

minimize the information collection burden. See **DATES** and **ADDRESSES** for instructions for submitting comments.

While we will review all comments received, we may choose not to post off-topic or inappropriate comments. Otherwise, all comments will be posted without edit under the applicable docket number, including any personal information that the commenter provides. Our response to such comments will be posted at [reginfo.gov](https://www.reginfo.gov) under the applicable OMB control number.

#### Medicaid and CHIP Program (MACPro)

At this time, MACPro is made up of the main umbrella (see collection number 1 in the following list) and nine individual generic collections of information (see collection numbers 2 through 10 in the following list). Details such as the collection's requirements and burden estimates can be found in the collection's supporting statement and associated materials (see **ADDRESSES** for instructions for obtaining such documents).

#### Docket Information

1. *Title:* Medicaid and CHIP Program (MACPro).

*Type of Request:* Revision of a currently approved collection.

*CMS ID Number:* CMS-10434.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0080.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0080>.

*For Policy Related Questions, Contact:* William N. Parham at 410-786-4669.

2. *Title:* Initial Application.

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #1.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0081.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0081>.

*For Policy Related Questions, Contact:* Stephanie Bell at 410-786-0617.

3. *Title:* CHIP State Plan Eligibility.

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #2.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0082.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0082>.

*For Policy Related Questions, Contact:* Stephanie Bell at 410-786-0617.

4. *Title:* Alternative Benefit Plans (ABPs).

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #3.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0083.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0083>.

*For Policy Related Questions, Contact:* Adrienne Delozier at 410-786-0278.

5. *Title:* Medicaid State Plan

Eligibility.

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #15.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0090.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0090>.

*For Policy Related Questions, Contact:* Suzette Seng at 410-786-4703.

6. *Title:* Health Home State Plan Amendment (SPA).

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #22.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0084.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0084>.

*For Policy Related Questions, Contact:* Mary Pat Farkas at 410-786-5731.

7. *Title:* Medicaid Adult and Child Core Set Measures.

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #26.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0085.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0085>.

*For Policy Related Questions, Contact:* Virginia (Gigi) Raney at 410-786-6117.

8. *Title:* Maternal and Infant Health Quality.

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #45.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0086.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0086>.

*For Policy Related Questions, Contact:* Virginia (Gigi) Raney at 410-786-6117.

9. *Title:* Health Home Core Sets.

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #47.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0087.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0087>.

*For Policy Related Questions, Contact:* Mary Pat Farkas at 410-786-5731.

10. *Title:* Medicaid Extended Postpartum Coverage and Continuous Eligibility for Children.

*Type of Request:* Extension of a currently approved collection.

*CMS ID Number:* CMS-10434 #77.

*OMB Control Number:* 0938-1188.

*eRulemaking Docket ID Number:* CMS-2023-0088.

*Docket Web Address:* <https://www.regulations.gov/docket/CMS-2023-0088>.

*For Policy Related Questions, Contact:* Alexa Turner at 410-786-8823.

Dated: July 24, 2023.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2023-15960 Filed 7-26-23; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-D-4417]

#### Center for Drug Evaluation and Research's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality; 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 "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality." This guidance describes a program at FDA's Center for Drug Evaluation and Research (CDER) to make public a comprehensive listing of recognized voluntary consensus standards related to pharmaceutical quality. This program facilitates submissions by external stakeholders and FDA staff proposing voluntary consensus standards related to pharmaceutical quality for recognition. CDER believes that this program will help promote innovation in pharmaceutical development and manufacturing and streamline the preparation and assessment of marketing applications for products regulated by CDER. This guidance

finalizes the draft guidance of the same title issued on February 14, 2019.

**DATES:** The announcement of the guidance is published in the **Federal Register** on July 27, 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-2018-D-4417 for "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality." 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 office

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. 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:** Colleen Thomas, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, Rm. 4159, Silver Spring, MD 20993-0002, 301-796-4853.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for industry entitled "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality." This guidance describes a program at CDER to make public a comprehensive listing of recognized voluntary consensus standards related to pharmaceutical quality. This program, established by publication of this final guidance, facilitates submissions by external stakeholders and FDA staff proposing voluntary consensus standards related to pharmaceutical quality for recognition.

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104-113) and Circular A-119 by the Office of Management and Budget (OMB) have established Federal Government policies to improve the internal management of the executive branch by directing Agencies to use voluntary consensus standards developed or adopted by a standards-developing organization—rather than Government-unique standards—except where these standards are inconsistent with applicable law or otherwise impractical. FDA's development and use of standards have been integral to the execution of FDA's mission.

This program will help promote innovation in pharmaceutical development and manufacturing and streamline the preparation and review of marketing applications for products regulated by CDER. CDER also believes that this program (1) allows CDER to communicate to external stakeholders that its relevant expert(s) have evaluated a consensus standard and determined if that standard is potentially useful both to industry and FDA staff, and (2) provides transparency to industry regarding CDER's thinking about a method or approach.

This guidance finalizes the draft guidance entitled "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality" issued on February 14, 2019 (84 FR 4076). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include: clarification of the program's policies and procedures and the program's relationship to existing guidances, regulations, and policies under which CDER operates.

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 "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality." 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 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 collection of information in this guidance has been approved under OMB control number 0910–0139.

## 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/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: July 24, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–15916 Filed 7–26–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2022–D–0986]

### Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions; 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 "Hydrogen Peroxide-Based Contact Lens Care Products:

Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions." FDA is issuing this guidance to provide labeling recommendations for Hydrogen Peroxide-Based Contact Lens Care Products (HPCPs) submitted in premarket notification (510(k)) submissions. The labeling recommendations in this guidance are intended to promote the safe and effective use of HPCPs and help consumers receive and understand information regarding the benefits and risks associated with the use of the device.

**DATES:** The announcement of the guidance is published in the **Federal Register** on July 27, 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–0986 for "Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions." 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