



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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to revoke the regulations for human tissue intended for transplantation and human dura mater recovered prior to May 25, 2005. The proposed 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. FDA is proposing this action because these regulations are obsolete or no longer necessary to achieve public health goals. This action is part of FDA's implementation of Executive Orders 13771 and 13777. Under these Executive Orders, FDA is comprehensively reviewing existing regulations to identify opportunities for repeal, replacement, or modification that will result in meaningful burden reduction, while allowing the Agency to achieve our public health mission and fulfill statutory obligations.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments

until 11:59 p.m. Eastern Time at the end of [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2020-N-1519 for “Revocation of the Regulations for Human Tissue Intended for Transplantation.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” will be publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, 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.

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I. Executive Summary

A. Purpose of the Proposed Rule

FDA proposes to remove 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 Proposed Rule

The proposed rule would remove 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 would also remove § 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 (the FD&C Act).

D. Costs and Benefits

Because this proposed rule would not impose any additional burden on the industry, this regulation is not anticipated to result in any compliance costs. The costs and cost savings to FDA resulting from removing an obsolete regulation are expected to be minimal.

II. Background

A. Introduction

On February 24, 2017, Executive Order 13777, entitled “Enforcing the Regulatory Reform Agenda” (<https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda>, 82 FR 12285, March 1, 2017) was issued. One of the provisions of the Executive Order requires Agencies to evaluate existing regulations and make recommendations to the Agency head regarding their repeal, replacement, or modification, consistent with applicable law. As part of this initiative, FDA is proposing to revoke certain regulations as specified in this proposed rule.

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) as HCT/Ps. Tissues as defined in § 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, ligament, 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 currently regulates human dura mater recovered prior to May 25, 2005, under § 882.5975.

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 which 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.” The purpose was to develop a plan to address the regulation of human cellular and tissue-based products in a more comprehensive, but not unduly burdensome manner. The plan 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 as follows:

(1) “Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing” (66 FR 5447, January 19, 2001), which set forth part 1271, subpart A (General Provisions) and subpart B (Procedures for Registration and Listing) (effective dates April 4, 2001, and January 21, 2004 based on the applicability of the HCT/P establishment). The final rule requires HCT/P establishments to register with the Agency and list the HCT/Ps they manufacture.

(2) “Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products” (69 FR 29786, May 25, 2004), which set forth part 1271, subpart C (Donor Eligibility) (effective date May 25, 2005). The final rule requires HCT/P establishments to screen and test cell and tissue donors for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases.

(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), which set forth part 1271, subpart D (Current Good Tissue Practice), subpart E (Additional Requirements for Establishments Described in §1271.10), and subpart F (Inspection and Enforcement of Establishments Described in § 1271.10) (effective date May 25, 2005). The final rule requires HCT/P establishments to follow current good tissue practice, which governs

the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; recordkeeping; and the establishment of a quality program.

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 and 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 21 CFR 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 § 1271.15. Further, human dura mater is regulated solely under section 361 of the PHS Act and part 1271 when the HCT/P meets all the criteria set out in § 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, 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 part 1270 are outdated and obsolete.

III. Legal Authority

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

IV. Description of the Proposed Rule

Part 1270 became effective in 1997, and applies only to human tissue defined in § 1270.3(j) and recovered prior to May 25, 2005. It is highly unlikely there is any human tissue regulated under part 1270 remaining in inventory today that is suitable for human transplantation. This regulation is outdated and has been replaced with part 1271.

V. Proposed Effective Date

FDA is proposing that any final rule based on the proposed rule become effective 30 days after the date of its publication in the *Federal Register*.

VI. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, 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). Executive Order 13771 requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed 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 proposed rule, if finalized, would not create new regulatory responsibilities for small entities, we propose to certify that the proposed 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 proposing “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 \$156 million, using the most current (2019) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

This proposed rule, if finalized, would 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 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 proposed rule therefore is not anticipated to result in any compliance costs to the industry. We expect the economic impact on the FDA resulting from removing an obsolete regulation to be minimal.

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

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

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	\$0	\$0	\$0	2019	7%	10 years	
		\$0	\$0	\$0	2019	3%	10 years	
	Annualized Quantified							
	Qualitative	Field investigators would 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	2019	7%	10 years	
		\$0	\$0	\$0	2019	3%	10 years	
	Annualized Quantified					7%		
						3%		
Transfers	Qualitative							
	Federal Annualized Monetized \$millions/year					7%		
						3%		
	From/ To	From:			To:			
Effects	Other Annualized Monetized \$millions/year					7%		
						3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: None Small Business: None Wages: None Growth: None							

In line with Executive Order 13771, in table 2 we estimate present and annualized values of costs and cost savings over an infinite time horizon. The present value of the net costs and cost savings would be \$0 at both 3 and 7 percent discount rate.

Table 2.--Executive Order 13771 Summary Table (in \$ Millions 2016 Dollars, Over an Infinite Time Horizon)

Item	Primary Estimate (7%)	Lower Estimate (7%)	Upper Estimate (7%)	Primary Estimate (3%)	Lower Estimate (3%)	Upper Estimate (3%)
Present Value of Costs	\$0	\$0	\$0	\$0	\$0	\$0
Present Value of Cost Savings	\$0	\$0	\$0	\$0	\$0	\$0
Present Value of Net Costs	\$0	\$0	\$0	\$0	\$0	\$0
Annualized Costs	\$0	\$0	\$0	\$0	\$0	\$0
Annualized Cost Savings	\$0	\$0	\$0	\$0	\$0	\$0
Annualized Net Costs	\$0	\$0	\$0	\$0	\$0	\$0

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 1) and

<https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VII. 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.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paper Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed 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 proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. References

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, “Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Revocation of the Regulations for Human Tissue Intended for Transplantation; Proposed Rule” dated March 24, 2020. Also available at: <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

List of Subjects

21 CFR Part 882

Medical devices, Neurological 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, it is proposed that 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, 21 CFR part 1270 is removed.

Dated: December 2, 2020

Stephen M. Hahn,

Commissioner of Food and Drugs.

Dated: December 11, 2020

Alex M. Azar II,
Secretary,
Department of Health and Human Services.

[FR Doc. 2020-27828 Filed: 12/18/2020 8:45 am; Publication Date: 12/21/2020]