V–53 [Amended]

From Charleston, SC; Columbia, SC; Spartanburg, SC; Sugarloaf Mountain, NC; to Holston Mountain, TN. From Lexington, KY; Louisville, KY; INT Louisville 333° and Brickyard, IN, 170° radials; Brickyard. The airspace within R–3401B is excluded.

* * * * *

V–115 [Amended]

From Crestview, FL; INT Crestview 001° and Montgomery, AL, 204° radials; Montgomery; INT Montgomery 323° and Vulcan, AL, 177° radials; Vulcan; Choo Choo, TN; to Volunteer, TN. From Charleston, WV; to Parkersburg, WV.

* * * * *

V–140 [Amended]

From Panhandle, TX; Burns Flat, OK; Kingfisher, OK; INT Kingfisher 072° and Tulsa, OK, 261° radials; Tulsa; Razorback, AR; Harrison, AR; Walnut Ridge, AR; Dyersburg, TN; Nashville, TN; Livingston, TN; to London, KY. From Bluefield, WV; INT Bluefield 071° and Montebello, VA, 250° radials; Montebello; to Casanova, VA.

* * * * *

V–339 [Removed]

* * * * *

6011 United States Area Navigation Routes.

* * * * *

T–215 Holston Mountain, TN (HMV) to Gamke, IN [Amended]

Holston Mountain, TN (HMV)	VORTAC	(Lat. 36°26′13.40″ N, long. 082°07′46.56″ W)
HILTO, VA	WP	(Lat. 36°41′48.46″ N, long. 082°26′07.44″ W)
FLENR, VA	WP	(Lat. 36°56′44.27″ N, long. 082°43′42.75″ W)
RISTE, KY	WP	(Lat. 37°09′02.92″ N, long. 082°58′24.38″ W)
Hazard, KY (AZQ)	DME	(Lat. 37°23′28.52″ N, long. 083°15′46.83″ W)
HUGEN, KY	FIX	(Lat. 37°31′46.14″ N, long. 083°32′58.54″ W)
Lexington, KY (HYK)	VOR/DME	(Lat. 37°57′58.86″ N, long. 084°28′21.06″ W)
GAMKE, IN	WP	(Lat. 38°46′12.99″ N, long. 085°14′35.37″ W)

* * * * * * *

T–323 CROCS, GA to Hazard, KY (AZQ) [Amended]

CROCS, GA	WP	(Lat. 32°27′17.69″ N, long. 082°46′29.06″ W)
BOBBR, GA	WP	(Lat. 33°19′57.07″ N, long. 083°08′19.47″ W)
BIGNN, GA	WP	(Lat. 34°20′34.38″ N, long. 083°33′06.80″ W)
ZPPLN, NC	WP	(Lat. 34°59′47.42″ N, long. 083°49′37.73″ W)
HIGGI, NC	WP	(Lat. 35°26′46.57″ N, long. 083°46′41.05″ W)
KIDBE, TN	WP	(Lat. 35°51′16.23″ N, long. 083°40′19.66″ W)
ZADOT, TN	WP	(Lat. 36°35′32.17″ N, long. 083°28′40.09″ W)
WELLA, KY	WP	(Lat. 37°02′15.68″ N, long. 083°21′31.07″ W)
Hazard, KY (AZQ)	DME	(Lat. 37°23′28.52″ N, long. 083°15′46.83″ W)

* * * * *

Issued in Washington, DC, on July 20, 2020.

Scott M. Rosenbloom,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–15992 Filed 7–23–20; 8:45 am]

BILLING CODE 4910–13–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: Proposed rule.

SUMMARY: To facilitate implementation of the reporting requirements of the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act), the Food and Drug Administration (FDA, the Agency, or we) is proposing to establish requirements for the deadline and contents of submission of an annual summary. This proposed rule, if finalized, would implement the statutory requirement under provisions of the Right to Try Act for submission of an annual summary by sponsors and manufacturers who provide an eligible investigational drug for use by an eligible patient.

DATES: Submit either electronic or written comments on the proposed rule by September 22, 2020. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by September 22, 2020.

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 September 22, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 22, 2020]. 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–2019–N–5553 for ''Annual Summary Reporting Requirements Under the Right to Try Act.'' 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.

Submit comments on the information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this proposed collection is ''Annual Summary Reporting Requirements Under the Right to Try Act.''

