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**DATES:** This notice is withdrawn on April 28, 2005.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

**BILLING CODE 4160–01–S**

## 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

800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1512) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

To receive a hard copy or electronic copy of ''Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices,'' you may either send a fax request to 301–443–8818, or send an e-mail request to *gwa@cdrh.fda.gov*. Please use the document number (1512) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

### IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

### V. 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. Comments are to be identified 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.

Dated: April 4, 2005.

**Linda S. Kahan,**

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

[FR Doc. 05–8468 Filed 4–27–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 1999D–1540] (formerly Docket No. 99D–1540)**

### Guidance for Reviewers on Evaluating the Risks of Drug Exposure in Human Pregnancies; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for reviewers entitled ''Reviewer Guidance: Evaluating the Risks of Drug Exposure in Human Pregnancies.'' This guidance is intended to help FDA staff evaluate human fetal outcome data generated after medical product exposures during pregnancy. The goal of such evaluations is to assist in the development of product labeling that is useful to medical care providers when they care for patients who are pregnant or planning pregnancy. The review of human pregnancy drug exposure data and assessment of fetal risk (or lack of risk) requires consideration of human embryology and teratology, pharmacology, obstetrics, and epidemiology. Consequently, FDA staff also are encouraged to consult with experts in these fields, as appropriate.

The guidance announced in this document finalizes the draft guidance entitled ''Guidance for Reviewers: Evaluation of Human Pregnancy Outcome Data'' announced in the **Federal Register** of June 4, 1999.

**DATES:** Submit written comments or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist either office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5162, e-mail: *kennedyd@cder.fda.gov*, or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, e-mail: *stifano@cber.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA is announcing the availability of a guidance for reviewers entitled ''Reviewer Guidance: Evaluating the Risks of Drug Exposure in Human Pregnancies.'' The guidance provides FDA staff with critical factors to consider when evaluating data on the effects of drug exposure during human pregnancies. It also describes the sources of human data on gestational drug exposures and available resources for more information. The guidance is intended to provide FDA reviewers with a standardized and scientific approach to the evaluation of the effects of human gestational drug exposures.

In the **Federal Register** of June 4, 1999 (64 FR 30040), FDA announced the availability of a draft version of the guidance entitled ''Guidance for Reviewers: Evaluation of Human Pregnancy Outcome Data.'' When the draft guidance was published, FDA requested comments on the document. Three public comments were received. The comments were supportive of the agency's efforts to provide this type of guidance. However, the comments also recommended revision/clarification of several sections, as well as provided a number of suggestions of a more technical nature. Additionally, comments regarding the draft guidance raised the following three broader concerns: (1) That it contained redundant information already presented in the guidance for industry entitled ''Establishing Pregnancy Exposure Registries'' (draft: 64 FR