

AIRAC date	State	City	Airport	FDC No.	FDC Date	Subject
6-Oct-22	NE	North Platte	North Platte Rgnl/Lee Bird Fld.	2/2134	8/5/22	RNAV (GPS) RWY 35, Amdt 1B.
6-Oct-22	NE	North Platte	North Platte Rgnl/Lee Bird Fld.	2/2136	8/5/22	VOR RWY 35, Amdt 18D.
6-Oct-22	TX	El Paso	El Paso Intl	2/2211	8/2/22	RNAV (GPS) Y RWY 26L, Amdt 1C.
6-Oct-22	WY	Big Piney	Miley Meml Fld	2/2325	8/4/22	RNAV (GPS) RWY 31, Orig-D.
6-Oct-22	FL	Daytona Beach	Daytona Beach Intl	2/2367	8/5/22	RNAV (GPS) RWY 34, Amdt 2E.
6-Oct-22	KS	El Dorado	El Dorado/Capt Jack Thomas Meml.	2/2387	8/1/22	RNAV (GPS) RWY 15, Amdt 1A.
6-Oct-22	KS	El Dorado	El Dorado/Capt Jack Thomas Meml.	2/2390	8/1/22	RNAV (GPS) RWY 33, Amdt 1A.
6-Oct-22	AL	Eufaula	Weedon Fld	2/3013	8/5/22	RNAV (GPS) RWY 18, Amdt 1B.
6-Oct-22	AL	Eufaula	Weedon Fld	2/3014	8/5/22	VOR RWY 18, Amdt 8B.
6-Oct-22	AL	Eufaula	Weedon Fld	2/3017	8/5/22	VOR/DME RWY 36, Amdt 3B.
6-Oct-22	AL	Eufaula	Weedon Fld	2/3019	8/5/22	RNAV (GPS) RWY 36, Amdt 1B.
6-Oct-22	TN	Winchester	Winchester Muni	2/3176	8/5/22	RNAV (GPS) RWY 36, Orig-C.
6-Oct-22	VT	Lyndonville	Caledonia County	2/3180	8/5/22	RNAV (GPS) RWY 2, Orig-C.
6-Oct-22	KY	Elizabethtown	Addington Fld	2/3197	8/3/22	VOR-A, Amdt 3A.
6-Oct-22	WI	Sheboygan	Sheboygan County Meml	2/3319	8/2/22	RNAV (GPS) RWY 31, Orig-C.
6-Oct-22	GA	Savannah	Savannah/Hilton Head Intl	2/3428	8/5/22	RNAV (GPS) RWY 10, Amdt 2B.
6-Oct-22	TN	Athens	McMinn County	2/3856	8/5/22	RNAV (GPS) RWY 20, Amdt 1C.
6-Oct-22	TN	Athens	McMinn County	2/3859	8/5/22	RNAV (GPS) RWY 2, Orig-C.
6-Oct-22	GA	Canton	Cherokee County Rgnl	2/4025	8/8/22	RNAV (GPS) RWY 5, Amdt 1B.
6-Oct-22	KS	Washington	Washington County Veteran's Meml.	2/4059	8/2/22	RNAV (GPS) RWY 17, Amdt 1A.
6-Oct-22	KS	Washington	Washington County Veteran's Meml.	2/4060	8/2/22	RNAV (GPS) RWY 35, Amdt 1A.
6-Oct-22	NM	Santa Fe	Santa Fe Muni	2/5667	8/9/22	VOR/DME-A, Amdt 1B.
6-Oct-22	KS	Ulysses	Ulysses	2/5691	8/8/22	RNAV (GPS) RWY 12, Amdt 2.
6-Oct-22	NM	Santa Fe	Santa Fe Muni	2/5841	8/9/22	VOR RWY 33, Amdt 9B.
6-Oct-22	TX	Borger	Hutchinson County	2/6319	8/1/22	RNAV (GPS) RWY 35, Amdt 1.
6-Oct-22	MI	West Branch	West Branch Community	2/6458	8/10/22	RNAV (GPS) RWY 9, Orig-A.
6-Oct-22	OK	Holdenville	Holdenville Muni	2/6472	8/10/22	RNAV (GPS) RWY 17, Orig-A.
6-Oct-22	OK	Holdenville	Holdenville Muni	2/6474	8/10/22	RNAV (GPS) RWY 35, Orig-A.
6-Oct-22	OK	Frederick	Frederick Rgnl	2/6487	8/10/22	RNAV (GPS) RWY 35, Orig-A.
6-Oct-22	OH	Oxford	Miami University	2/6623	8/10/22	RNAV (GPS) RWY 23, Orig-A.
6-Oct-22	OH	Oxford	Miami University	2/6625	8/10/22	RNAV (GPS) RWY 5, Orig-A.
6-Oct-22	FL	Boca Raton	Boca Raton	2/6895	8/5/22	RNAV (GPS) RWY 5, Amdt 1.
6-Oct-22	OK	Norman	University Of Oklahoma Westheimer.	2/7210	7/27/22	LOC RWY 3, Amdt 4A.
6-Oct-22	IA	Ames	Ames Muni	2/8536	6/23/22	RNAV (GPS) RWY 19, Amdt 1B.
6-Oct-22	WA	Bellingham	Bellingham Intl	2/8592	8/3/22	RNAV (GPS) Y RWY 34, Amdt 2.
6-Oct-22	OK	Elk City	Elk City Rgnl Business	2/9269	8/3/22	RNAV (GPS) RWY 17, Amdt 2A.
6-Oct-22	KS	Ulysses	Ulysses	2/9934	8/8/22	RNAV (GPS) RWY 17, Amdt 1B.