FOR FURTHER INFORMATION CONTACT: Kathleen Davies, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3121, Silver Spring, MD 20993, 301–796–2205, *kathleen.davies@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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
  A. Purpose of the Proposed Rule
  B. Summary of the Major Provisions of the Proposed Rule
  C. Legal Authority
  D. Costs and Benefits
II. Background
  A. Introduction
  B. Criteria for Use Under Section 561B of the FD&C Act
III. Legal Authority
IV. Description of the Proposed Rule
  A. Scope/Applicability
  B. Definitions
  C. Proposed Deadline for Submission of Annual Summary
  D. Proposed Annual Summary Submission Contents
  E. Proposed Annual Summary Submission Location
V. Proposed Effective Date
VI. Preliminary Economic Analysis of Impacts
VII. Analysis of Environmental Impact
VIII. Paperwork Reduction Act of 1995
IX. Federalism
X. Consultation and Coordination With Indian Tribal Governments
XI. References

I. Executive Summary

A. Purpose of the Proposed Rule

The purpose of this proposed rule is to implement section 561B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–0a(d)(1)), added by the Right to Try Act, which requires sponsors and manufacturers who provide an ''eligible investigational drug'' under section 561B of the FD&C Act to submit to FDA an annual summary of such use, and directs FDA to specify by regulation the deadline of submission. The proposed rule, if finalized, would provide information on the necessary contents of the annual summary and the deadline for its submission.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule would add § 300.200 to part 300 (21 CFR part 300) as a new subpart D, to specify the deadline and content for submission of an annual summary of investigational drugs supplied under section 561B of the FD&C Act, and the uses for which they were supplied. The manufacturer or sponsor of an eligible investigational drug shall submit to FDA an annual summary of any use of such drug supplied under section 561B of 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

Section 561B of the FD&C Act, in conjunction with FDA's general rulemaking authority in section 701(a) of the FD&C Act (21 U.S.C. 371(a)), serve as FDA's legal authority for this proposed rule.

D. Costs and Benefits

This proposed rule, if finalized, would establish the deadline for submission of annual summaries of use of investigational drugs supplied under the Right to Try Act. The proposed rule would also establish the required contents of these submissions. 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 costs is $39,991991 at a seven percent discount rate and $49,345345 at a three percent discount rate (in 2018 dollars). The annualized cost of this rule over 10 years is $5,694694 at a seven percent discount rate and $5,785785 at a three percent discount rate.

We are unable to quantify the expected benefits of this proposed rule because there is no data that would allow us to predict the extent to which direct benefits would be generated. 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. Without these reports, FDA would not be made aware in a systematic manner of the use of eligible drugs under the Right to Try Act and any known serious adverse events. With these reports, there may be increased awareness of investigational drugs, the diseases or conditions for which patients are seeking access, and

any known serious adverse events associated with such use.

These reporting requirements instruct firms to collect all known serious adverse events and submit them once per year to FDA. In addition, based on the information in these annual summaries, FDA intends to post online an annual summary report in accordance with section 561B(d)(2) of the FD&C Act. FDA's posting of these reports may increase awareness about the availability of investigational drugs.

II. Background

A. Introduction

On May 30, 2018, the Right to Try Act (Pub. L. 115–176) was signed into law, creating section 561B of the FD&C Act. The Right to Try Act amends the FD&C Act to establish an option for patients who meet certain criteria to request access to certain unapproved medical products, and for sponsors and manufacturers who agree to provide certain unapproved medical products other than through FDA's expanded access program.[1] This law provides a new pathway for patients to request, and manufacturers or sponsors to choose to provide, access to certain unapproved, investigational drugs, including biological products, for patients diagnosed with life-threatening diseases or conditions (as defined in § 312.81 (21 CFR 312.81)) who, as certified by a physician, have exhausted approved treatment options and who are unable to participate in a clinical trial involving the investigational drug.[2] This proposed rule is not proposing to require that physician determinations be submitted to FDA. Manufacturers or sponsors who provide their investigational product under the Right to Try Act are required to submit to FDA an annual summary of the use of their drug. Specifically, manufacturers or sponsors of an eligible investigational drug must submit to FDA an annual summary that includes the number of doses supplied of an eligible investigational drug, the number of patients treated, the use for which the drug was made available, and any known serious adverse events. Per section 561B of the FD&C Act, FDA is required to specify, through regulation, the deadline for such submissions (section 561B(d)(1)). This proposed rule, if finalized, would specify that deadline.

