

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 Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that the agency proposes to use as a special control for the device.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

repair,” requiring premarket approval. Consistent with section 520(l)(2) the act and the regulations in 21 CFR 860.136, FDA consulted with the panel regarding reclassification of this device.

Other bone grafting materials in the form of synthetic hard tissue replacements have been used in dentistry since the 1970s (Ref. 2). Because they were inadvertently omitted from the August 12, 1987, final rule classifying most dental devices, these other bone grafting materials are unclassified preamendments devices. Although unclassified, they are nevertheless subject to general controls, such as premarket notification. TCP and other bone grafting materials share the same indications, risks, and recommended mitigation measures.

FDA believes that one classification identification that encompasses all bone grafting materials for dental indications would provide a more scientifically accurate and more administratively transparent regulation for these materials. Therefore, FDA is identifying bone grafting material as a naturally or synthetically derived material, such as hydroxyapatite, tricalcium phosphate, demineralized bone additives, collagen, or polylactic acids, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

B. Recommended Classification of the Panel

At the meeting of the Dental Products Advisory Panel held on May 22, 2003, the panel voted five to zero (with no abstentions) to recommend that TCP for dental indications be reclassified from class III to class II (special controls). The panel considered all forms of TCP, including beta-tricalcium phosphate, and concluded that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of these bone grafting materials devices (Ref. 3).

In addition, on August 8 and 9, 1995, in accordance with the procedures set forth in 21 CFR 860.84, the panel considered classification of the non-TCP materials. The panel recommended unanimously that non-TCP bone grafting materials be classified into class II, except when intended to be used alone in filling or repair of bony defects and/or augmentation of the alveolar ridge. For that indication, the panel recommended placing the device in class III, but with a low priority for establishing an effective date for the requirement for premarket approval (Ref. 4).

C. Summary of Reasons for the Recommendation

For TCP for dental indications and for bone grafting materials for certain dental indications, the panel believed that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information to establish special controls to provide such assurance.

The panel recommended that TCP should remain in class III when used alone in filling or repair of bony defects and/or augmentation of the alveolar ridge because they believed that the materials present risks to health that cannot be addressed by special controls.

D. Summary of the Data for the Recommendation

For TCP for dental indications, the panel based its recommendation on the information provided by the petitioner and FDA, the presentations made by stakeholders and FDA at the panel meeting, the open discussion during the panel meeting, and the panel members' personal knowledge of and clinical experience with the device (Ref. 5). The panel did not discuss bone grafting materials containing a drug or biologic component.

For non-TCP materials, the panel based its recommendation on the information provided by FDA, presentations made by stakeholders who marketed bone filling and augmentation devices, the open discussion during the panel meeting, and the panel members' personal knowledge of and clinical experience with the device.

III. Risks to Health

The panel identified the following risks to health associated with bone grafting material: Ineffective bone formation, adverse tissue reaction, infection, and improper use.

A. Ineffective Bone Formation

The quality and physical properties of bone grafting material may be insufficient to support the required loads and lead to device failure. Device failure may result in ineffective treatment, revision, and permanent impairment for the patient.

B. Adverse Tissue Reaction

Inadequate biocompatibility of any of the components contained in bone grafting material may result in adverse tissue reaction and presents the potential for surgical revision (i.e., reoperation).

C. Infection

Implantation of an improperly sterilized device may result in an infection. Infection may result in revision or explantation of the device, which presents the potential for permanent impairment.

D. Improper Use

Inadequate labeling may result in improper use. Improper use may result in ineffective treatment and may cause permanent impairment.

IV. Proposed Rule

FDA believes that bone grafting material that does not contain a drug or biologic component should be classified into class II and that TCP should be reclassified 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 to provide such assurance.

FDA disagrees with the (1995) panel's recommendation that bone grafting materials should remain in class III when used alone in filling or repair of bony defects and/or augmentation of the alveolar ridge. FDA believes that when used for these indications, the risks to health can be addressed by special controls and that all of these bone grafting material devices share the same risks and recommended mitigation measures. Accordingly, FDA has developed the draft guidance document entitled "Class II Special Controls Guidance Document: Dental Bone Grafting Material" to serve as the special control for TCP and other bone grafting material devices for dental indications. As noted previously, bone grafting material that contains a drug or biologic component would remain in class III and the special control guidance document would not apply.

