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