

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing

by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA/Economics Staff, "Revised Procedures for the Announcement of Approvals and Denials of Premarket Approval Applications and Humanitarian Device Exemption Applications, Regulatory Impact Analysis, Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis," 2020 (available at: <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>).

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 379k–1, 381.

§ 814.40 [Amended]

2. In § 814.40, remove "515(d)(3)" and add in its place "515(d)(4)".

§ 814.44 [Amended]

3. Amend § 814.44 as follows:

- a. In the fourth sentence in paragraph (d)(1), remove "515(d)(3)" and add in its place "515(d)(4)" and remove the sixth sentence;

- b. In paragraph (d)(2), remove "Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852" and add in its place "Freedom of Information Staff's address listed on the Agency's website at <https://www.fda.gov>."; and
- c. In paragraphs (e)(2)(ii) and (f)(2), remove "515(d)(3)" and add in its place "515(d)(4)".

§ 814.45 [Amended]

4. Amend § 814.45 as follows:

- a. In paragraph (d)(1), remove the third sentence and

- b. In paragraph (e)(3), remove "515(d)(3)" and add in its place "515(d)(4)".

5. In § 814.116 revise the fourth sentence in paragraph (b) to read as follows:

§ 814.116 Procedures for review of an HDE.

* * * * *

(b) * * * The notice of approval of an HDE will be placed on the FDA's home page on the internet (<https://www.fda.gov>) in accordance with the rules and policies applicable to PMAs submitted under § 814.20. * * *

* * * * *

§ 814.118 [Amended]

6. In § 814.118(c)(3), remove "515(d)(3)" and add in its place "515(d)(4)".

Dated: January 6, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022–00501 Filed 1–12–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 1270

[Docket No. FDA–2020–N–1519]

RIN 0910–AI41

Revocation of the Regulations for Human Tissue Intended for Transplantation and Human Dura Mater

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to revoke the regulations for human tissue intended for transplantation and human dura mater recovered prior to May 25, 2005. The revocation does not affect the regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps) recovered on or after May 25, 2005. The rule is being finalized because these regulations are obsolete or no longer necessary to achieve public health goals.

DATES: This rule is effective February 14, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the

docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:

Shruti Modi, 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:

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I. Executive Summary

A. Purpose of the Final Rule

FDA is removing the regulations under part 1270 (21 CFR part 1270), “Human Tissue Intended for Transplantation” and § 882.5975 (21 CFR 882.5975), “Human dura mater.” These regulations apply to certain tissues recovered prior to May 25, 2005. The Agency does not believe there are currently any tissues intended for transplantation remaining in inventory that were recovered prior to this date and that would be subject to these regulations. Therefore, the regulations under this part are outdated and obsolete. All HCT/Ps recovered on or after May 25, 2005, are subject to the regulations under part 1271 (21 CFR part 1271), “Human Cells, Tissues, and Cellular and Tissue-Based Products.”

B. Summary of the Major Provisions of the Final Rule

The final rule removes part 1270, “Human Tissue Intended for Transplantation,” which applies to certain human tissue and to establishments or persons engaged in

the recovery, screening, testing, processing, storage, or distribution of human tissue. It also removes § 882.5975, “Human dura mater,” which identifies and classifies human dura mater recovered prior to May 25, 2005.

C. Legal Authority

FDA is taking this action under the communicable disease provisions of the Public Health Service Act (the PHS Act) and the device provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

D. Costs and Benefits

Because this final rule will not impose any additional burden on the industry, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

II. Background

A. Introduction

FDA is issuing a final rule to revoke the regulations for human tissue intended for transplantation (part 1270) and human dura mater (§ 882.5975) recovered prior to May 25, 2005, because these regulations are obsolete or no longer necessary to achieve public health goals. The revocation does not affect the regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps) recovered on or after May 25, 2005.