B. Criteria for Use Under Section 561B of the FD&C Act

The Right to Try Act provides a pathway for patients who meet certain criteria (*i.e.,* eligible patients) to request, and manufacturers or sponsors to choose to provide access, to eligible investigational drugs under certain conditions. An eligible patient, as defined in the Right to Try Act, is a patient who has:

- Been diagnosed with a life-threatening disease or condition, as defined in § 312.81 (or any successor regulations) (section 561B(a)(1)(A));
- Exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug (this must be certified by a physician who is in good standing with their licensing organization or board and who will not be compensated directly by the manufacturer for so certifying) (section 561B(a)(1)(B)); and
- Provided, or their legally authorized representative has provided, to the treating physician written informed consent regarding the eligible investigational drug (section 561B(a)(1)(C)).

An eligible investigational drug, as defined in the Right to Try Act, is an investigational drug, including a biological product:

- For which a Phase 1 clinical trial (as described in 21 CFR 312.21) has been completed (section 561B(a)(2)(A));
- That has not been approved or licensed for any use by FDA (section 561B(a)(2)(B));
- For which an application has been filed with FDA, or that is under investigation in a clinical trial that is intended to form the primary basis of a claim of effectiveness in support of FDA approval or licensure and is the subject of an active investigational new drug application submitted to FDA (section 561B(a)(2)(C)); and
- Whose active development or production is ongoing, and that has not been discontinued by the manufacturer or placed on clinical hold by FDA (section 561B(a)(2)(D)).

A manufacturer or sponsor is in the best position under the Right to Try Act to determine if an investigational drug meets these criteria. In contrast, if patients contact FDA with questions about whether a product is eligible, FDA likely will not be able to answer such inquiries because disclosure laws and regulations generally prevent the Agency from publicly sharing information about the status or existence of an investigational new drug application (IND). For these reasons, under this proposed rule, FDA is not proposing to make determinations about whether a particular investigational product is an eligible investigational drug under the Right to Try Act.

III. Legal Authority

The Right to Try Act amended Chapter V of the FD&C Act by inserting section 561B (21 U.S.C. 360bbb–0a). New section 561B(d)(1) (21 U.S.C. 360bbb–0a(d)(1)) requires FDA to specify by regulation the deadline of submission of an annual summary of the use of any eligible investigational drug under the Right to Try Act by manufacturers or sponsors, and specifies the contents of such summaries. This section, in conjunction with our general rulemaking authority in section 701(a) of the FD&C Act, serves as our legal authority for this proposed rule.

IV. Description of the Proposed Rule

We are proposing to establish a new subpart D for part 300 of Title 21 of the Code of the **Federal Register**. The proposed rule, if finalized, would specify a deadline for submission of an annual summary of use under the Right to Try Act and identify the contents for that annual summary. Although the Right to Try Act provides that FDA may require the submission of this annual summary in conjunction with the annual report for an applicable investigational drug application for such drug (as required under 21 CFR 312.33), FDA is not proposing to require that the annual summaries be submitted in the annual report. We concluded that a separate process will help to ensure that information about the use of eligible investigational drugs under the Right to Try Act is identified by FDA. We believe sponsors who provide drugs under the Right to Try Act will appreciate this effort to keep the information separate. This approach will also enhance FDA's ability to quickly identify and compile this information so we can post the required annual summary of these reports. For these reasons, we believe that a separate process will be least burdensome overall on FDA, sponsors who provide drugs under the Right to Try Act, and sponsors who do not provide drugs under the Right to Try Act (for whom there will be no obligation to review any changes with respect to the process for annual summaries). We request comment on this assumption.

[1] FDA's Expanded Access Program Information: *https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm20080392.htm.*

[2] Physicians who have questions should consult with sponsors and manufacturers of eligible investigational drugs. Resources for determining whether there are available clinical trials include the sponsors of an eligible investigational drug or the website *https://www.clinicaltrials.gov/.*

A. Scope/Applicability (Proposed § 300.200)

This proposed rule, if finalized, would apply to any manufacturer or sponsor who provides an eligible investigational drug for use by an eligible patient under section 561B of the FD&C Act.

