Therefore, even though BMS has never marketed IFEX alone, it is appropriate to categorize IFEX (as a single agent) as having been withdrawn from sale. Once a listed drug has been withdrawn from sale, FDA must make a determination that the withdrawal from sale was not for reasons of safety or effectiveness before it can approve any ANDAs referencing the listed drug.

The agency has determined that IFEX as a single agent has not been withdrawn for reasons of safety or effectiveness. FDA agrees with BMS that ifosfamide should be used with a uroprotective agent like mesna. However, that does not preclude the safe use of ifosfamide as a single agent with MESNEX or a generic version of mesna. FDA approved two ANDAs for mesna in April 2001. The FDA has no requirement that coadministered products must also be copackaged. There are many drugs whose labeling identifies them for use in combination with other drugs with which they are not copackaged, including Taxol and Taxotere. Neither the petitioner nor BMS identified any data suggesting that marketing IFEX alone would compromise patients' safety. Moreover, the relevant literature and adverse event reports do not bear out BMS's claim that marketing IFEX as a single agent would be unsafe. In the absence of data suggesting a safety risk, and because IFEX was approved as a single agent, we conclude that FDA may approve ANDAs referencing IFEX alone.

After considering the citizen petition and the comments thereon and reviewing its records, FDA determines that, for the reasons outlined previously in this document, IFEX as a single agent was not withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list IFEX in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to IFEX, 1-g and 3-g vials, may be approved by the agency.

Dated: May 6, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–11971 Filed 5–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0113]

Medical Devices; Draft Guidance for Industry and FDA on Class II Special Controls: Root-Form Endosseous Dental Implants and Abutments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA.'' This draft guidance document was developed as a special control guidance to support the reclassification of the root-form endosseous dental implant device from class III to class II and the reclassification of the endosseous dental implant abutment device from class III to class II. Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to reclassify these device types. This guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by August 12, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA'' 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 two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the draft guidance to the Dockets Management Branch (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: Angela E. Blackwell, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document describes a means by which the root-form endosseous dental implant device and the endosseous dental implant abutment device may comply with the requirement of special controls for class II devices. A root-form endosseous dental implant device is intended to be surgically placed in the bone of the upper or lower arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. An endosseous dental implant abutment device is a separate component that is attached to the implant and is intended to aid in prosthetic rehabilitation.

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 root-form endosseous dental implant and endosseous dental implant abutment 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 statutes and regulations.

III. Electronic Access

In order to receive the draft guidance entitled ''Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA'' via your 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 the system. At the second voice prompt press 1 to order a document. Enter the document number (1389) followed by the pound sign (ι). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so 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. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers'

assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at *http://www.fda.gov/cdrh*. Guidance documents are also available at *http://www.fda.gov/ohrms/dockets/default.htm*.

IV. Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments on the draft guidance by August 12, 2002. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 23, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–12042 Filed 5–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Evaluation of the NCI State of the Science Web Site

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 12, 2001 pages 31678 and 31679, Volume 66, No. 113 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days fro public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Web-Survey of the State of the Science Web Site.

Type of Information Collection Request: New.

Need and Use of Information Collection: The NCI seeks to evaluate its State-of-the-Science (SOTS) meetings project that offers audio-visual presentations of SOTS meetings via the Internet. The SOTS disseminates, with expediency and immediacy, the most recent oncology research results to a potentially vast audience of researchers. The proposed data collection will pro6vide feedback to NCI on the value of the Web site to those who NCI deem as the Web site's target population (*i.e.,* clinical oncology researchers unable to attend SOTs meetings in person because of cost or time limitations). The first tier of respondents will consist of researchers who have attended any one of the three most recent State of the Science meetings. The tier-one survey participants will be asked to provide the names, emails, and any other contact information for five colleagues who are clinical research oncologists. The oncologists will be asked only once to provide the names and contact information for colleagues. The second tier of respondents will consist of the clinical oncology researchers nominated by the first tier respondents. It is the second tier respondents who will be asked to go to the Web site and complete the Web survey. They are asked to do this only once. Other tier two respondents will be oncology fellows whose current and full contact information is available in a national register of oncology fellows, Reports generated by the study will allow NCI to determine the success of the SOTS Web site (in terms of clarity of content, ease of navigation, and usefulness and information), and indirectly, the potential wider use and applications of Internet-based programs to improve the overall cancer clinical trails systems at NCI.

Frequency of Response: One time.

Affected Public: Individuals, researchers.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Tier One Clinical Oncology Researchers	220	1	0.0835	18.37
Tier Two Clinical Oncology Researchers	400	1	0.75	300
Total				318.37

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to responded, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk