

Management Plan to Reduce Predation of Juvenile Salmonids in the Columbia River Estuary, Review Period Ends: 03/16/2015, Contact: Robert Winters 503-808-4738. Revision to FR Notice Published 02/13/2015; Correction to Document Status should be Final EIS.

Dated: February 17, 2015.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2015-03524 Filed 2-19-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9922-98-Region 6]

Underground Injection Control Program; Hazardous Waste Injection Restrictions; Petition for Exemption Reissuance—Class I Hazardous Waste Injection; Lucite International, Inc. Beaumont Site, Nederland, TX

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of a final decision on a no migration petition reissuance.

SUMMARY: Notice is hereby given that a reissuance of an exemption to the land disposal Restrictions, under the 1984 Hazardous and Solid Waste Amendments to the Resource Conservation and Recovery Act, has been granted to Lucite International, Inc. for two Class I hazardous injection wells located at their Beaumont site located in Nederland, TX. The company has adequately demonstrated to the satisfaction of the Environmental Protection Agency by the petition reissuance application and supporting documentation that, to a reasonable degree of certainty, there will be no migration of hazardous constituents from the injection zone for as long as the waste remains hazardous. This final decision allows the continued underground injection by Lucite, of the specific restricted hazardous wastes identified in this exemption reissuance, into Class I hazardous waste injection wells WDW-100 & 101 until December 31, 2030, unless EPA moves to terminate this exemption. Additional conditions included in this final decision may be reviewed by contacting the Region 6 Ground Water/UIC Section. A public notice was issued December 18, 2014. The public comment period closed on February 2, 2015. No comments were received. This decision constitutes final Agency action and there is no Administrative appeal. This decision may be reviewed/appealed in

compliance with the Administrative Procedure Act.

DATES: This action is effective as of February 5, 2015.

ADDRESSES: Copies of the petition reissuance and all pertinent information relating thereto are on file at the following location: Environmental Protection Agency, Region 6, Water Quality Protection Division, Source Water Protection Branch (6WQ-S), 1445 Ross Avenue, Dallas, Texas 75202-2733.

FOR FURTHER INFORMATION CONTACT:

Philip Dellinger, Chief Ground Water/UIC Section, EPA—Region 6, telephone (214) 665-8324.

Dated: February 5, 2015.

William K. Honker,

Director, Water Quality Protection Division.

[FR Doc. 2015-03463 Filed 2-19-15; 8:45 am]

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FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the “Government in the Sunshine Act” (5 U.S.C. 552b), notice is hereby given that at 10:03 a.m. on Tuesday, February 17, 2015, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters related to the Corporation’s supervision, corporate, and resolution activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Thomas M. Hoenig, seconded by Director Jeremiah O. Norton (Appointive), concurred in by Director Thomas J. Curry (Comptroller of the Currency), Director Richard Cordray (Director, Consumer Financial Protection Bureau), and Chairman Martin J. Gruenberg, that Corporation business required its consideration of the matters which were to be the subject of this meeting on less than seven days’ notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the “Government in the Sunshine Act” (5 U.S.C. 552b(c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held by telephone.

Dated: February 17, 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015-03605 Filed 2-18-15; 4:15 pm]

BILLING CODE 6714-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0349]

Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271” dated February 2015. The draft guidance document is intended to provide manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps) for which no premarket submissions are required because they are not also regulated as drugs, devices, and/or biological products, with recommendations for complying with the requirements for investigating and reporting adverse reactions involving communicable disease in recipients of these HCT/Ps. The draft guidance, when finalized, is intended to supplement section XXII of FDA’s guidance entitled “Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated December 2011 and supersede the guidance entitled “Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated November 2005.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 21, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271” dated February 2015. The draft guidance document is intended provide manufacturers of HCT/Ps, with recommendations for complying with the requirements for investigating and reporting adverse reactions involving communicable disease in recipients of HCT/Ps that are regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR part 1271 (361 HCT/Ps).

The draft guidance, when finalized, is intended to supplement section XXII of FDA’s guidance entitled “Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated December 2011 by providing additional recommendations specific to the responsibilities to investigate complaints of adverse reactions concerning 361 HCT/Ps under §§ 1271.160(b)(2), 1271.320 and 1271.350(a)(1).

The draft guidance, when finalized, is intended to supersede the guidance

entitled “Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated November 2005. The guidance will provide updated information specific to reporting adverse reactions related to HCT/Ps to supplement the general instructions accompanying the MedWatch mandatory reporting form, Form FDA 3500A.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 1271 have been approved under OMB control number 0910-0543 and OMB control number 0910-0291.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-03490 Filed 2-19-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than April 21, 2015.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail to the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Radiation Exposure Screening and Education Program OMB No. 0915-xxxx—New.

Abstract: The Radiation Exposure Screening and Education Program (RESEP) is authorized by section 417C of the Public Health Service Act (42 U.S.C. 285a-9). The purpose of RESEP is to assist individuals who live (or lived) in areas where U.S. nuclear weapons testing occurred and who are