B. Definitions (Proposed § 300.200)

We are proposing to define ''eligible investigational drug'' and ''eligible patient'' as those terms are defined in section 561B(a)(1)–(2) of the FD&C Act. In addition, we are proposing to define IND as defined in 21 CFR 312.3.

We are proposing to define ''known serious adverse event'' as any serious adverse event (as defined in 21 CFR 312.32) of which the manufacturer or sponsor is aware. A manufacturer or sponsor can learn about a serious adverse event related to use of an eligible investigational drug by an eligible patient from a variety of sources. The manufacturer or sponsor should review all information about the use of an eligible investigational drug under section 561B of the FD&C Act that is obtained or otherwise received by the manufacturer or sponsor from any source. A serious adverse event would be considered to be known if information about the adverse event was reported to the manufacturer or sponsor by an eligible patient, their treating physician or representative, or another person associated with the use of an eligible investigational drug under the Right to Try Act. If a sponsor or manufacturer becomes aware of serious adverse events associated with the use of their eligible investigational drug under section 561B of the FD&C Act through a review of reports in the scientific literature, unpublished scientific papers, or other sources, the sponsor would be considered aware of the event and, as a result, it would be a known serious adverse event. Any information that the manufacturer or sponsor receives about serious adverse events from use outside of section 561B of the FD&C Act would not be considered ''known serious adverse events'' for purposes of the Right to Try Act's annual summary requirement, although they may be required to be submitted under other applicable regulations.

We are proposing to define the term ''manufacturer or sponsor'' as the person who either: (1) Meets the definition of ''sponsor'' in § 312.3 for the eligible investigational drug; (2) has submitted an application for the eligible investigational drug under section 505(b) of the FD&C Act or section 351(a) of the Public Health Service Act; or (3) produces the eligible investigational drug on behalf of such persons. Sponsors under § 312.3 take responsibility for or initiate the clinical investigation, so we expect that such persons would be well-positioned to fulfill the reporting requirements for investigational drugs provided under the Right to Try Act. Similarly, drugs and biologics applicants also take responsibility for monitoring the safety of their products, so we also expect such persons to be able to meet the reporting requirements. In addition, any person who produces the eligible investigational drug on behalf of such persons should also be able to provide FDA with the required information. Under the proposed definition, the manufacturer or sponsor would not be a person who produces only a component of the eligible investigational drug. For example, the manufacturer or sponsor would not be an excipient manufacturer that produces an inactive pharmaceutical ingredient but not the drug product provided to the eligible patient. Rather, the manufacturer or sponsor would be the person who produces the drug product that is provided to an eligible patient. Because the Right to Try Act only applies to unapproved products, we believe that the person who submits annual summaries should be closely connected to the clinical investigation or approval process. We do not believe that the reporting requirements should apply to contract manufacturers who are not closely connected to such processes. We request comment on this proposed definition. In particular, we request comment on our proposal that the term ''manufacturer or sponsor'' should only encompass persons who initiate or take responsibility for either the clinical investigations of the product or the pending applications to FDA, or who produce the eligible investigational drug provided to an eligible patient on behalf of such persons. We request comment on whether other persons would be well-positioned to provide FDA with the required information. We also request comment on whether, for persons who produce the eligible investigational drug on behalf of a sponsor or applicant, the regulatory text should specify that such persons would only meet the definition of ''manufacturer or sponsor'' if they produce the finished dosage form provided to the eligible patient.

C. Proposed Deadline for Submission of Annual Summary

We are proposing that manufacturers or sponsors submit the annual summary to FDA no later than March 31 of each year. The summary must include data for the preceding calendar year on the use of an eligible investigational drug in eligible patients under the Right to Try Act. The ''preceding calendar year'' is the period of January 1 through December 31. For example, if a sponsor provides one eligible patient with one eligible investigational drug during the period between January 1, 2021, and December 31, 2021, the sponsor would be required to submit the annual summary with information about that Right to Try Act activity no later than March 31, 2022. We propose that the first annual summary submitted by a manufacturer or sponsor under this section must cover the period from enactment of section 561B of the FD&C Act, May 30, 2018, through the date the final rule becomes effective. We also propose that the deadline for submitting the annual report will be 60 calendar days after the rule becomes effective. For example, if the final rule becomes effective February 1, 2021, then: (1) The first annual submission would be required to cover the period between May 30, 2018, and February 1, 2021; and (2) the deadline for submitting the first annual summary would be April 1, 2021. The second annual summary would cover the remaining calendar year. Thus, using the same example, the second annual summary would cover information about investigational drugs provided under section 561B of the FD&C Act between February 2, 2021, and December 31, 2021. For the second annual summary, the deadline would be March 31, 2022.

