

Dated: April 24, 2003.

Alvin Hall,

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

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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.*

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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

debaring 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