Dated: April 24, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–10636 Filed 4–29–03; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–63]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden 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 through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project

Information Collection Procedures for Requesting Public Health Assessments—(0923–0002)—Extension—The Agency for Toxic Substances and Disease Registry (ATSDR).

ATSDR is announcing the request for extension of the OMB-approved Information Collection Procedures for Requesting Public Health Assessments. ATSDR is authorized to consider petitions from the public that request public health assessments of sites where there is a threat of exposure to hazardous substances (42 U.S.C. 9604(i)(6)(B)). The Agency may conduct public health assessments of releases or facilities for which individuals provide information that people have been exposed to a hazardous substance, and for which the source of such exposure is a release, as defined under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). The general administrative procedures for conducting public health assessments, including the information that must be submitted with each request, is described at 42 CFR 90.3, 90.4, and 90.5. Procedures for responding to petitions, decision criteria, and methodology for determining priorities may be found at 57 FR 37382–89. There is no cost to the respondents other than the time required for preparing a letter and for postage.

ATSDR anticipates approximately 34 requests will be received each year. This estimate is based on the number of requests received in the past five years and the expressions of interest (via telephone, letter, etc.) from members of the public, attorneys, and industry representatives.

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs.)	Total burden (in hrs.)
General public	34	1	30/60	17
Total				17

Dated: April 24, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–10631 Filed 4–29–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0539]

Edwin Kokes; 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 Edwin Kokes from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Kokes was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Kokes failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective April 30, 2003.

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: Carol Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On August 19, 1998, the U.S. District Court for the District of Nebraska entered judgement against Mr. Kokes for one count of mail fraud, a Federal felony offense under 18 U.S.C. 1341. This offense was committed as part of a health care fraud scheme involving the sale of unapproved drug products to patients.

As a result of this conviction, FDA served Mr. Kokes by certified mail on July 31, 2002, a notice proposing to permanently debar Mr. Kokes from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Kokes an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Kokes was convicted of a felony under Federal law for conduct relating to the

regulation of a drug product under the act. Mr. Kokes was provided 30 days to file objections and request a hearing. Mr. Kokes did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.34), finds that Mr. Edwin Kokes has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Mr. Edwin Kokes is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262)(see sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Kokes, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Kokes, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Kokes during his period of debarment.

Any application by Mr. Kokes for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 01N–0539 and sent to the Dockets Management Branch (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 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.

Dated: March 28, 2003.

Steven K. Galson,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. 03–10569 Filed 4–29–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0161]

Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions From Premarket Notification; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a list (List I) of critical reprocessed single-use devices (SUDs) whose exemption from premarket submission is being terminated and for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), is necessary in a premarket notification (510(k)); and a list (List II) of reprocessed SUDs that are currently subject to 510(k) requirements for which FDA has determined that validation data, as specified under MDUFMA, is necessary in a 510(k). FDA is requiring submission of these data to ensure that these reprocessed SUDs are substantially equivalent to predicate devices in accordance with MDUFMA.

DATES: These actions are effective April 30, 2003. Manufacturers of SUDs identified in List I whose exemption is being terminated must submit 510(k)s for these devices by July 30, 2004, or their devices may no longer be marketed. Manufacturers who already have clearance letters for SUDs identified in List II must submit validation data for these devices by January 30, 2004, or marketing of these devices must cease.

ADDRESSES: Submit written comments 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*. Comments on Lists I and II should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Barbara A. Zimmerman, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA (Pub. L. 107–250), amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this new provision, in order to ensure that reprocessed SUDs are substantially equivalent to predicate devices, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data. These required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Before enactment of the new law, a manufacturer of a reprocessed SUD was required to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt reprocessed SUDs will no longer be exempt from premarket notification requirements. Manufacturers of these identified devices will need to submit 510(k)s that include validation data to be specified by FDA. Reprocessors of certain SUDs that are currently subject to cleared 510(k)s also will need to submit the validation data specified by the agency.

In the near future, FDA will publish a guidance document providing more specific information about the types of validation data that should be submitted in premarket notification submissions for the reprocessed SUDs listed in this notice.

A. Definitions

Under section 302(b) of MDUFMA, a reprocessed SUD is defined as an ''original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.''

B. Reprocessed SUDs Exempt From Premarket Notification

Reprocessed SUDs are divided into three groups: (1) Critical, (2) semicritical, and (3) noncritical. The first two categories reflect definitions set forth in MDUFMA, and all three reflect a classification scheme recognized in