recommendations on re-programming of funds and negotiating for funds on behalf of OMH. Interacts with CMS OMH staff and other CMS components to maximize the effectiveness and efficiency of CMS spending.

• Works with other CMS components to develop programs and initiatives that support healthcare providers who practice in minority and underserved geographic regions, and whose patient mix contains a disproportionate share of minority and other minority and underserved populations.

• Develops tools, resources, training and educational materials, and outreach activities to foster awareness of health disparities and Agency efforts to improve minority health and reduce disparities for internal and external stakeholders, beneficiaries and the public in consultation with the Office of Communications, Division of Tribal Affairs, Regional Offices and other CMS components and offices, and HHS as appropriate.

• Serves as a conduit for beneficiary and stakeholder feedback and works closely with communications staff in CMS and HHS to ensure that the perspectives of vulnerable populations are represented in the development of agency communication and outreach strategies and that the implementation of these strategies is done in a manner that is culturally and linguistically appropriate and responsive to the needs of vulnerable populations.

• Coordinates grants, contracts and memorandums of understanding including partnerships with external entities including learning institutions, States, Territories and Tribal Nations.

• Serves as an agency resource and conduit responsible for outward/external promotion of messaging and the progress of CMS's work to decrease health disparities. Develop holistic and comprehensive marketing plans on resources and information that incorporate and leverage existing communication channels and vehicles in CMS to reach CMS OMH target populations.

• Manage the CMS OMH website, CMS OMH listserv announcements, social posts, partner emails, webinars and events, external information campaigns and internal communication trainings and technical support on messaging health equity and the needs of vulnerable populations.

• Provides management and administrative support to the CMS OMH Director's office.

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–06396 Filed 3–27–23; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4843]

Soft (Hydrophilic) Daily Wear Contact Lenses—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Soft (Hydrophilic) Daily Wear Contact Lenses—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' The device-specific guidance identified in this notice was developed in accordance with the final guidance entitled ''Safety and Performance Based Pathway.''

DATES: The announcement of the guidance is published in the **Federal Register** on March 28, 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–2019–D–4843 for ''Soft (Hydrophilic) Daily Wear Contact Lenses—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Soft (Hydrophilic) Daily Wear Contact Lenses—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–4908.

SUPPLEMENTARY INFORMATION:

I. Background

This device-specific guidance document provides performance criteria for premarket notification (510(k)) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled ''Safety and Performance Based Pathway.'' [1] As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the above-listed guidance, rather than using direct predicate comparison testing for some of the performance characteristics.

A notice of availability of the draft guidance appeared in the **Federal Register** of March 4, 2020 (85 FR 12788). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarifying the recommended contact lens thickness for spectral transmittance and ultraviolet transmittance performance testing. Additionally, clarification has been included to describe how this guidance relates to FDA's special controls guidance document entitled ''Premarket Notification [510(k)] Guidance Document for Class II Daily Wear Contact Lenses.'' [2]

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 ''Soft (Hydrophilic) Daily Wear Contact Lenses.'' 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. 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Soft (Hydrophilic) Daily Wear Contact Lenses—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00019022 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

[1] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.*

[2] Available at: *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-daily-wear-contact-lenses-premarket-notification-510k-guidance-document*

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06374 Filed 3–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3419]

General Considerations for Animal Studies Intended To Evaluate Medical Devices; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''General Considerations for Animal Studies Intended to Evaluate Medical Devices.'' FDA developed this guidance document to assist medical device sponsors, testing facilities, and other persons involved in designing, conducting, and reporting the results of animal studies intended to assess the safety of medical devices to support premarket submissions. These animal studies typically provide initial evidence of device safety, which may include device performance and handling, and the biological effects when used in a living system.

DATES: The announcement of the guidance is published in the **Federal Register** on March 28, 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–2015–D–3419 for ''General Considerations for Animal Studies Intended to Evaluate Medical Devices.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''General Considerations for Animal Studies Intended to Evaluate Medical Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Judith A. Davis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2220, Silver Spring, MD 20993–0002, 301–796–6636.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this guidance document to assist medical device sponsors, testing facilities, and other persons involved in designing, conducting, and reporting the results of animal studies intended to support the safety of medical devices for premarket submissions. These animal studies typically provide initial evidence of device safety, which may include their performance and handling, and the biological effects when used in a living system. This guidance outlines general considerations for certain animal studies used to support device premarket submissions, when a suitable alternative to an animal study is not available. This guidance provides recommendations on study planning,