

satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating conformance to all performance criteria necessary to support a finding of substantial equivalence for a device type established in FDA guidance, rather than using direct predicate comparison testing for some of the performance characteristics.

Use of objective performance criteria developed for this approach may promote predictability and consistency in the review of 510(k) submissions, thereby reducing burdens on the Agency and possibly review times on individual submissions. At the same time, this approach satisfies the statutory standard for demonstrating substantial equivalence. The reviews of Safety and Performance Based Pathway 510(k) submissions remain subject to the same timeframes as Traditional 510(k) submissions, but FDA anticipates that faster review timeframes may be possible for the Safety and Performance Based Pathway 510(k) submissions. As a result, this pathway is intended to promote the public health by helping patients gain more timely access to new medical devices that are high quality, safe, and effective. Moreover, as FDA stated in its April 2018 Medical Device Safety Action Plan,<sup>2</sup> this approach would provide an opportunity for device developers to demonstrate that their product meets these modern performance criteria as well as the ability to do so in a more straightforward and efficient manner than under the traditional 510(k) Pathway. Through this more transparent approach, FDA may drive greater market competition to develop safer devices. Manufacturers would be able to demonstrate that their products meet established performance criteria (including those related to safety), and thus, may be able to more readily demonstrate that their products perform equivalent to or better than other devices on the market (including that they are safer).

FDA considered comments received on the draft guidance entitled “Expansion of the Abbreviated 510(k) Program: Demonstrating Substantial Equivalence Through Performance Criteria” that appeared in the **Federal Register** of April 12, 2018 (83 FR 15847). FDA has changed the name of this draft guidance to the “Safety and

Performance Based Pathway” and revised it as appropriate in response to the comments received. Among others, FDA received comments requesting additional clarity on the device types that will be appropriate for the Safety and Performance Based Pathway and how the performance criteria will be developed. FDA intends to maintain a list of device types appropriate for the Safety and Performance Based Pathway on the FDA website. Additionally, industry and other stakeholders may suggest device types for which FDA should consider establishing performance criteria, by for example, identifying products for which there are comprehensive FDA-recognized consensus standards. FDA also welcomes evidence-based suggestions on what the performance criteria should be for such device types. FDA intends to develop performance criteria for appropriate device types through guidance in accordance with the good guidance practices regulation (§ 10.115), which includes an opportunity for FDA to receive input from stakeholders.

## II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on the “Safety and Performance Based Pathway.” 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. This guidance is not subject to Executive Order 12866.

## III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov> or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Persons unable to download an electronic copy of “Safety and Performance Based Pathway” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 17046 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved 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. 3501–3520). The collections of information in 21 CFR 807, subpart E have been approved under OMB control number 0910–0120.

Dated: January 15, 2019.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2019–00568 Filed 1–31–19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–4629]

### Survey Methodologies To Assess Risk Evaluation and Mitigation Strategies Goals That Relate to Knowledge; Draft 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 draft guidance for industry entitled “Survey Methodologies to Assess REMS Goals That Relate to Knowledge; Draft Guidance For Industry.” This draft guidance provides recommendations to industry on conducting risk evaluation and mitigation strategies (REMS) assessment surveys used to evaluate respondent knowledge of REMS-related information. Most applicants use surveys to evaluate patients’ and healthcare providers’ understanding of the serious risks associated with, and safe use of, their drugs to assess REMS knowledge goals. The draft guidance discusses general principles and recommendations related to conducting REMS assessment knowledge surveys, including study design, survey instrument development, survey data collection and processing, and data analysis.

**DATES:** Submit either electronic or written comments on the draft guidance by April 2, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

<sup>2</sup> “Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health,” April 2018, available at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf>.

### 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-2018-D-4629 for the "Survey Methodologies to Assess REMS Goals That Relate to Knowledge." 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.

- **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.gpo.gov/fdsys/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.

