DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 26

[Docket No. FDA–2024–N–4016]

RIN 0910–AI92

Revocation of Regulations Regarding the Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to revoke the regulations entitled ''Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community.'' FDA is proposing this action because the existing regulations have been superseded in part by the ''United States-European Union Amended Sectoral Annex for Pharmaceutical Good Manufacturing Practices (GMPs)'' that entered into force in 2017 (2017 Amended Pharmaceutical Annex), are outdated, do not reflect current Agency practice, and are unnecessary.

DATES: Either electronic or written comments on the proposed rule must be submitted by November 19, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 19, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–4016 for ''Revocation of Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/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: Perlesta Hollingsworth, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–5874, *Perlesta.Hollingsworth@fdahhs.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

FDA proposes to revoke the regulations at part 26 (21 CFR part 26), which substantially reflect certain

provisions of the ''Agreement on Mutual Recognition Between the United States of America and the European Community'' that was signed in 1998 (1998 MRA). These regulations have been superseded in part by the 2017 Amended Pharmaceutical Annex, do not reflect current Agency practice, and are unnecessary.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would revoke part 26—Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community. This part substantially reflects the 1998 MRA between the United States and the European Community that was created to better utilize the inspectional resources of each signatory by recognizing one another's inspection reports. Part 26 consists of 3 subparts: Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices (which substantially reflects the 1998 MRA's ''pharmaceutical sectoral annex''), Subpart B—Specific Sector Provisions for Medical Devices (which substantially reflects the 1998 MRA's ''medical device sectoral annex''), and Subpart C—''Framework'' Provisions (which substantially reflects the 1998 MRA's ''umbrella'' agreement that contained general provisions applicable to the operation of all of the sectoral annexes).

C. Legal Authority

FDA is taking this action under the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). We discuss our legal authority in greater detail in part III.

D. Costs and Benefits

Because this proposed rule would not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

II. Table of Abbreviations/Acronyms

Abbreviation/ acronym	What it means
EC	European Community.
E.O	Executive Order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
GMP	Good Manufacturing Practice.
MRA	Mutual Recognition Agreement.

III. Background

A. Introduction

Part 26 was issued in response to the 1998 MRA between the United States and the European Community (EC), whereby both parties would recognize certain drug and device inspections/evaluation reports of the other, in order to more effectively allocate limited inspection resources (Mutual Recognition of Pharmaceutical Good Manufacturing Practice Inspection Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports Between the United States and the European Community, 63 FR 60122 at 60141 (November 6, 1998)). Subparts A and B of part 26 substantially reflect the 1998 MRA's pharmaceutical and medical device sectoral annexes, respectively. Subpart C of part 26 sets forth the framework provisions by which subparts A and B can be implemented. Subpart A governs ''the exchange between the parties and normal endorsement by the receiving regulatory authority of official [pharmaceutical] good manufacturing practices (GMP) inspection reports[.]'' (21 CFR 26.2) Subpart B specifies ''the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.'' (21 CFR 26.31(a))

The pharmaceutical sectoral annex to the 1998 MRA was superseded by the 2017 Amended Pharmaceutical Annex (*https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra*). The 2017 Amended Pharmaceutical Annex included new terms, rendering Subpart A obsolete. The medical device sectoral annex was not addressed in the 2017 Amended Pharmaceutical Annex, but since the 1998 MRA went into effect, it has never been fully implemented. As other mechanisms (*e.g.,* Medical Device Single Audit Program) now exist for mutual recognition with Europe with respect to medical device inspections, Subpart B is no longer necessary.

Moreover, we do not believe it is required or would be beneficial for us to issue regulations that substantially reflect the 2017 Amended Pharmaceutical Annex with the European Union. The 2017 Amended Pharmaceutical Annex is in force and has been successfully implemented without regulations that substantially reflect it. The same is true for the MRAs that FDA entered into subsequently with Switzerland and the United Kingdom (*https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra*). FDA's proposed revocation of part 26 should not be interpreted as FDA retreating from our commitment to working with our foreign counterparts, including through mutual recognition agreements, to achieve greater efficiencies and increase our inspectional reach.

B. Need for Regulation

The Agency believes the regulations in part 26 should be revoked because they have been superseded in part by the 2017 Amended Pharmaceutical Annex, do not reflect current Agency practice, and are unnecessary.

IV. Legal Authority

We are issuing this proposed rule under the drugs, medical devices, and general administrative provisions of the FD&C Act (21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 384e, and 393) and under certain provisions of the Public Health Service Act (42 U.S.C. 216, 241, 242l, 262, 264, and 265). Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA has the authority to issue regulations, and under section 809 of the FD&C Act (21 U.S.C. 384e), FDA has the authority to ''enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 510(i) in order to facilitate preapproval or risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 510(h)[.]''