FDA is proposing March 31 of each year as the date of annual summary submission in order to provide adequate time for sponsors and manufacturers to compile the necessary data for submission to FDA after December 31 of the preceding year. We conclude that 90 days is a reasonable timeframe to compile the required information and send in the annual submissions. FDA is proposing to require annual summaries for the period between enactment of the Right to Try Act and the effective date of the final rule in order to ensure that FDA receives information about Right to Try Act activities during that period.

D. Proposed Annual Summary Submission Content

The following describes how manufacturers or sponsors can meet the statutory requirements regarding the content of the annual summary. We conclude that this information is necessary for FDA to efficiently carry out the requirements of the Right to Try Act.

1. The Name of the Eligible Investigational Drug and Applicable IND Number

FDA proposes that sponsors include the drug name and the relevant IND number as identifiers in the annual summary for the eligible investigational drug provided under the Right to Try Act.

2. Number of Doses Supplied

FDA proposes that the manufacturer or sponsor submit the total number of doses of the eligible investigational drug supplied to patients for use under the Right to Try Act during the reporting period. FDA proposes that the number of doses supplied is the total number of doses supplied regardless of whether the doses are all to one patient or to multiple patients. For example, if one patient receives three doses of an eligible investigational drug and another patient receives two doses of the same drug, the number of doses supplied is five. FDA is proposing that manufacturers or sponsors submit a total number of doses supplied and not an itemized list of doses per patient. We believe that this will make the reporting requirements less burdensome for sponsors. However, if sponsors choose, they may voluntarily provide an itemized list of doses per patient.

3. Number of Patients Treated

FDA proposes that the manufacturer or sponsor submit the total number of patients for whom the manufacturer or sponsor provided the eligible investigational drug for use under the Right to Try Act. FDA proposes that each patient be counted once, regardless of the number of doses or the number of courses of therapy they receive. For example, if a patient receives three courses of treatment with an eligible investigational drug during the reporting period, each time receiving three doses, that patient is only counted once. FDA is proposing a total number of patients treated be provided. Manufacturers and sponsors should not list individual patients to whom the drug was provided in the submission (other than for reporting of individual serious adverse events, see section IV.D.5). The Right to Try Act specifies that the annual summaries provide information about the ''*number* of patients treated'' (emphasis added).

4. Use for Which the Eligible Investigational Drug Was Made Available

FDA proposes that the manufacturer or sponsor submit a tabular summary identifying the disease or conditions for which the eligible investigational drug was made available for use under the Right to Try Act (*i.e.,* a table of diseases or conditions with the number of patients with each disease or condition). A tabular summary will streamline reporting for sponsors and manufacturers and assist FDA in efficiently fulfilling the Agency's responsibilities.

5. Any Known Serious Adverse Events and Outcomes.

FDA proposes that the manufacturer or sponsor submit a tabular summary of any known serious adverse events, including resulting outcomes of such events, experienced by patients treated with an eligible investigational drug under the Right to Try Act. The outcome of the adverse event can provide important context to enable FDA to determine if the outcomes are critical to understanding safety issues associated with the eligible investigational drug without requesting additional information for each event.

When including a known serious adverse event or its resulting outcome in the tabular summary, FDA suggests the use of medical terminology included in the Medical Dictionary for Regulatory Activities (medDRA).[3]

As discussed above, manufacturers or sponsors who provide an eligible investigational drug for use under the Right to Try Act must submit known serious adverse events associated with that use. Such sponsors and manufacturers may consider combining the table of uses and the table of known serious adverse events and outcomes of the serious adverse event. An example of a tabular summary that could be used to capture this information is provided below. To promote patient privacy, we are not proposing to require that identifying information on individual patients be provided in the submission. However, we suggest that the manufacturer or sponsor should provide an ID number used only by the manufacturer or sponsor in identifying the patient provided the drug (which could be simply a sequential numbering to identify individual patients). However, we are not proposing to include such a requirement in the regulatory text.

