regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE MA E5 Pittsfield, MA [Amended]

Pittsfield Municipal Airport, MA
(Lat. 42°25′39″ N, long. 73°17′27″ W)

That airspace extending upward from 700 feet above the surface within a 9.6-mile radius of the Pittsfield Municipal Airport, and within 6-miles each side of the 064° bearing of the airport, extending from the 9.6-mile radius to 18-miles northeast of the airport.

Issued in College Park, Georgia, on December 4, 2019.

Ryan Almasy,

Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2019–26857 Filed 12–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. FDA–2017–N–6924]

RIN 0910–AH47

Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation

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 repealing a regulation that requires an FDA-approved new drug application (NDA) or abbreviated new drug application (ANDA) for any drug product that is sterilized by irradiation (the irradiation regulation). Repealing the irradiation regulation will mean that over-the-counter (OTC) drug products that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements can be marketed legally without an NDA or ANDA, even if they are sterilized by irradiation. FDA is taking this action because the irradiation regulation is out of date and unnecessary.

DATES: This rule is effective January 15, 2020.

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.

FOR FURTHER INFORMATION CONTACT: Sudha Shukla, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5234, Silver Spring, MD 20993–0002, 301–796–3345.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

In this final rule, FDA repeals the irradiation regulation, which provided that any drug sterilized by irradiation was a new drug. OTC drugs marketed pursuant to the OTC Drug Review that are generally recognized as safe and effective, are not misbranded, and comply with all applicable regulatory requirements now can be marketed legally without an FDA-approved NDA or ANDA, even if the drugs are sterilized by irradiation. As the Agency explained in the proposed rule published in the **Federal Register** of September 12, 2018 (83 FR 46121), FDA is taking this action because the Agency no longer concludes that drugs sterilized by irradiation are necessarily new drugs. The technology of controlled nuclear radiation for sterilization of drugs is now well understood. In addition, drugs that are marketed pursuant to the OTC Drug Review must be manufactured in compliance with current good manufacturing practices (CGMPs). Appropriate and effective sterilization of drugs, including by irradiation, is adequately addressed by the CGMP requirements. Repealing the irradiation regulation eliminates a requirement that is no longer necessary and will not diminish public health protections.

The estimated one-time costs of this rule range from $25 to $32. Avoiding the unnecessary preparation and review of a premarket drug application will generate an estimated one-time cost savings that range from about $0.40 million to $2.16 million. Over 10 years with a 7 percent discount rate, the annualized net cost savings range from $0.05 million to $0.29 million, with a primary estimate of $0.06 million; with a 3 percent discount rate, the annualized net cost savings range from $0.05 million to $0.25 million, with a primary estimate of $0.05 million. Over an infinite horizon, we assume that one sponsor will benefit from this deregulatory action every 10 years; the present value of the net cost savings over the infinite horizon range from $0.76 million to $4.11 million with a 7

percent discount rate and from $1.52 million to $8.21 million with a 3 percent discount rate.

II. Background

On February 24, 2017, E.O. 13777, ''Enforcing the Regulatory Reform Agenda'' (*https://www.gpo.gov/fdsys/pkg/FR-2017-03-01/pdf/2017-04107.pdf*) was issued (82 FR 12285). One of the provisions in the E.O. 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 repealing the irradiation regulation as specified in this rule.

In the November 29, 1955, issue of the **Federal Register**, FDA issued a statement of interpretation relating to the sterilization of drugs by irradiation (20 FR 8747 at 8748).[1] In the statement, FDA explained that there was an interest in the utilization of newly developed sources of radiation for the sterilization of drugs. The Agency went on to state that it was necessary in the interest of protecting the public health to establish by adequate investigations that the irradiation treatment does not cause the drug to become unsafe or otherwise unsuitable for use. For this reason, all drug products sterilized by irradiation would be regarded as new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(p)), which would mean that an effective new drug application would be required for such products.