V. Description of the Proposed Rule

The proposed rule revokes part 26, which substantially reflects a 1998 agreement between the United States and the EC created to better utilize the inspectional resources of each signatory by recognizing one another's inspection reports. Revocation would eliminate regulations that have been superseded in part by the 2017 Amended Pharmaceutical Annex, do not reflect current Agency practice, and are unnecessary.

FDA is proposing this action because the pharmaceutical sectoral annex to the 1998 MRA which subpart A substantially reflects has been superseded by the 2017 Amended Pharmaceutical Annex, and the medical device sectoral annex to the 1998 MRA,

which subpart B substantially reflects, was never fully implemented. Subpart C contains general provisions applicable to both subparts A and B that will be unnecessary once subparts A and B are revoked.

VI. Proposed Effective Date

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

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14904, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are ''significant'' under Executive Order 12866 section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator [of the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule does not add any new regulatory burden on the pharmaceutical or medical device industries, 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 impacts, 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 $183 million, using the most current (2023) 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.

We believe industry will maintain their current practices following the removal of part 26. FDA will also maintain its current practices, similarly generating no quantifiable costs or cost savings. Therefore, we expect this proposed rule to be cost neutral. Table 1 summarizes the estimated benefits and costs of the proposed rule, if finalized.

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 (years)	
Benefits:							
Annualized Monetized $millions/year	$0	$0	$0	2024	7	10	
	0	0	0	2024	3	10	
Annualized Quantified							
Qualitative	Avoid confusion created by outdated and unnecessary regulations that do not reflect current Agency practice						
Costs:							
Annualized Monetized millions/year	0	0	0	2024	7	10	Qualified reduction in inspection reports reporting costs per industry. Affected firms would not incur costs to develop and submit inspection reports.
	0	0	0	2024	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized millions/year					7		
					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: No estimated effect.
Small Business: No estimated effect.
Wages: No estimated effect.
Growth: No estimated effect.

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 at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VIII. 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.

IX. 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 Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this 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.

XI. 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 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. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XII. 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.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA/Economics Staff, ''Revocation of Regulations Regarding the Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports, Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and The European Community Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,'' 2020. (Available at: *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*)

List of Subjects in 21 CFR Part 26

Animal, Animal drugs, Biologics, Drugs, Exports, Imports.

For reasons stated in the preamble, and under the authority of 21 U.S.C. 393 and delegated to the Commissioner of Food and Drugs, FDA proposes to remove 21 CFR part 26.

Dated: September 12, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–21559 Filed 9–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 3

[Docket ID: DoD–2024–OS–0099]

RIN 0790–AK98

Transactions Other Than Contracts, Grants, or Cooperative Agreements for Prototype Projects; Correction

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment (OUSD(A&S)), Department of Defense (DoD).

ACTION: Proposed rule; correction.

SUMMARY: On September 4, 2024, the DoD published a proposed rule titled Transactions Other Than Contracts, Grants, or Cooperative Agreements for Prototype Projects. Subsequent to publication of the proposed rule, DoD discovered that the docket identifier in the published proposed rule was incorrect. All other information in the September 4, 2024, remains the same.

DATES: This correction is effective on September 20, 2024.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION:

Correction

In proposed rule FR Doc. 2024–19457, published in the **Federal Register** on September 4, 2024 (89 FR 71865) make the following correction:

On page 71865, in the first column, in the document heading, the docket number ''Docket ID: DoD–2021–OS–0071'' is corrected to read ''Docket ID: DoD–2024–OS–0099''.

Dated: September 17, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–21551 Filed 9–19–24; 8:45 am]

BILLING CODE 6001–FR–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket Nos. 12–375, 23–62; FCC 24–75; FR ID 237560]

Incarcerated People's Communication Services; Implementation of the Martha Wright-Reed Act; Rates for Interstate Inmate Calling Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Communications Commission (Commission) seeks additional comment on establishing permanent rate caps for video incarcerated people's communications services (IPCS) that are just and reasonable, and will fairly compensate IPCS providers, including comment on the video IPCS marketplace and the types of data needed to support its efforts to adopt permanent video IPCS rate caps in the future. It also seeks comment on the possibly of further disaggregating the very small jail rate tier and the types of cost or other data that would identify any additional distinctions within this rate tier. The Commission seeks comment on its authority to address quality of service issues raised in this proceeding and whether it should develop minimum Federal quality of service standards. It again seeks comment on whether to expand the definitions of ''Prison'' and ''Jail'' to capture the full universe of confinement facilities and specifically, the costs providers incur in providing service to confinement facilities that are not correctional institutions. It also seeks comment on whether to