Eligible investigational drug	IND No.	Patient ID	Disease or condition treated	Number of doses received	Serious adverse event term	Severity—CTCAE grade 1–4 [4]	Outcome—e.g. resolved, fatal, improved, sequelae unknown
XDX501	9999999	1234567	Breast cancer	5	Hip fracture	3	Improved

E. Proposed Annual Summary Submission Location

FDA is proposing that manufacturers or sponsors submit their annual summaries under this proposed rule, if finalized, to a designated point of contact in the Office of the Commissioner. We propose to specify the designated point of contact on the FDA web page (*https://www.fda.gov*). We expect the designated point of contact would be an email contact or electronic portal. We will provide a direct weblink when this rule is finalized. All submissions of the annual summary are proposed to be submitted to FDA in an electronic format that FDA can process, review, and archive; however, we expect that eCTD format will not be required. The rationale for proposing a submission process separate from the IND submission process is to ensure that information about the use of eligible investigational drugs under the Right to Try Act can be more easily and more quickly identified by FDA. We also consider this separate submission to be preferable because many sponsors submit the same annual report to multiple regulators. By providing a separate mechanism for submitting information that is a unique reporting requirement for FDA is less burdensome than generating different annual reports for different regulators. FDA requests comment on the process proposed for submission of the required annual summaries.

V. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 60 days after publication in the **Federal Register**. FDA proposes that any manufacturer or

[3] *https://www.meddra.org/.*

[4] *https://evs.nci.nih.gov/ftp1/CTCAE/About.html.*

sponsor who provides an eligible investigational drug for use by an eligible patient in accordance with the Right to Try Act include in their first annual summary submitted under this section any use from the time of enactment of the Right to Try Act, May 30, 2018, through the date the final rule is effective. The first annual summary submitted under the Right to Try Act would be required to be submitted 60 calendar days after the rule becomes effective.

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.'' This proposed rule is not an economically 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 effects are low in cost and dispersed, 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 $154 million, using the most current (2018) 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, implements a statutory requirement in the Right to Try Act that sponsors and manufacturers who provide an eligible investigational drug under the Right to Try Act to eligible patients submit to FDA an annual summary of such uses. The Right to Try Act also requires FDA to specify by regulation the deadline for these submissions.

The proposed rule's costs are summarized in table 1; we are unable to quantify benefits for this rule. This analysis estimates the incremental impacts of this proposed rule, if finalized, for drug sponsors and these annual summary reports. Costs are calculated as the time spent by firms to prepare and submit annual summary reports based on participation in Right to Try Act requests from eligible patients for investigational new treatments. The total estimated present value of this rule's costs is $39,991 at a seven percent discount rate and $49,345 at a three percent discount rate (in 2018 dollars). The annualized cost of this rule over ten years is $5,694 at a seven percent discount rate and $5,785 at a three percent discount rate.

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. Without these reports, FDA would not be made aware in a systematic manner of the use of eligible investigational drugs under the Right to Try Act and any known serious adverse events. With these reports, there may be increased awareness of investigational drugs, the diseases or conditions for which patients are seeking access, and any known serious adverse events associated with such use.

These reporting requirements require firms to compile information about known serious adverse events and submit them in a streamlined manner once per year to FDA. In addition, based on the information in these annual summaries, FDA will post an annual summary report in accordance with section 561B(d)(2) of the FD&C Act. FDA's posting of these reports may increase awareness about the availability of investigational drugs.

Consistent with Executive Order 12866, Table 1 provides the costs and a description of benefits for this proposed rule. In line with Executive Order 13771, in Table 2, we estimate present and annualized values of costs continuing over an infinite time horizon.

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN 2018 DOLLARS OVER A 10-YEAR TIME HORIZON

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $/ year.	.....	.....	.....	2018 2018	7 3	10 10	
Annualized Quantified	.....	.....	.....	.....	7 3		
Qualitative	.....	.....	.....	.....	.....	.....	Disclosure of serious adverse events and outcomes related to investigational new drug treatments.
Costs:							
Annualized Monetized $/ year.	$5,6944 $5,7855	.....	.....	2018 2018	7% 3%	10 10	
Annualized Quantified	.....	.....	.....	.....	7% 3%		
Qualitative							
Transfers:							
Federal Annualized	.....	.....	7				
Monetized $/year	.....	.....	.....	.....	3	.....	