In 1996, FDA proposed to revise the statement and consolidate it with similar provisions into a single list of drugs that have been determined by previous rulemaking procedures to be new drugs within the meaning of section 201(p) of the FD&C Act (61 FR 29502 at 29503 to 29504 (June 11, 1996)). The Agency proposed to remove from the regulatory text any existing background information describing the Agency's basis for its determination of new drug status.

In 1997, FDA finalized these provisions, now located in § 310.502 (21 CFR 310.502), entitled ''Certain drugs accorded new drug status through rulemaking procedures'' (62 FR 12083 at 12084 (March 14, 1997)). Section 310.502(a) sets forth a list of drugs that have been determined by rulemaking procedures to be ''new drugs'' within the meaning of section 201(p) of the FD&C Act. Included on the list was ''[s]terilization of drugs by irradiation'' (§ 310.502(a)(11)). Because this regulation reflected an FDA determination that the drugs on the list are ''new drugs,'' an NDA or ANDA had to be submitted and approved by FDA before those drugs could be marketed legally.

When the paragraph now reflected in § 310.502(a)(11) was published in 1955, the technology of controlled nuclear radiation for sterilization of drugs was not well understood. In addition, neither the OTC drug monograph system nor the CGMP requirements existed. The authorizing legislation that the CGMP regulations implement, section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), was enacted in 1962 (''Drug Amendments of 1962,'' October 10, 1962, Public Law 87–781, Title I, sec. 101), and the first CGMP regulations followed in 1963 (''Part 133—Drugs; Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding,'' 28 FR 6385 (June 20, 1963) available at: *https://www.loc.gov/item/fr028120/*). The regulations creating procedures for establishing OTC drug monographs were issued in 1972 (37 FR 9464 (May 11, 1972)) available at: *https://www.loc.gov/item/fr037092/*).

Today, as the proposed rule explained (83 FR 46121 at 46123 to 46124), the technology of controlled nuclear radiation for sterilization of drugs is well understood, and all drug products marketed under the OTC Drug Review are subject to the requirement set forth in 21 CFR 330.1(a) that they be manufactured in compliance with current good manufacturing practices, as established by parts 210 and 211 (21 CFR parts 210 and 211). The CGMP requirements in parts 210 and 211 encompass sterilization, including by irradiation. As a result, as discussed in the proposed rule (83 FR 46121 at 46124), § 310.502(a)(11) can be repealed and manufacturers will still be obligated to ensure that, if they use radiation: (1) The drug products that they purport to be sterile are in fact sterile and (2) their use of radiation does not have a detrimental effect on their drug products' identity, strength, quality, purity, or stability.

III. Legal Authority

We are issuing this final rule under the drugs and general administrative provisions of the FD&C Act (sections 201, 301, 501, 502, 503, 505, 510, 701, 702, and 704 (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 371, 372, and 374)) and under section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264). The FD&C Act gives us the authority to issue and enforce regulations designed to help ensure that drug products are safe, effective, and manufactured according to current good manufacturing practices, while section 361 of the PHS Act gives us the authority to issue and enforce regulations designed to prevent the introduction, transmission, or spread of communicable diseases.

IV. Comments on the Proposed Rule

We received five comment letters on the proposed rule by the close of the comment period, all from individuals. Each of the five comment letters contained general remarks supporting the proposed rule.

V. Effective Date

This final rule is effective January 15, 2020.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, E.O. 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 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). E.O. 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 final rule is not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because few entities will be affected and the net effect will be cost savings to affected firms, we certify that the final 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

[1] Available at: *https://www.loc.gov/item/fr020231/*. A month later, this provision was included in § 3.45 in the republication of chapter 21 of the Code of Federal Regulations (CFR) in the **Federal Register**. See 20 FR 9525 at 9554 (December 20, 1955), available at: *http://cdn.loc.gov/service/ll/fedreg/fr020/fr020246/fr020246.pdf*. In 1975, FDA republished and recodified the rule in 21 CFR 200.30. See 40 FR 13996 at 13997 (March 27, 1975), available at: *https://www.loc.gov/item/fr040060/*.

