, Marketing quotas, Northern Mariana Islands, Reporting and record keeping requirements, Virgin Islands, Watches and jewelry.

For reasons set forth above, the Departments propose to amend 15 CFR Part 303 as follows:

PART 303—WATCHES, WATCH MOVEMENTS AND JEWELRY PROGRAMS

1. The authority citation for 15 CFR Part 303 continues to read as follows:

Authority: Pub. L. 97-446, 96 Stat. 2331 (19 U.S.C. 1202, note); Pub. L. 103-465, 108 Stat. 4991; Pub. L. 94-241, 90 Stat. 263 (48 U.S.C. 1681, note); Pub. L. 106-36, 113 Stat. 167.

§ 303.14 [Amended]

2. Section 303.14 is amended by removing “\$500” from the first sentence of paragraph (b)(3) and adding “\$800” in its place.

James J. Jochum,

Assistant Secretary for Import Administration, Department of Commerce.

Nikolao Pula,

Acting Deputy Assistant Secretary for Insular Affairs, Department of the Interior.

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JOINT BOARD FOR THE ENROLLMENT OF ACTUARIES

20 CFR Part 901

[REG-159704-03]

RIN 1545-BC82

Regulations Governing the Performance of Actuarial Services Under the Employee Retirement Income Security Act of 1974: Solicitation for Comments

AGENCY: Joint Board for the Enrollment of Actuaries.

ACTION: Solicitation for comments.

SUMMARY: The Joint Board for the Enrollment of Actuaries (Joint Board) is seeking public comments regarding possible revisions to the regulations governing actuarial services under the Employee Retirement Income Security Act of 1974, as amended (ERISA).

DATES: Comments are requested on or before September 28, 2004.

ADDRESSES: Send written comments to: Internal Revenue Service; Attn: SE:OPR (Joint Board regulations); 1111 Constitution Avenue, NW., Washington, DC 20224. Comments may be submitted electronically at www.irs.gov/regs or via the Federal eRulemaking portal www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Elizabeth Van Osten, (202) 622-8257 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The Joint Board for the Enrollment of Actuaries (Joint Board) was established on October 31, 1974, pursuant to section 3041 of the Employee Retirement Income Security Act of 1974 (ERISA). Section 3042 of ERISA provides that the Joint Board shall, by regulations, establish reasonable standards and qualifications for persons performing actuarial services under ERISA and enroll qualified actuaries. It also provides that the Joint Board may, after notice and an opportunity for a hearing, suspend or terminate the enrollment of an actuary who fails to discharge his or her duties under ERISA or who does not satisfy the requirements for enrollment.

Consistent with section 3042 of ERISA, the Joint Board has promulgated regulations, addressing eligibility for enrollment, requirements for continuing education of enrolled actuaries, professional standards for performance of actuarial services under ERISA, bases for disciplinary actions and the procedures to be followed in taking those actions. Those regulations are found at 20 CFR part 901 and were last amended in 1988.¹

Comments

In recent years, the Joint Board has noted that changes in the actuarial profession, as well as modern innovations, such as the availability of alternative modes of training, are not adequately addressed in the regulations, thus necessitating revision of the regulations.

¹ 40 FR 18776 (April 30, 1975); 42 FR 39200 (August 3, 1977); 43 FR 39757 (September 7, 1978); 44 FR 11751 (March 2, 1979); 44 FR 68458 (November 29, 1979); 53 FR 34484 (September 7, 1988).

Prior to issuing proposed regulations, the Joint Board wishes to obtain comments from the public regarding matters for consideration, including but not limited to the following areas:

(1) Whether and to what extent the provisions in the current regulations on the procedures and conditions for enrollment and renewal of enrollment should be updated or revised, including provisions on qualifying experience, the structure and content of the basic and pension examinations, the completion of professional society examinations and qualifying formal education in lieu of the basic and pension examinations, and the definitions of terms used in the regulations.