TABLE 1—SUMMARY OF BENEFITS AND COSTS IN 2018 DOLLARS OVER A 10-YEAR TIME HORIZON—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
From/To	From:			To:			
Other Annualized Monetized $/year.					7% 3%		
From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:						

TABLE 2—E.O. 13771 SUMMARY TABLE

[in 2016 dollars, over a perpetual time horizon]

	Primary (7%)	Primary (3%)
Present Value of Costs	$63,120	$176,799
Present Value of Cost Savings		
Present Value of Net Costs	63,120	176,799
Annualized Costs	4,418	5,304
Annualized Cost Savings		
Annualized Net Costs	4,418	5,304

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

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(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

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Annual Summary Reporting Requirements Under the Right to Try Act—OMB Control Number 0910–NEW.

Description: The proposed rule would establish requirements for the deadline and contents of an annual summary for sponsors and manufacturers who provide an eligible investigational drug for use by an eligible patient.

As described in Section IV.C. Proposed Deadline for Submission of Annual Summary, sponsors and manufacturers would submit to us an annual summary no later than March 31 of each year, including data for the preceding calendar year, which is the period from January 1 through December 31. The first summary under this proposed rule, if finalized, would cover a longer period of time in order to cover the period since enactment of the Right to Try Act. As described in Section IV.E. Proposed Annual Summary Submission Location, we propose to specify the designated point of contact for submissions on the FDA web page at *https://www.fda.gov.* A direct link will be provided when the rule is finalized.

Under the proposed rule, manufacturers or sponsors would submit to us an annual summary containing the following information:

- As described in section IV.D.1, the name of the eligible investigational drug and applicable IND number;
- As described in section IV.D.2, the number of doses supplied to the eligible patient;
- As described in section IV.D.3, the number of eligible patients treated;
- As described in section IV.D.4, use for which the eligible investigational drug was made available to the eligible patient; and
- As described in section IV.D.5, any known serious adverse events and outcomes experienced by the eligible patient treated with an eligible investigational drug.

Description of Respondents: Sponsors and manufacturers who provide an eligible investigational drug to eligible patients under the Right to Try Act.

We estimate that 6 sponsors and manufacturers would prepare and submit 6 annual summaries and that it would take approximately 2.5 hours to prepare and submit each report, totaling 15 hours.

We base our estimates for the number of sponsors and manufacturers subject to this information collection and for

the number of hours on data and information discussed in Section VI. Preliminary Economic Analysis of Impacts.

In the table below, we estimate the burden of this collection of information.

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Citation; type of IC activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
300.200; Annual summaries from sponsors and manufacturers under the Right to Try Act.	6	1	6	2.5 (150 minutes)	15

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the **Federal Register**.

IX. 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.

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. 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. Preliminary Economic Analysis, available at *https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

List of Subjects in 21 CFR Part 300

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 300 be amended as follows:

PART 300—GENERAL

■ 1. The authority citation for part 300 shall be revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 360b, 360bbb–0a, 371.

■ 2. Add subpart D to part 300, consisting of § 300.200, to read as follows:

Subpart D—Annual Summary Reporting Requirements.

Sec.

300.200 Annual summary requirements under the Right to Try Act.

§ 300.200 Annual summary requirements under the Right to Try Act.

(a) Definitions. The following definitions of terms apply only to this section:

(1) *Eligible investigational drug.* An eligible investigational drug is as defined in section 561B(a)(2) of the Federal Food, Drug, and Cosmetic Act.

(2) *Eligible patient.* An eligible patient is as defined in section 561B(a)(1) of the Federal Food, Drug, and Cosmetic Act.

(3) *Investigational New Drug (IND).* An IND is as defined in § 312.3 of this chapter.

(4) *Known serious adverse event.* A serious adverse event (as defined in § 312.32 of this chapter) is considered ''known'' if the manufacturer or sponsor is aware of it.

(5) *Manufacturer or sponsor.* A manufacturer or sponsor is the person who:

(i) Meets the definition of ''sponsor'' in § 312.3 of this chapter for the eligible investigational drug;

(ii) Has submitted an application for the eligible investigational drug under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act; or

(ii) Produces the eligible investigational drug provided to an eligible patient on behalf of the persons described in paragraphs (a)(5)(i) or (ii) of this section.

(b)(1) Except as described in (b)(2) of this section, a manufacturer or sponsor of an eligible investigational drug shall submit to the Food and Drug Administration (FDA), no later than March 31 of each year, an annual summary of any use of eligible investigational drugs supplied to any eligible patient under section 561B of the Federal Food, Drug, and Cosmetic Act for the period of January 1 through December 31 of the preceding year.

