box: ''By checking this box, the prospective primary participant is agreeing to the Assurances set out above.''

Section 22—Attachments

- Add optional attachment section for the following items: Policy Manual; Subrecipient Contract; Model Plan Participation Notes for Tribes.

Respondents: States, the District of Columbia, U.S. territories, and tribal governments.

Annual Burden Estimates

The estimated time per response for the FY 2025 Model Plan has been increased based on the revisions. The estimated time per response for the FY 2026 Model Plan will reduce back after revisions are in place and respondents can duplicate response in OLDC.

Instrument	Total annual number of respondents	Total annual number of responses per respondent	Average burden hours per response	Annual burden hours for each form
LIHEAP Detailed Model Plan—FY24	210	1	.5	105
LIHEAP Detailed Model Plan—FY25	206	1	1	206
LIHEAP Detailed Model Plan FY26	206	1	.5	103
Estimated Total Burden Hours:				414
Average Annual Burden Hours:				138

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 8621.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–21663 Filed 9–29–23; 8:45 am]

BILLING CODE 4184–80–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3976]

Support for Clinical Trials Advancing Rare Disease Therapeutics Pilot Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research's (CBER) Office of Therapeutic Products (OTP) and Center for Drug Evaluation and Research's (CDER) Office of New Drugs are announcing the opportunity for a limited number of development programs to participate in the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program, with the goal of further accelerating the pace of development of certain CBER- and CDER-regulated products (novel drug and biological products) that are intended to treat a rare disease. Because each Center has identified specific needs concerning regulated products for rare diseases, the eligibility criteria for the pilot differ between CBER and CDER. This pilot would augment the currently available formal meetings between FDA and sponsors by addressing issues related to the development of individual products through more rapid, ad-hoc communication mechanisms. Sponsors, if selected for the pilot, would receive more frequent advice related to such specific issues through additional interactions to facilitate novel drug and biological product program development and generate high quality and reliable data intended to support a Biologics License Application (BLA) or New Drug Application (NDA). This notice outlines the eligibility criteria, what to submit in a request to participate in the pilot, selection criteria, process, and FDA-Sponsor interactions expected to occur for programs participating in the pilot.

DATES: From January 2, 2024, to March 1, 2024, FDA will accept requests to participate in the START Pilot Program and select no more than three participants from each Center (CBER and CDER). See the ''Participation'' section for eligibility criteria, instructions on how to submit a request to participate, and information regarding the selection process.

FOR FURTHER INFORMATION CONTACT: Andrew Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911; or Quyen Tran, Center for Drugs Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6301, Silver Spring, MD 20993–0002, 301–796–2771.

For general questions about the START Pilot Program for CBER: Industry.biologics@fda.hhs.gov. For general questions about the START Pilot Program for CDER: CDER.STARTProgram@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the START Pilot Program is to further accelerate the pace of development of novel drug and biological products that are intended to address an unmet medical need as a treatment for a rare disease. The pilot is designed to be milestone-driven (*i.e.,* to facilitate the progression of a development program to pivotal clinical study stage or the pre-BLA or pre-NDA meeting stage) where product development programs selected would benefit from enhanced communications with FDA. Participation in the pilot will be considered concluded when the development program has reached a significant regulatory milestone such as initiation of the pivotal clinical study stage or the pre-BLA or pre-NDA meeting stage as agreed upon with the sponsor. Pilot participants will be selected based on demonstrated development program readiness. The START Pilot Program is intended to provide a mechanism for addressing clinical development issues that otherwise would delay or prevent a promising novel drug or biological product from progressing to the pivotal clinical trial stage or pre-BLA/pre-NDA meeting stage.

The pilot would augment the currently available formal meetings between FDA and sponsors (see FDA's draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' ((September 2023) (Ref. 1))) through more rapid, ad-hoc communications with FDA by addressing issues with specific programmatic needs for individual products. For example, these issues can be related to clinical study design, choice of control group, fine-tuning the choice of patient population, selecting appropriate endpoints for efficacy trials to support marketing approval, selecting statistical methodology, leveraging nonclinical information, or product characterization. For eligible development programs sponsors and FDA could benefit from such additional communication beyond the currently available formal meeting mechanisms to address specific programmatic needs that require in-depth discussions. The increased communication between FDA review staff and sponsors is intended to facilitate program development for specific products and to help generate high quality and reliable data intended to support a BLA or NDA.

II. Participation

From January 2, 2024, to March 1, 2024, FDA will accept requests to participate in the START Pilot Program and will initially select up to three participants in each Center. Taking into consideration lessons and sponsors' experiences from the initial iteration of this program, a second iteration of the pilot may be conducted to include more participants in the future. At a later date, FDA may also publish another notice in the **Federal Register** to announce a second iteration of the program.

Sponsors who are interested in participating in the START Pilot Program should submit a request to participate as an amendment to their Investigational New Drug (IND) application.

A. Eligibility Criteria

To be considered for the START Pilot Program, participants must meet the following eligibility criteria:

1. Joint CBER and CDER Eligibility Criteria

• IND has been submitted in or converted to Electronic Common Technical Document (eCTD) format, unless the IND is of a type granted a waiver from eCTD format (see FDA's guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications'' ((February 2020) (Ref. 2))) and remains in active status.