[FR Doc. 2022-19750 Filed 9-13-22; 8:45 am]  
 BILLING CODE 4910-13-P

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**15 CFR Part 922**

[Docket No. 220908-0186]

RIN 0648-AV85

**Amendments to National Marine Sanctuary Regulations; Delay of Effective Date**

**AGENCY:** Office of National Marine Sanctuaries (ONMS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Interim final rule; delay of effective date.

**SUMMARY:** On May 13, 2022, the National Oceanic and Atmospheric Administration (NOAA) published an interim final rule that appeared in the **Federal Register** and that amended the Office of National Marine Sanctuaries (ONMS) regulations. That rule was published with a 30-day comment period, which ended on June 13, 2022, and a 45-day delayed effective date (June 27, 2022). A subsequent notice delaying the effective date until September 26, 2022, was published on June 24, 2022. This action further delays the effective date of the interim final rule by an additional 120 days, until January 24, 2023.

**DATES:** As of September 14, 2022, the effective date for the interim final rule

published at 87 FR 29606, May 13, 2022, and delayed at 87 FR 37728, June 24, 2022, is further delayed until January 24, 2023.

**FOR FURTHER INFORMATION CONTACT:** Vicki Wedell, NOAA Office of National Marine Sanctuaries, (240) 533-0650, [Vicki.Wedell@noaa.gov](mailto:Vicki.Wedell@noaa.gov).

**SUPPLEMENTARY INFORMATION:** In response to the interim final rule published on May 13, 2022 (87 FR 29606), which updated and streamlined ONMS regulations, NOAA received eight comments before the end of the comment period on June 13, 2022. The submitted comments are posted at [regulations.gov](https://www.regulations.gov) under docket NOAA-NOS-2011-0120. Based on issues raised by some of the public comments, NOAA is preparing technical corrections and responses to those comments for the final rule. A subsequent notice delaying

the effective date until September 26, 2022, was published on June 24, 2022 (87 FR 37228). In this action, NOAA is delaying the effective date of the interim final rule by an additional 120 days, to January 24, 2023. This action does not extend or reopen the comment period for NOAA's previous request for comments on the interim final rule.

### National Marine Sanctuaries Act

The National Marine Sanctuaries Act (NMSA) authorizes the Secretary of Commerce to designate, manage, and protect, as a national marine sanctuary, any area of the marine environment that is of special national significance due to its conservation, recreational, ecological, historical, scientific, cultural, archeological, educational, or esthetic qualities (16 U.S.C. 1431 *et seq.*). NMSA provides the legal basis and serves as the authority under which NOAA issues this action.

