results of national and State health care policies;

• Supply data for modeling the demand for health insurance; and

• Providing data on health plan choices, costs, and benefits that can be linked back to households' use of health care resources in the MEPS–HC for studies of the consumer health insurance selection process.

These data provide the basis for researchers to address important questions for employers and policymakers alike.

Method of Collection

The data will be collected using a combination of modes. The Census Bureau's first contact with employers will be made by telephone. This contact will provide information on the availability of health insurance from that employer and essential persons to contact. Based upon this information, Census will mail a questionnaire to the employer.

In order to assure high response rates, Census will follow-up with a second mailing after an interval of approximately 30 working days, followed by a telephone call to collect data from those who have not responded by mail.

As part of this process, for larger respondents with high burdens, such as State employers and very large firms, we will, if needed, perform personal visits and do customized collection, such as, acceptance of data in computerized formats and use of special forms.

Estimated Annual Respondent Burden

Survey years	Annual number of respondents	Estimated time per respondent in hours	Estimated total annual burden hours	Estimated annual cost to the government
2004	34,507	.6	19,708	$8,800,000
2005	34,507	.6	19,708	9,138,000
2006	39,791	.6	23,550	10,660,000

Request for Comments

In accordance with the above cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of the AHRQ, including whether the information will have practical utility; (b) the accuracy of the AHRQ's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: June 23, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04–14734 Filed 6–29–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Correction—Technical Review Meeting Date

The original notice was published in the **Federal Register** on June 10, 2004 under Volume 69, Number 112, Pages 32558–32559 (*http://a257.g.akamaitech.net/7257/2422/06jun20041800/edocket.access.gpo.gov/2004/04–13102.htm*). With this Notice, the Agency for Healthcare Research and Quality (AHRQ) is informing the public that the correct meeting date for the ''AHRQ State and Regional Demonstrations in Health Information Technology'' is July 7 and 8, 2004.

Dated: June 23, 2004.

Carolyn M. Clancy,

Director, AHRQ.

[FR Doc. 04–14733 Filed 6–29–04; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004M–0203]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and FDA's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at *http://www.fda.gov*. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were

announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness were placed on the Internet from January 1, 2004, through March 31, 2004. There were no denial actions during the period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE JANUARY 1, 2004, THROUGH MARCH 31, 2004

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP 030025/02004M–0203	Trinity Biotech plc	Trinity Uni-Gold Recombigen HIV, Uni-Gold Recombigen HIV Positive and Negative Controls	December 23, 2003

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cber/products.htm*.

Dated: May 17, 2004.

Jesse Goodman,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 04–14805 Filed 6–29–04; 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 FDA Staff; Draft Class II Special Controls Guidance Document: Dental Bone Grafting Material; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Dental Bone Grafting Material.'' Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify tricalcium phosphate granules for dental bone repair from class III (premarket approval) to class II (special controls) and to classify other dental bone grafting materials into the same class II (special controls) classification identification. The draft guidance describes a means by which dental bone grafting material devices may comply with the requirement of special controls for class II devices. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by September 28, 2004.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Dental Bone Grafting Material'' 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 draft 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, ext. 123, e-mail: *mea@cdrh.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify tricalcium phosphate granules for dental bone repair from class III (premarket approval) to class II (special controls) and to classify other dental bone grafting materials into the same class II (special controls) classification identification. This draft guidance document describes a means by which the device 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) premarket notification for the device 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 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on dental bone grafting material. 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 an 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'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter