

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 FDA Draft Guidance for Industry “Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products” (September 2023); 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

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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Chris Wheeler, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-0151; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Background**

FDA is announcing the availability of a 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.’” This guidance provides recommendations for incorporating dose banding information into the labeling of an injectable drug product that is seeking approval through a new drug application submitted under section 505(b) of the FD&C Act (21 U.S.C. 355(b)), a biologics license application submitted under section 351(a) of the PHS Act (42 U.S.C. 262(a)), or a supplement to one of these approved applications. The recommendations and examples in this guidance are relevant to situations in which an applicant (1) proposes to develop ready-to-use containers with a range of different strengths for an injectable drug product and (2) seeks to incorporate dose banding information into the prescribing information based on dosing information of a previously approved drug product that is based on weight or BSA.

This guidance finalizes the draft guidance entitled “Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—‘Dose Banding.’” issued on July 21, 2022 (87 FR 43533). FDA considered comments received on the draft guidance as it developed the final guidance. Changes from the draft guidance are primarily intended to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Human Prescription Drug and Biological Products—Labeling for Dosing Based on Weight or Body Surface Area for Ready-to-Use Containers—‘Dose Banding.’” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### **II. Paperwork Reduction Act of 1995**

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by Office of Management Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 201 have been approved

under OMB control number 0910-0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

### **III. Electronic Access**

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 26, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Regional Pediatric Pandemic Network**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Announcing supplemental funding for Regional Pediatric Pandemic Network award recipients in Maryland and Ohio.

**SUMMARY:** HRSA provided additional award funds to the two Regional Pediatric Pandemic Network (RPPN) Program recipients in Maryland and Ohio with periods of performance ending in fiscal year 2024.

**FOR FURTHER INFORMATION CONTACT:** Sara Kinsman, MD, Director, Division of Child, Adolescent and Family Health, Maternal and Child Bureau, Health Resources and Services Administration, at [SKinsman@hrsa.gov](mailto:SKinsman@hrsa.gov) and 301-443-2250.

#### **SUPPLEMENTARY INFORMATION:**

*Intended Recipient(s) of the Award:* The two award recipients of the HRSA Regional Pediatric Pandemic Network Program are Children’s National Medical Center in Maryland, and University Hospitals Cleveland Medical Center in Ohio, as listed in Table 1.