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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 Therefore, the regulations under this part are outdated and obsolete.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]

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

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

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 impractical to apply part 1271 retroactively to human tissue, as defined in § 1270.3(j), that was recovered before the effective date of the final rule. Instead, the Agency decided that human tissue, as defined in § 1270.3(j), that was recovered prior to May 25, 2005, would remain subject to the regulations in part 1270. However, in the final rules applicable to HCT/Ps (66 FR 5447 at 5448; 69 FR 68611), FDA noted its intention to revoke part 1270 in the future when we were confident that there was no human tissue regulated under part 1270 available for use.

Part 1270 applies only to human tissue defined in § 1270.3(j) and recovered prior to May 25, 2005. The device classification set forth in § 882.5975, "Human dura mater," is only

applicable to human dura mater recovered prior to May 25, 2005. Human dura mater recovered on or after May 25, 2005, is subject to the regulations in part 1271 when an establishment does not qualify for any of the exceptions in 21 CFR 1271.15. Further, human dura mater is regulated solely under section 361 of the PHS Act (42 U.S.C. 264) and part 1271 when the HCT/P meets all the criteria set out in 21 CFR 1271.10(a) . Otherwise the HCT/P is regulated as a drug, device, and/or biological product under the FD&C Act, and/or section 351 of the PHS Act (42 U.S.C. 262), and applicable regulations, including part 1271.

Products that meet the definition of an HCT/P in § 1271.3(d) that are recovered on or after May 25, 2005, including those that have been regulated after May 25, 2005, as drugs, devices, and/or biological products under section 351 of the PHS Act and/or the FD&C Act will not be affected by revocation of part 1270.

We do not believe there are currently any tissues intended for transplantation remaining in inventory that were recovered prior to May 25, 2005, that would be subject to these regulations. Therefore, the regulations under § 882.5975 and its accompanying special control guidance, and the regulations under part 1270 are outdated and obsolete.

D. Comments to the Proposed Rule

In the *Federal Register* of December 21, 2020 (85 FR 82990), FDA published a proposed rule entitled "Revocation of the Regulations for Human Tissue Intended for Transplantation and Human Dura Mater" to revoke the regulations for human tissue intended for transplantation and human dura mater recovered prior to May 25, 2005. We did not receive any comments on the proposed rule. Therefore, we are finalizing the proposed rule without change.

III. Legal Authority

FDA is issuing this final rule under the communicable disease provisions of the PHS Act, which provide FDA with the authority to issue and enforce regulations designed to prevent the introduction, transmission, and spread of communicable disease (42 U.S.C. 216, 243, 264, and

271), and provisions of the FD&C Act applicable to devices (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, and 371)).

IV. Effective Date

This final rule will become effective 30 days after the date of its publication in the *Federal Register*.

V. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the rule will not create new regulatory responsibilities for small entities, we certify that the rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This final rule will remove the obsolete regulations under part 1270 for human tissue intended for transplantation into a human recipient and § 882.5975 for human dura matter. These regulations only apply to certain tissue derived from a human body and recovered prior to May 25, 2005. We believe it is highly unlikely any such human tissues remain available for use today. The final rule, therefore, is not anticipated to result in any compliance costs to the industry. We expect the economic impact on FDA resulting from removing an obsolete regulation to be minimal.

Table 1 summarizes the estimated benefits and costs of the final rule. Annualized over 10 years, the estimated benefits (i.e. cost savings) of the final rule will be $0 at both the 3 and 7 percent discount rate. The present value of the estimated benefits (i.e., cost savings) of the final rule will also be $0 at both the 3 and 7 percent discount rate. The annualized costs of the final rule will be $0 at both 3 and 7 percent discount rate. The present value of costs of the final rule will also be $0 at both 3 and 7 percent discount rate.

Table 1.--Summary of Benefits, Costs, and Distributional Effects of Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$0	$0	$0	2020	7%	10 years	
		$0	$0	$0	2020	3%	10 years	
	Annualized Quantified							
	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 years	
		$0	$0	$0	2020	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized $millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized					7%		
						3%		

	Monetized $millions/year							
	From/To	From:			To:			
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: 1/12/2022 8:45 am; Publication Date: 1/13/2022]