that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the requested information and fill in the answers.

Dated: April 19, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–10564 Filed 4–29–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0205]**

### Agency Information Collection Activities; Announcement of OMB Approval; Application for FDA Approval to Market a New Drug

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Application for FDA Approval to Market a New Drug'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 29, 2001 (66 FR 29143), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0001. The approval expires on March 31, 20005. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: April 19, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–10561 Filed 4–29–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01N–0359]**

### Craig H. Petrik; Debarment Order

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Craig H. Petrik from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. FDA bases this order on a finding that Mr. Petrik was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. After being given notice of his proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation, Mr. Petrik failed to request a hearing. Mr. Petrik's failure to request a hearing is deemed a waiver of his right to a hearing concerning this action.

**DATES:** This order is effective April 30, 2002.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

On January 19, 2001, the U.S. District Court for the Central District of California accepted a plea of guilty and entered a judgment against Mr. Petrik for one count of making a false statement to a government agency, a Federal felony under 18 U.S.C. 1001. As a result of this conviction, FDA sent a letter dated August 31, 2001, to Mr. Petrik proposing to issue an order to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application, and offering him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) and (c)(2)(A)(ii) of the act (21 U.S.C. 355a(a)(2)(B) and (c)(2)(A)(ii)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Petrik was provided 30 days to file objections and request a hearing. Mr. Petrik did not request a hearing. His failure to request a hearing constitutes a waiver of his right to a hearing concerning the proposed order.

#### II. Findings and Order

Therefore, the Director, Center for Biologics Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Craig H. Petrik has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Mr. Craig H. Petrik is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application. A drug product means a drug, including a biological product, subject to regulation under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or section 351 of the Public Health Service Act (42 U.S.C. 262), effective April 30, 2002 (21 U.S.C. 335a(a)(2), (c)(1)(B), and (c)(2)(A)(ii), and 321(dd)). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly uses the services of Mr. Petrik, in any capacity, during his period of debarment, will be subject to civil money penalties (21 U.S.C. 335a(a)(6)). If Mr. Petrik, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a biologics license application, he will be subject to civil money penalties (21 U.S.C. 335a(a)(7)).

Any application by Mr. Petrik for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N–0359 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies (§ 10.20(a) (21 CFR 10.20(a))). The public availability of information in these submissions is governed by § 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch

between 9 a.m. and 4 p.m., Monday through Friday (§ 10.20(j)(1)).

Dated: April 10, 2002.

**Kathryn C. Zoon,**

*Director, Center for Biologics Evaluation and Research.*

[FR Doc. 02–10562 Filed 4–29–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 01D–0318]**

### Medical Devices; Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis; 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: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to reclassify this type of device into class II.

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

**ADDRESSES:** Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing you request, or fax your request to 301–443–8818. Submit written comments on the 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:** John S. Goode, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

In the **Federal Register** of September 6, 2001 (66 FR 46641), FDA published a proposed rule to reclassify the hip joint metal/polymer constrained cemented or uncemented prosthesis from class III (premarket approval) to class II (special controls) based on new information regarding this device contained in a reclassification petition submitted by the Orthopedic Surgical Manufacturers Association. FDA also identified the document ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' as the special control capable of providing reasonable assurance of safety and effectiveness for this device.

Interested persons were invited to comment on the draft guidance by December 5, 2001. FDA received three comments. Two comments commended FDA's proposal to reclassify these devices and agreed that the guidance proposed as the special control was adequate to provide reasonable assurance of the safety and effectiveness of the device. One comment stated that FDA's proposed special control was inadequate to protect against certain types of device failure, specifically shell-bone interface failure that may occur after implantation of this highly constrained device.

FDA agrees that shell-bone interface failure may occur after implantation of the device. FDA has revised the precaution section in the guidance document to clarify that it addresses device failure at the shell-bone interface.

#### II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on special controls for the hip joint metal/polymer constrained cemented or uncemented prosthesis. 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 applicable statutes and regulations.

#### III. Electronic Access

In order to receive the guidance entitled ''Class II Special Controls Guidance Document: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis'' 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 (1393) followed by the pound sign (#). 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. Updated on a regular basis, the CDRH home page includes 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. A search capability for all CDRH guidance documents is available at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available at http://www.fda.gov/ohrms/dockets.

#### IV. Comments

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (see **ADDRESSES**). 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 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 15, 2002.

**Linda S. Kahan,**

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

[FR Doc. 02–10510 Filed 4–29–02; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Fiscal Year 2002 Competitive Application Cycle for the Radiation Exposure Screening and Education Program 93.257

**AGENCY:** Health Resources and Services Administration, HHS.