(2) For a manufacturer or sponsor of an eligible investigational drug that has supplied an eligible patient with an eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act between the period from enactment of section 561B (May 30, 2018) and [DATE THE FINAL RULE BECOMES EFFECTIVE], the following deadlines apply:

(i) The manufacturer or sponsor shall submit to FDA a first annual summary covering that period no later than [DATE 60 CALENDAR DAYS AFTER THE FINAL RULE BECOMES EFFECTIVE]; and

(ii) The manufacturer or sponsor shall submit to FDA a second annual summary covering the period from [DATE THE FINAL RULE BECOMES EFFECTIVE] to December 31 [YEAR THE FINAL RULE BECOMES EFFECTIVE] by March 31 [DATE THE YEAR AFTER THE FINAL RULE

BECOMES EFFECTIVE], for any eligible investigational drugs supplied to any eligible patients under section 561B of the Federal Food, Drug, and Cosmetic Act.

(c) For each eligible investigational drug, the annual summary must include:

(1) *The name of the eligible investigational drug and applicable IND number.* The name and IND number of the eligible investigational drug supplied by the manufacturer or sponsor for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(2) *Number of doses supplied.* The total number of doses supplied by the manufacturer or sponsor to eligible patients for use under section 561B of the Federal Food, Drug, and Cosmetic Act. Each dose of an eligible investigational drug supplied for an eligible patient shall be counted as a dose supplied.

(3) *Number of patients treated.* The total number of eligible patients for whom the manufacturer or sponsor provided the eligible investigational drug for use under section 561B of the Federal Food, Drug, and Cosmetic Act. An eligible patient treated more than one time or with multiple doses of an eligible investigational drug shall be counted as a single patient.

(4) *Use for which the eligible investigational drug was made available.* A tabular summary identifying the disease or conditions for which the eligible investigational drug was made available for use under section 561B of the Federal Food, Drug, and Cosmetic Act.

(5) *Any known serious adverse events and outcomes.* A tabular summary of any known serious adverse events, including resulting outcomes, experienced by patients treated with the eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

(d) Annual summaries submitted pursuant to this section shall be submitted in an electronic format that FDA can process, review, and archive, and shall be sent directly to a designated point of contact for submissions made under section 561B of the Federal Food, Drug, and Cosmetic Act. The annual summaries must be submitted to the designated point of contact and shall not be submitted to a particular IND. FDA will specify the designated point of contact for submission of the annual summary on FDA's website, located at *https://www.fda.gov*.

Dated: July 10, 2020.

Stephen M. Hahn,

Commissioner of Food and Drugs.

[FR Doc. 2020–16016 Filed 7–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Parts 5 and 576

[Docket No. FR–6152–P–01]

RIN 2506–AC53

Making Admission or Placement Determinations Based on Sex in Facilities Under Community Planning and Development Housing Programs

AGENCY: Office of the Secretary, HUD.

ACTION: Proposed rule.

SUMMARY: This proposed rule would provide that grant recipients, subrecipients, owners, operators, managers, and providers under HUD programs that permit single-sex or sex-specific facilities (such as temporary, emergency shelters or other facilities with physical limitations or configurations that require and are permitted to have shared sleeping quarters or bathrooms) may establish a policy, consistent with federal, state, and local law, to accommodate persons based on sex. The proposed rule would maintain requirements from HUD's 2012 final rule entitled ''Equal Access to Housing in HUD Programs Regardless of Sexual Orientation or Gender Identity'' and would require shelters to uniformly and consistently apply any such policy the shelter develops. The proposed rule would require any determination of sex by the shelter provider to be based on a good faith belief, and require the shelter provider to provide transfer recommendations if a person is of the sex not accommodated by the shelter and in some other circumstances.

DATES: *Comment Due Date:* September 22, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this Proposed Rule to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410–0500. Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

2. Electronic Submission of Comments. Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* website can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. All submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (FAX) comments are not acceptable.

Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the Federal Relay Service at 800–877–8339 (toll-free number). Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Andrew Hughes, Chief of Staff, U.S. Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, telephone number 202–402–7204 (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8389 (toll-free number).

SUPPLEMENTARY INFORMATION:

I. History

HUD has always supported effective models at reducing homelessness and providing emergency shelter for those in