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

Submit written requests for single copies of the draft 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 to 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 draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Brian Gordon, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2486, Silver Spring, MD 20993-0002, 301-796-3960, [Brian.Gordon@fda.hhs.gov](mailto:Brian.Gordon@fda.hhs.gov); Doris Auth, Center for Drug Evaluation

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2480, Silver Spring, MD 20993-0002, 301-796-0487, [Doris.Auth@fda.hhs.gov](mailto:Doris.Auth@fda.hhs.gov); or Stephen Ripley, 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 draft guidance for industry entitled "Survey Methodologies to Assess REMS Goals That Relate to Knowledge." The Food and Drug Administration Amendments Act of 2007 (FDAAA) created section 505-1 (21 U.S.C. 355-1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which authorizes FDA to require a REMS for certain drugs if FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh its risks.

REMS elements may include a medication guide, a patient package insert, and/or a communication plan. FDA may also require certain elements to assure safe use (ETASU) as part of a REMS. The ETASU can include, for example, requirements that health care providers who prescribe the drug have particular training or experience, that patients using the drug be monitored, or that the drug be dispensed to patients with evidence or other documentation of safe use conditions. Certain REMS with ETASU may also include an implementation system through which the sponsor is able to monitor and evaluate implementation of the ETASU and work to improve their implementation. All REMS for drugs approved under a new drug application or a biologics license application must include a timetable for submission of assessments of the REMS. The timetable for submission of assessments must be, at a minimum, an assessment by 18 months after the strategy is initially approved, an assessment by 3 years after the strategy is initially approved, and an assessment in the 7th year after the initial approval of the REMS. For additional information about REMS, see the draft guidance for industry "Format and Content of a REMS Document," (82 FR 47529, October 12, 2017) available at <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm184128.pdf>.

The FD&C Act requires applicants to conduct assessments to evaluate the effectiveness of REMS. The statute specifies that the assessment for REMS must include an assessment of the extent to which the approved strategy,

including each element of the strategy, is meeting the goal or whether one or more such goals or such elements should be modified (section 505–1(g)(3) of the FD&C Act). The statute does not specifically describe how this assessment should be conducted. Many REMS include a goal related to knowledge, such as to inform or educate patients and healthcare providers about the serious risks associated with and safe use of a drug. When knowledge goals are part of a REMS, the REMS assessment plan generally includes, as appropriate, an evaluation of patients' and healthcare providers' understanding of the serious risk(s) associated with, and safe use of, the drug.

The purpose of the REMS knowledge assessment is to evaluate the target populations' knowledge about the serious risk(s) and safe use of the drug. Most applicants use surveys to evaluate patients' and healthcare providers' understanding of the serious risk(s) associated with, and safe use of, their drugs to assess REMS knowledge goals.

This draft guidance, which describes best practices for the design, conduct, and data analyses of the results of REMS assessment knowledge surveys to evaluate patients' and healthcare providers' understanding of the serious risk(s) associated with, and safe use of, a drug, incorporates input obtained from the June 7, 2012, public workshop on "REMS Assessments: Social Science Methodologies to Assess Goals Related to Knowledge," and the comments submitted to the docket opened in association with the workshop (FDA–2012–N–0408).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on conducting risk evaluation and mitigation strategy assessment surveys used to assess respondent knowledge of REMS-related information. 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. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This guidance refers to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance "REMS Assessment: Planning and Reporting."

The assessment of burden hours included in the NOA for the draft guidance "REMS Assessment: Planning and Reporting" includes the burden for conducting knowledge surveys when conducted in support of a REMS Assessment.

## III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: January 17, 2019.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2018–D–4524]

#### **S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines; International Council for Harmonisation; Draft 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 draft guidance for industry entitled "S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines." The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance recommends international standards for the nonclinical safety studies recommended to support the development of pediatric medicines. Tissue engineered products, gene and cellular therapies, and vaccines are excluded from the scope of this guidance. The guidance provides a weight of evidence approach to determine when nonclinical toxicity studies may be recommended in juvenile animals. If such studies are recommended, the guidance provides appropriate study designs. The draft guidance is intended to promote

harmonization of recommendations for such studies and should facilitate the timely conduct of pediatric clinical trials and reduce the use of animals in accordance with the 3Rs (replace/reduce/refine) principles.

**DATES:** Submit either electronic or written comments on the draft guidance by April 2, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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–2018–D–4524 for "S11 Nonclinical Safety Testing in Support of Development of Pediatric Medicines." Received comments will be placed in