

Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund). This public law directed ATSDR to prepare toxicological profiles for hazardous substances most commonly found at facilities on the CERCLA National Priorities List (NPL) and that pose the most significant potential threat to human health, as determined by ATSDR and the EPA. The current ATSDR priority list of hazardous substances at DOE NPL sites was announced in the **Federal Register** on July 24, 1996 (61 FR 38451).

Notice of the availability of the draft toxicological profiles for public review and comment was published in the

Federal Register on October 28, 1997 (62 FR 55817), with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments were addressed, and where appropriate, changes were incorporated into each profile. The public comments and other data submitted in response to the **Federal Register** notices bear the docket control number ATSDR-129. This material is available for public inspection at the Division of Toxicology, Agency for Toxic Substances and Disease Registry, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia,

(not a mailing address) between 8 a.m. and 4:30 p.m., Monday through Friday, except legal holidays.

Availability

This notice announces the availability of two new final toxicological profiles, comprising the 1st set developed for the Department of Energy. The following toxicological profiles are now available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, telephone 1-800-553-6847. There is a charge for these profiles as determined by NTIS.

Toxicological profile	NTIS order No.	CAS No.
1. URANIUM	PB99-163362	MULTIPLE.
URANIUM 235	15117-96-1.
URANIUM HEXAFLUORIDE	7783-81-5.
URANIUM METAL	7440-61-1.
URANIUM ORE	53125-22-7.
URANIUM OCTAOXIDE	1344-59-8.
URANIUM PEROXIDE	19525-15-6.
URANIUM TETRACHLORIDE	10026-10-5.
URANIUM TETRAFLUORIDE	10049-14-6.
URANYL ACETATE	541-09-3.
URANYL NITRATE	10102-06-4.
URANYL NITRATE HEXAHYDRATE	13520-83-7.
URANYL SULFATE	1314-64-3.
2. IONIZING RADIATION	PB99-163388	NA.

Dated: December 10, 1999.

Georgi Jones,

*Director, Office of Policy and External Affairs,
Agency for Toxic Substances and Disease
Registry.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-5199]

Medical Devices; Draft Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery; 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, "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery." This draft guidance is not final nor is it in effect at this time. This draft guidance is being issued because of the increasing interest on the part of sponsors in

developing adhesion barrier products and increasing questions regarding the study requirements for development of these products. In addition, because two review groups evaluate these products for use in abdominal and/or pelvic surgery, this draft guidance was developed to encourage consistency between the two review groups when they evaluate investigational device exemption (IDE) and premarket approval application (PMA) applications for these products.

DATES: Submit written comments concerning this guidance by March 16, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled, "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery" to the Division of Small Manufacturers 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. Written comments concerning this guidance must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration,

5630 Fisher Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

David B. Berkowitz, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is being issued because of the increasing interest on the part of sponsors in developing adhesion barrier products and in answering questions regarding the study requirements for development of these products. In addition, because two branches and divisions are evaluating these products for use in abdominal and/or pelvic surgery, this guidance was developed to encourage consistency between the two review groups when they evaluate IDE and PMA applications for these products.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on resorbable adhesion barrier devices for use in abdominal and/or pelvic

surgery. 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 statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (1356) followed by the pound sign (#). Then 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. The Center for Devices and Radiological Health (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 access to the Internet. Updated on a regular basis, the CDRH home page includes the draft guidance entitled "Guidance for Resorbable Adhesion Barrier Devices for Use in Abdominal and/or Pelvic Surgery," 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>.

IV. Comments

Interested persons may, on or before March 16, 2000, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 7, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4443-N-10]

Notice of Proposed Information Collection for Public Comments for Life-Cycle Cost Analysis of Utility Combinations in Public Housing

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* February 14, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4238, Washington, DC 20410-5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708-3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for

review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information of those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Life-Cycle Cost Analysis of utility Combinations in Public Housing.

OMB Control Number: 2577-0024.

Description of the need for the information and proposed use: HUD will use the information collected to analyze the selection of the most cost effective utilities, fuels, related mechanical equipment, and methods of purchase for public housing projects.

Agency form numbers, if applicable: HUD-51994.

Members of affected public: State, Local or Tribal government and not for profit institutions.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: 238 respondents (PHAs), one-time, on occasion, six hours per response, 1,428 hours total reporting burden.

Status of the proposed information collection: Extension.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: December 13, 1999.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

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