V. Proposed Special Control

FDA believes that the special controls guidance document entitled "Class II Special Controls Guidance Document: Dental Bone Grafting Material," in addition to general controls, can address the risks to health described in section III of this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance document.

If adopted, following the effective date of a final rule reclassifying and classifying the device, any firm submitting a 510(k) premarket notification for the device would need to address the issues covered in the special control guidance. However, the firm would need to show only that its

device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

The special controls guidance document contains recommendations with regard to the information and testing that should be included in a premarket notification. The guidance document addresses the following topics: Characterization, biocompatibility, sterilization, and labeling. Adequate characterization of the composition, physical properties, and in vivo performance can address the risk of ineffective bone formation. Adequate biocompatibility can address the risk of adverse tissue reaction. Sterilization can address the risk of infection, and labeling can address the risk of improper use.

The agency is not proposing to exempt this device from the premarket notification requirements of the act, as permitted by section 510(m) of the act (21 U.S.C. 360(m)). FDA believes that it needs to review information in a premarket notification submission that addresses the risks identified in the guidance document in order to assure that a new device is at least as safe and effective as legally marketed devices of this type.

VI. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

VII. Environmental Impact

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

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed 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 proposed 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. Manufacturers of the preamendments devices that FDA is reclassifying are being relieved of the burden of eventually submitting a premarket approval application. Manufacturers of these devices are already subject to the premarket notification requirements. FDA has designated a guidance document as the special control. FDA believes that manufacturers, including small manufacturers, are already substantially in compliance with the recommendations in the guidance document, and they will not need to submit substantially more information in their premarket notification submissions in order to meet the recommendations in the guidance document or otherwise provide reasonable assurances of safety and effectiveness. FDA believes that any regulation based on this proposed rule will impose no significant economic impact on any small entities. The agency, therefore, certifies that this proposed rule will not have a significant impact on a substantial number of small entities. In addition, it 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

X. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Bicon, Inc., Boston, MA to FDA, November 12, 2002.
2. Le Geros, R. Z., "Calcium Phosphate Materials in Restorative Dentistry: A Review," *Advances in Dental Research*, vol. 2, pp. 164–180, 1988.
3. Dental Products Panel of the Medical Devices Advisory Committee, meeting transcript, May 22, 2003.
4. Dental Products Panel of the Medical Devices Advisory Committee, meeting transcript, August 8 and 9, 1995.
5. Dental Products Panel of the Medical Devices Advisory Committee, information package, May 22, 2003.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended in subpart D as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR Part 872 continues to read as follows:

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

2. Section 872.3930 is revised to read as follows:

§ 872.3930 Bone grafting material.

(a) *Identification.* Bone grafting material is a naturally or synthetically derived material, such as hydroxyapatite, tricalcium phosphate, demineralized bone additives, collagen, or polylactic acids, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

(b) *Classification.* (1) Class II (special controls) if it contains no drug or biologic component. The special control for bone grafting materials that do not contain a drug or biologic component is FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Material." (See § 872.1(e) for the availability of this guidance document.)

(2) Class III (premarket approval) if it contains a drug or biologic component. Bone grafting materials that contain a drug or biologic component, such as biological response modifiers, require premarket approval.

(c) *Date PMA or notice of PDP is required.* For devices described in paragraph (b)(2) of this section, no

effective date has been established for the requirement of premarket approval. (See § 872.3).

Dated: May 4, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-14767 Filed 6-29-04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[CGD01-03-107]

RIN 1625-AA01

Anchorage Regulations: Yonkers, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish two Special Anchorage areas along the Hudson River adjacent to the City of Yonkers. This proposed action is necessary to facilitate safe navigation in that area and provide safe and secure anchorages for vessels not more than 20 meters in length. This action is intended to increase the safety of life and property on the Hudson River, improve the safety of anchored vessels in both anchorages, and provide for the overall safe and efficient flow of recreational vessel traffic and commerce.