• Sponsor has demonstrated substantial effort to ensure that that Chemistry, Manufacturing, and Controls (CMC) development aligns with clinical development, for example, through documented control of manufacturing and testing procedures to ensure clinical and CMC development timeline are in alignment.

Given the specific identified needs for the products regulated by each Center for rare diseases, the following eligibility criteria differ between CBER and CDER:

2. CBER-Specific Eligibility Criteria

• Existing OTP-regulated IND for a cellular or gene therapy under which the product is being developed toward a marketing application.

• Such product is intended to address an unmet medical need as a treatment for a rare disease [1] or serious condition, which is likely to lead to significant disability or death within the first decade of life.

3. CDER-Specific Eligibility Criteria

• Such product is intended to treat rare neurodegenerative conditions (including those of rare genetic metabolic etiology).

B. What To Submit in a Request To Participate in the START Pilot

To participate in the START Pilot Program, sponsors should submit a written request as an amendment to the IND. The cover letter should (1) state ''Request to participate in the START Pilot Program'', (2) note whether there is a breakthrough therapy (BT) designation for the product and for CBER-regulated products only—whether there is a BT designation and/or regenerative medicine advanced therapy (RMAT) designation, and (3) provide a point of contact.

The request should include the initial specific development issue(s) for a given product for enhanced communication and a proposed communication plan between the sponsor and review staff. In addition, the following information should be provided:

1. Program development plan.

The plan should describe the current state of program development, including any ongoing activities not already detailed in the IND.

• CMC development plan and current status.

• Nonclinical development plan and current status.

• Clinical development plan and current status.

2. Any specific issue(s) (grouped by review disciplines) for which the prospective applicants are seeking enhanced communications with FDA review staff to facilitate program development, including, for example, to ensure a mutual understanding of information needed to facilitate initiating the pivotal clinical study or to the pre-BLA/pre-NDA meeting stage.

3. The planned timeline for initiation of the clinical study(ies) intended to provide the primary evidence of effectiveness to support a marketing application or for a pre-BLA/pre-NDA meeting request.

4. The proposed communication plan for interactions between FDA review staff and the sponsor, including the proposed timing (*i.e.,* month and year) for the initial teleconference and format (*e.g.,* email or teleconference) of the subsequent communications on a scheduled and/or as needed basis.

C. Selection Criteria and Process

FDA intends to select participant CBER and CDER INDs based on the criteria outlined below. FDA will make its determination of participants following the close of the application period. FDA intends to issue a letter to notify each sponsor of FDA's decision on sponsor requests to participate within 90 days of the application deadline.

For the initial selection of up to three INDs from each Center for the START Pilot Program from eligible applicants, FDA intends to consider factors such as: (1) potential clinical benefits of the product, (2) whether resolution of the specific issues noted by the sponsor in their request to participate in the pilot could be facilitated through enhanced communication to improve efficiency of program development, (3) whether there is an BT or RMAT designation for the product, (4) whether CMC development timeline aligns with clinical development plans, and (5) while INDs for combination products (21 CFR 3.2(e)(1)) may be eligible, products that require significant cross-Center interactions (*e.g.,* complex combination products) may be less likely to be

[1] A rare disease or condition ''means any disease or condition which affects less than 200,000 persons in the United States . . .'' (Section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb(a)(2))). The START Pilot Program in CBER is not intended to encompass all rare diseases, but only a subset of rare diseases that are likely to lead to significant disability or death within the first decade of life.

selected for the pilot. Overall, pilot participants will be selected based on application readiness (*e.g.,* sponsors who demonstrate having the ability to move the program forward towards a marketing application).

D. FDA-Sponsor Interactions During the START Pilot Program

If selected for the START Pilot Program, sponsors will receive enhanced communications with FDA review staff. These enhanced communications may vary between CBER and CDER but will include at a minimum an initial meeting to review features of the pilot, discuss a pathway intended to support a marketing application, and to discuss specific issues for which a sponsor requests enhanced communication with FDA. Additional communications will include ongoing interactions via email or teleconference that take place on a scheduled and/or as needed basis as agreed upon by the sponsor and FDA.

III. Paperwork Reduction Act of 1995

This notice refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

IV. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are 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 Draft Guidance for Industry ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (September 2023): *https://www.fda.gov/media/172311/download.*

2. FDA Guidance for Industry ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions using the eCTD Specifications'' (February 2020): *https://www.fda.gov/media/135373/download.*

Dated: September 25, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21235 Filed 9–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0219]

Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—''Dose Banding''; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—'Dose Banding.' '' The guidance is intended to assist applicants in incorporating dose banding information, based on dosing information of a previously approved drug product that is based on weight or body surface area (BSA), into the proposed labeling of injectable drug products that are the subject of certain marketing applications submitted to FDA. This guidance finalizes the draft guidance of the same title issued on July 21, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on October 2, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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–2022–D–0219 for ''Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—'Dose Banding.' '' Received comments 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