DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0010]

High Chemical Co. et al.; Proposal to Withdraw Approval of 13 New Drug Applications; Opportunity for a Hearing; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a notice that published in the **Federal Register** on January 28, 2005 (70 FR 4134). This notice is being reissued elsewhere in this issue of the **Federal Register**

DATES: This notice is withdrawn on April 28, 2005.

FOR FURTHER INFORMATION CONTACT: Darlease Hyman, Regulations Policy Management Staff (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3480.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 28, 2005 (70 FR 4134), FDA published a notice announcing an opportunity for a hearing on the agency's proposal to withdraw approval of 13 new drug applications from multiple sponsors. This notice published with an inadvertent error. Therefore, the agency is withdrawing the notice. Elsewhere in this issue of the **Federal Register**, FDA is reissuing the corrected notice for the convenience of the reader and to give sponsors the fully allotted time to respond.

Dated: April 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8470 Filed 4–27–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0178]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices.'' This guidance document describes a means by which class II dental bone grafting material devices may comply with the requirement of special controls. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify tricalcium phosphate (TCP) granules for dental bone repair from class III (premarket approval) to class II (special controls), classify into class II (special controls) other bone grafting material for dental indications, and revise the classification name and identification of the device.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

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: *michael.adjodha@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 30, 2004 (69 FR 39485), FDA announced the availability of a draft of this special controls guidance document and invited interested persons to comment on it by September 28, 2004. In addition, in the same **Federal Register** (69 FR 39377), FDA proposed to reclassify tricalcium phosphate (TCP) granules for dental bone repair from class III to class II (special controls). Concurrently, FDA proposed to classify into class II (special controls) all other bone grafting material for dental indications, except those that contained a drug or biologic component; and to revise the classification name and identification of the device. In the proposed rule, FDA identified bone grafting material as a material such as hydroxyapatite, tricalcium phosphate, polylactic acids, or collagen, intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. FDA received one comment on the proposed rule and draft special controls guidance document. The comment is addressed in the final rule published elsewhere in this issue of the **Federal Register**.

The final rule published elsewhere in this issue of the **Federal Register** reclassifies tricalcium phosphate (TCP) granules for dental bone repair from class III (premarket approval) to class II (special controls) and also classifies other dental bone grafting materials that do not contain a drug that is a therapeutic biologic into class II (special controls). Bone grafting material devices that contain a drug that is a therapeutic biologic will remain in class III and continue to require premarket approval. The guidance document provides a means by which the dental bone grafting materials in class II may comply with the requirement of special controls for class II devices.

Following the effective date of the final rule, any firm submitting a 510(k) for the class II devices 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.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on class II dental bone grafting material devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices'' by fax, call the CDRH Facts-On-Demand system at