B. Need for Regulation/History of Rulemaking

FDA regulates articles containing or consisting of human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient. These are defined in § 1271.3(d) (21 CFR 1271.3(d)) as HCT/Ps. Tissues as defined in § 1270.3(j) (21 CFR 1270.3(j)) recovered prior to May 25, 2005, are regulated under part 1270. HCT/Ps recovered on or after May 25, 2005, are subject to the regulations in part 1271. Examples of HCT/Ps include, but are not limited to the following: Bone, ligament, skin, cornea, dura mater, heart valve, hematopoietic stem/progenitor cells derived from peripheral and cord blood, and semen or other reproductive tissue. Vascularized human organs for transplantation are not considered HCT/Ps. FDA previously regulated human dura mater recovered prior to May 25, 2005, under § 882.5975 subject to special controls and premarket notification.¹

¹ The special controls for human dura matter recovered prior to May 25, 2005, can be found in “Class II Special Controls Guidance Document:

In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA published an interim rule (1993 interim rule) for human tissue intended for transplantation. This rule provided specific donor suitability and testing requirements for certain tissue products. As the use of human tissue for transplantation increased, FDA determined that there was a need for a much more comprehensive set of regulatory requirements that included a broader scope of products. In the **Federal Register** of July 29, 1997 (62 FR 40429), FDA issued a final rule that clarified and modified provisions of the 1993 interim rule.

In the **Federal Register** of March 4, 1997 (62 FR 9721), FDA announced the availability of a document entitled “Proposed Approach to the Regulation of Cellular and Tissue-Based Products” that detailed how cellular and tissue-based products would be regulated with a tiered approach based on risk and the necessity for FDA review.

As part of this approach, FDA advanced three regulatory proposals including: (1) Registration and listing; (2) communicable-disease screening and testing; and (3) processing standards. FDA published three final rules to implement the proposed approach, which are codified in part 1271 as follows: (1) “Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing” (66 FR 5447, January 19, 2001); (2) “Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products” (69 FR 29786, May 25, 2004); and (3) “Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments, Inspection and Enforcement” (69 FR 68611, November 24, 2004).

FDA issued these regulations to increase the safety of HCT/Ps, and public confidence in their safety, by helping to prevent the introduction, transmission, and spread of communicable disease. The regulations were issued to protect the public health while minimizing regulatory burden, which in turn would encourage significant innovation.

C. Applicability of § 882.5975 and Part 1270

The Agency did not revoke part 1270 at the same time the Agency proposed part 1271 because it would have been

Human Dura Mater—Guidance for Industry and FDA Staff”, available at <https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-guidance-document-human-dura-mater-guidance-industry-and-fda-staff>.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE—Continued

| Category | Primary estimate | Low estimate | High estimate | Units | | | Notes |
|--|--|--------------|---------------|--------------|-------------------|------------------------|-------|
| | | | | Year dollars | Discount rate (%) | Period covered (years) | |
| Qualitative | Field investigators will no longer need to reference the obsolete regulations, resulting in very minor cost savings for FDA in terms of employee time. | | | | | | |
| Costs: | | | | | | | |
| Annualized Monetized \$millions/year | 0 | 0 | 0 | 2020 | 7 | 10 | |
| Annualized Quantified | 0 | 0 | 0 | 2020 | 3 | 10 | |
| Qualitative | | | | | 7 | | |
| Transfers: | | | | | | | |
| Federal Annualized Monetized \$millions/year | | | | | 7 | | |
| From/To | | | | | 3 | | |
| Other Annualized Monetized \$millions/year | | | | | 7 | | |
| From/To | | | | | 3 | | |
| Effects: | | | | | | | |
| State, Local or Tribal Government: None | | | | | | | |
| Small Business: None | | | | | | | |
| Wages: None | | | | | | | |
| Growth: None | | | | | | | |

FDA has examined the economic implications of the rule as required by the Regulatory Flexibility Act. If a rule will have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires us to analyze regulatory options that would lessen the economic effect of the rule on small entities. This rule will not impose any new burdens on small entities, and thus will not impose a significant economic impact on a substantial number of small entities.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VI. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a

tribal summary impact statement is not required.

X. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA, Final Regulatory Impact Analysis; Final Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Revocation of the Regulations for Human Tissue Intended for Transplantation; Final Rule. Also available at: <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

List of Subjects

21 CFR Part 882

Medical devices.

21 CFR Part 1270

Communicable diseases, HIV/AIDS, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food

and Drugs, 21 CFR parts 882 and 1270 are amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

§ 882.5975 [Removed]

■ 2. Remove § 882.5975.

PART 1270—[REMOVED]

■ 3. Under the authority of 42 U.S.C. 216, 243, 264, 271, part 1270 is removed.

Dated: January 6, 2022.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

[FR Doc. 2022-00492 Filed 1-12-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2022-0022]

RIN 1625-AA00

Safety Zones; Delaware River Dredging, Marcus Hook, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is re-establishing temporary safety zones on the waters of the Delaware River in portions of Marcus Hook Range and Anchorage 7 off Marcus Hook Range. The safety zones temporarily restrict vessel traffic from transiting or anchoring in portions of the Delaware River while maintenance dredging is being conducted within the Delaware River. The safety zones are needed to protect personnel, vessels, and the marine environment from hazards created by dredging operations. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the COTP or his designated representatives.

DATES: This rule is effective without actual notice from January 13, 2022 through January 31, 2022. For the purposes of enforcement, actual notice will be used from January 6, 2022, until January 13, 2022.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG-2022-

0022 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Jennifer Padilla, Waterways Management Branch, U.S. Coast Guard Sector Delaware Bay; telephone (215) 271-4889, email Jennifer.I.padilla@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

On September 2, 2021, the Coast Guard established temporary safety zones on the waters of the Delaware River in portions of Marcus Hook Range and Anchorage 7 off Marcus Hook Range to temporarily restrict vessel traffic from transiting or anchoring in portions of the Delaware River in association with maintenance dredging within the Delaware River (86 FR 49241, Sept. 2, 2021). That rule expired November 2, 2021. On January 6, 2022, the dredging company informed the Coast Guard about additions to the original contract and the need to extend the project. The new estimated completion date is January 31, 2022.

The Coast Guard is issuing this rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable and contrary to the public interest. There is insufficient time to allow for a reasonable comment period prior to the start date for dredging operations. The rule must be in force by January 6, 2022, to serve its purpose of ensuring the safety of the public from hazards associated with dredging operations such as submerged and floating pipeline, booster pumps, head sections and vessels with a restricted ability to maneuver.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable and contrary to the public interest because immediate action is needed to mitigate the potential safety hazards associated with dredging operations in these locations.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that there are potential hazards associated with dredging operations. The purpose of this rulemaking is to ensure the safety of personnel, vessels, and the marine environment within a 250-yard radius of dredging operations and all associated pipeline and equipment.

IV. Discussion of the Rule

This rule re-establishes the safety zones established on September 2, 2021, (86 FR 49241, Sept. 2, 2021). The re-established zones will be in effect from January 6, 2022, through January 31, 2022. This change is reflected in a revised enforcement paragraph, paragraph (e). This rule makes no other changes to the previous rule. The locations and restrictions of the safety zones established by the September rule remain the same.

The safety zones are necessary to facilitate annual maintenance dredging of the Delaware River in the vicinity of Marcus Hook Range and Anchorage 7 off Marcus Hook Range (as described in 33 CFR 110.157(a)(8)). Dredging will most likely be conducted with the dredge ESSEX, though other dredges may be used, along with associated dredge pipeline and boosters. The pipeline consists of a combination of floating hoses immediately behind the dredge and submerged pipeline leading to upland disposal areas. Due to the hazards related to dredging operations, the associated pipeline, and the location of submerged pipeline, safety zones are being established in the following areas:

(1) Safety zone one includes all navigable waters within 250 yards of the dredge displaying lights and shapes for vessels restricted in ability to maneuver as described in 33 CFR 83.27, and all related dredge equipment when the dredge is operating in Marcus Hook Range, and Anchorage 7. This safety zone is being established for the duration of the maintenance project. Vessels requesting to transit the safety zone must contact the dredge on VHF channel 13 or 16 at least 1 hour prior