**Nicole R. LeBoeuf,**

*Assistant Administrator for Ocean Services and Coastal Zone Management, National Ocean Service, National Oceanic and Atmospheric Administration.*

[FR Doc. 2022-19877 Filed 9-13-22; 8:45 am]

BILLING CODE 3510-NK-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 300

[Docket No. FDA-2019-N-5553]

RIN 0910-AI36

### Annual Summary Reporting Requirements Under the Right to Try Act

**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 specify the deadline and content for submission of an annual summary of investigational drugs supplied under the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act) and the uses for which the investigational drugs were supplied. This final rule implements a provision in the Right to Try Act that requires sponsors and manufacturers who provide an “eligible investigational drug” under the provisions of the Right to Try Act to submit to FDA an annual summary of

such use, and directs FDA to specify by regulation the deadline of submission.

**DATES:** This rule is effective November 14, 2022. For additional information on the effective and compliance dates, see section V of this document.

**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:

*With regard to the final rule:* Allison Hoffman, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3138, Silver Spring, MD 20993, 301-796-9203, [Allison.Hoffman@fda.hhs.gov](mailto:Allison.Hoffman@fda.hhs.gov).

*With regard to the information collection:* Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Table of Contents

- I. Executive Summary
  - A. Purpose of the Final Rule
  - B. Summary of the Major Provisions of the Final Rule
  - C. Legal Authority
  - D. Costs and Benefits
- II. Background
  - A. Need for the Regulation/History of the Rulemaking
  - B. Summary of Comments to the Proposed Rule
  - C. General Overview of the Final Rule
- III. Legal Authority
- IV. Comments on the Proposed Rule and FDA Response
  - A. Introduction
  - B. Description of General Comments and FDA Response
  - C. Comments on the Submission Deadline
  - D. Comments on Combining Right to Try Reporting
  - E. Comments on Submitting Dosing Information
  - F. Comments on Adverse Event Reporting
  - G. Comments on the Definition of Manufacturer or Sponsor
  - H. Comments on Reporting Patient Demographic Information
  - I. Comments on Outcomes Reporting
  - J. Comments on the Clarity of the Proposed Rule
- V. Effective/Compliance Date(s)
- VI. Economic Analysis of Impacts
  - A. Introduction
  - B. Summary of Costs and Benefits
- VII. Analysis of Environmental Impact
- VIII. Paperwork Reduction Act of 1995
- IX. Federalism

- X. Consultation and Coordination with Indian Tribal Governments
- XI. Reference

### I. Executive Summary

#### A. Purpose of the Final Rule

The purpose of this rule is to implement provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by the Right to Try Act, which requires sponsors and manufacturers who provide an “eligible investigational drug” under the Right to Try Act to submit to FDA an annual summary of such use, and directs FDA to specify by regulation the deadline of submission. The rule provides information on the necessary contents of the annual summary and the deadline for its submission.

#### B. Summary of the Major Provisions of the Final Rule

The rule adds a new subpart to the regulations, to specify the deadline and content for submission of an annual summary of investigational drugs supplied under the Right to Try provisions of the FD&C Act and the uses for which they were supplied. The Right to Try Act provides that the manufacturer or sponsor of an eligible investigational drug shall submit to FDA an annual summary of any use of such drug supplied under the FD&C Act. Per the statute, the summary shall include the number of doses supplied, the number of patients treated, the use for which the drug was made available, and any known serious adverse events from use of the drug.

#### C. Legal Authority

The enacted provisions of the Right to Try Act, in conjunction with FDA's general rulemaking authority serve as FDA's legal authority for this rule.

#### D. Costs and Benefits

This final rule establishes the deadline for submission of annual summaries of use of investigational drugs supplied under the FD&C Act. The rule also establishes the required contents of these submissions.

The benefits of this rule consist of societal and public health outcomes that may accrue from the disclosure of the use of investigational drugs and any known serious adverse events provided in these annual summary reports. There is no data that would allow us to predict the magnitude of generated benefits, and thus we are unable to quantify the expected benefits of this rule.

Costs are estimated as the time spent by firms to prepare and submit these annual summary reports. The total estimated present value of this rule's