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 $154 million, using the most current (2018) 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.

Table 1 summarizes our estimate of the annualized costs and benefits of the final rule.

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

[$ million]

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$0.06	$0.05	$0.29	2018	7	10	Benefits are cost savings.
	0.05	0.05	0.25	2018	3	10	Benefits are cost savings.
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.00	0.00	0.00	2018	7	10	Less than $100.
	0.00	0.00	0.00	2018	3	10	Less than $100.
Annualized Quantified				2018	7	10	
				2018	3	10	
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year	0.16	0.16	0.16	2018	7	10	User Fee.
	0.14	0.14	0.14	2018	3	10	User Fee.
	From:			To:			
Other Annualized Monetized $millions/year				2018	7	10	
				2018	3	10	
	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. With a 7 percent discount rate, the estimated annualized net cost-savings equal $0.06 million in 2016 dollars over an infinite horizon. Based on these cost savings, this final rule would be considered a deregulatory action under E.O. 13771.

TABLE 2—EXECUTIVE ORDER 13771 SUMMARY

[In $ millions 2016 dollars, over an infinite horizon]

	Primary (7%)	Lower bound (7%)	Upper bound (7%)	Primary (3%)	Lower bound (3%)	Upper bound (3%)
Present Value of Costs	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
Present Value of Cost Savings	0.88	0.75	4.01	1.75	1.50	8.01
Present Value of Net Costs	(0.88)	(0.75)	(4.01)	(1.75)	(1.50)	(8.01)
Annualized Costs	0.00	0.00	0.00	0.00	0.00	0.00
Annualized Cost Savings	0.06	0.05	0.28	0.05	0.05	0.24
Annualized Net Costs	(0.06)	(0.05)	(0.28)	(0.05)	(0.05)	(0.24)

Note: Net costs are calculated as costs minus cost savings. Values in parentheses denote net negative costs (*i.e.,* cost-savings).

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/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.31(a) 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 collections 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 E.O. 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 E.O. 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 E.O. 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 E.O. and, consequently, a tribal summary impact statement is not required.

XI. Reference

The following reference is on display in 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 addresses, 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, ''Regulation Requiring an Approved New Drug Application for Drugs Sterilized by Irradiation,'' available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, 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 part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 360hh–360ss, 361(a), 371, 374, 375, 379e, 379k–1; 42 U.S.C. 216, 241, 242(a), 262.

■ 2. In § 310.502, revise paragraph (a) introductory text and remove and reserve paragraph (a)(11) to read as follows:

§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. An approved new drug application under section 505 of the Federal Food, Drug, and Cosmetic Act and part 314 of this chapter is required for marketing the following drugs:

* * * * *

Dated: December 9, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27046 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 812, and 814

[Docket No. FDA–2018–N–0628]

RIN 0910–AH48

Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Required in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule amending requirements for medical device premarket submissions to remove paper and multiple copies and replace them with requirements for a single submission in electronic format. This action would reduce the number of copies in electronic format required, thus improving and making more efficient the FDA's premarket submission program for medical devices.

DATES: This rule is effective January 15, 2020.

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.

FOR FURTHER INFORMATION CONTACT: Diane Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993, 301–796–6559, email: *Diane.Garcia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

FDA is issuing this final rule to amend regulations on medical device premarket submissions to remove requirements for paper and multiple copies and replace them with requirements for a single submission in electronic format to improve the FDA's medical device premarket submission program and create a more efficient submission program. Because a medical device premarket submission in electronic format is easily reproducible, the requirement for multiple copies, whether in electronic format or paper form, is no longer necessary. FDA believes it is beneficial to the public to limit any burden and expense to