DATES: Comments and related material must reach the Coast Guard on or before August 30, 2004.

ADDRESSES: You may mail comments and related material to Commander (oan) CGD01-03-107, First Coast Guard District, 408 Atlantic Ave., Boston, Massachusetts 02110, or deliver them to room 628 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room 628, First Coast Guard District Boston, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. John J. Mauro, Commander (oan), First Coast Guard District, 408 Atlantic Ave., Boston, MA 02110, Telephone (617) 223-8355; E-mail jmauro@d1.uscg.mil.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking CGD01-03-107, indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of comments received.

Public Meeting

We do not plan to hold a public meeting, but you may submit a request for a meeting by writing to Commander (oan) CGD01-03-107, First Coast Guard District, 408 Atlantic Ave., Boston, Massachusetts 02110 or delivering your request to room 628 at the same address above between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. In your request please explain why a public meeting would be beneficial. If we determine that a public meeting would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

As part of a waterfront revitalization and redevelopment effort, the City of Yonkers is proactively encouraging waterfront use by the general public. This proposed rule is in response to a request made by the City of Yonkers to help ensure the safe navigation of increased vessel traffic expected to arrive along the city waterfront due to this revitalization effort.

The Coast Guard is designating the areas as special anchorage areas in accordance with 33 U.S.C. 471. In accordance with that statute, vessels will not be required to sound signals or exhibit anchor lights or shapes which are otherwise required by rule 30 and 35 of the Inland Navigation Rules, codified at 33 U.S.C. 2030 and 2035. The two proposed special anchorage areas will be located on the west side of the Hudson River in the vicinity of Main Street and the JFK Marina, well removed from the channel and located where general navigation will not endanger or be endangered by unlighted vessels. Providing anchorage well

removed from the channel and general navigation would greatly increase navigational safety.

While developing the proposed rule, in accordance with Title 33 of the Code of Federal Regulations, Part 109.05(b) the U.S. Coast Guard has consulted with the U.S. Army Corps of Engineers, New York District, located at 26 Federal Plaza, New York, NY 10278. The U.S. Army Corps of Engineers has determined that the proposed Special Anchorage Areas would not have an adverse affect on any federally maintained navigation channels in the area, structures the U.S. Army Corps of Engineers has permitted, or any pending permit applications submitted to the U.S. Army Corps of Engineers in this area.

Discussion of Proposed Rule

The proposed rule would create two new special anchorage areas. The first, located on the Hudson River at Main Street, Yonkers, New York, would be that portion of the Hudson River starting on shore at point 40°56'15.4" N, 073°54'11.1" W; thence northwest to point 40°56'18.0" N, 073°54'21.0" W; thence south to point 40°55'58.8" N, 073°54'24.8" W; thence southeast to shore at point 40°55'58.0" N, 073°54'21.0" W.

The second, located on the Hudson River at JFK Marina, Yonkers, New York, would be that portion of the Hudson River starting on shore at point 40°57'28.5" N, 073°53'46.0" W; thence west to point 40°57'30.5" N, 073°53'56.8" W; thence southwest to point 40°57'07.5" N, 073°54'06.2" W; thence east to shore at point 40°57'08.0" N, 073°53'58.5" W. All proposed coordinates are North American Datum 1983 (NAD 83).

The special anchorage areas would be limited to vessels no greater than 20 meters in length. Vessels not more than 20 meters in length are not required to sound signals as required by rule 35 of the Inland Navigation Rules (33 U.S.C. 2035) or exhibit anchor lights or shapes required by rule 30 of the Inland Navigation Rules (33 U.S.C. 2030) when at anchor in a special anchorage area. Additionally, mariners utilizing the anchorage areas are encouraged to contact local and state authorities, such as the local harbor master, to ensure compliance with additional applicable state and local laws. Such laws may involve, for example, compliance with direction from the local harbor master when placing or using moorings within the anchorage.