(2) Whether and to what extent provisions in the current regulations on Continuing Professional Education (CPE) should be updated or revised, including those relevant to formal and informal programs, the means for measuring attendance and completion, and acceptability of new technologies (computer-based programs, webcasts, recorded telecasts, audiotapes, videotapes, etc.).

(3) Whether and to what extent provisions in the current regulations relevant to waivers of the CPE requirement should be updated or revised, including the circumstances, conditions, and limitations under which a waiver might be granted.

(4) Whether and to what extent provisions in the current regulations on the types of enrollment statuses (active, inactive, retired) should be updated or revised, including the incorporation of limitations on the number of consecutive enrollment cycles during which an individual may be placed in either inactive or retired status.

(5) Whether and to what extent provisions in the current regulations relevant to standards of conduct, performance and practice that relate to enrolled actuaries' duties under ERISA should be updated or revised, including those relevant to conflicts of interest, professional independence, disciplinary procedures, and sanctions.

The Joint Board is also interested in obtaining information regarding the potential costs and benefits of any changes to the current regulations, including the potential impact of such changes on small entities. Therefore, in submitting comments in response to this notice, commentators are encouraged to include information with regard to the potential costs, benefits, and impact of any suggested regulatory changes for small businesses.

All comments submitted will be made available for public inspection and copying, although comments will not be

individually acknowledged. Therefore, commentators should refrain from including personal information or other information that they believe should not be publicly disclosed. Additionally, in submitting comments with regard to some or all of the listed areas, please refer to the item numbers specified above.

Martin L. Pippins,

Chairman, Joint Board for the Enrollment of Actuaries.

[FR Doc. 04-14719 Filed 6-29-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2002P-0520]

Dental Devices; Tricalcium Phosphate Granules and Other Bone Grafting Material for Dental Bone Repair

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify tricalcium phosphate (TCP) granules for dental bone repair from class III to class II (special controls); classify into class II (special controls) all other bone grafting material for dental indications, except those that contain drug or biologic components; and revise the classification name and identification of the device. Bone grafting materials that contain a drug or biologic component would remain in class III. The proposed classification identification includes materials such as hydroxyapatite, demineralized bone additives, collagen, and polylactic acids. After considering public comments on the proposed reclassification and classification, FDA will publish a final regulation, if appropriate. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that the agency proposes to use as a special control for the device.

DATES: Submit written or electronic comments by September 28, 2004. See section VI of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by Docket No. 2002P-0520, by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include Docket No. 2002P-0520 in the subject line of your e-mail message.
- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/dockets/ecomments>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/dockets/ecomments> and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michael E. Adjodha, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850; 301-827-5283; e-mail: mea@cdhr.fda.gov.

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 (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), and the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250) 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 the following requirements are met: (1) FDA has received a recommendation from a device classification panel (an FDA advisory committee); (2) FDA has published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA has published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Under section 520(l) of the act (21 U.S.C. 360j(l)), devices formerly regulated as new drugs are automatically classified into class III, unless the Secretary of Health and Human Services, in response to a reclassification petition, has classified the device into class I or II.

II. Recommendation of the Panel

A. Identification of the Device

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA issued a final rule codifying the classification of "tricalcium phosphate for dental bone repair" as a class III device under the 1976 amendments. At that time, FDA was not aware that bone grafting material, other than TCP, was a preamendments device and inadvertently omitted classifying it. Consistent with the act and regulations, FDA has since consulted with the Dental Products Advisory Panel (the panel), an FDA advisory committee, regarding classification of this device.

On November 12, 2002, Bicon, Inc., Boston, MA, submitted a petition to FDA to reclassify beta-tricalcium phosphate for dental indications from "Class III to Class Unclassified" (Ref. 1). On December 9, 2002, the petitioner amended its petition to make clear that it was requesting that FDA reclassify beta-tricalcium phosphate from class III to class II. Beta-tricalcium phosphate and all other forms of tricalcium phosphate for dental bone repair, including alpha and amorphous forms, are transitional devices and are currently regulated as class III devices under 21 CFR 872.3930, "Tricalcium phosphate granules for dental bone