of the guidance, the addition of flowcharts, updates to examples, and further clarification of terminology.

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 the replacement reagent and instrument family policy for in vitro diagnostic devices. 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 ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 950 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 and guidances 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
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
''Administrative Procedures for Clinical Laboratory Improvement Amendments (CLIA) of 1988 Categorization''.	CLIA Categorization	0910–0607
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: August 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17643 Filed 8–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2029]

Proposal To Withdraw Approval of MAKENA; Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of hearing.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has granted a hearing on the Center for Drug Evaluation and Research's (CDER's) proposal to withdraw approval of MAKENA (hydroxyprogesterone caproate injection, 250 milligrams (mg) per milliliter (mL), once weekly), new drug application (NDA) 021945, held by Covis Pharma Group/Covis Pharma GmbH (Covis). This notice provides information and details regarding the hearing, including the time, date, and format of the hearing, as well as the questions to be posed to the advisory committee at the hearing.

DATES: The hearing will be held virtually October 17 to 19, 2022, beginning at 8 a.m. Eastern Time on each day and concluding at 4 p.m. on Days 1 and 2 and 12:30 p.m. on Day 3. Either electronic or written comments on the hearing must be submitted by November 3, 2022.

ADDRESSES: The docket number for this matter is FDA–2020–N–2029. The docket will close on November 3, 2022. Either electronic or written comments on this hearing must be submitted by November 3, 2022. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on November 3, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date. Comments received on or before October 11, 2022, will be provided to the advisory committee for consideration.

You may submit comments 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–2020–N–2029 for ''Proposal to Withdraw Marketing Approval; Hearing.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 our 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.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993; 240–402–5931, *rachael.linowes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 506 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356) provides that a drug sponsor may request to expedite the review and approval of a drug intended to treat an unmet need related to a serious or life-threatening disease or condition. Under the accelerated approval pathway, FDA may grant accelerated approval based on the drug's effect on a surrogate or an intermediate clinical endpoint. FDA's regulations, at § 314.510 (21 CFR 314.510), require that accelerated approval be subject to a sponsor's engaging in further study ''to verify and describe [the drug's] clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome.''

Under section 506(c)(3) of the FD&C Act, FDA may withdraw approval of a drug approved under this pathway if, among other reasons, the required study fails to verify ''the predicted effect on irreversibility morbidity or mortality or other clinical benefit.'' Under § 314.530(a) (21 CFR 314.530(a)), FDA may withdraw accelerated approval of a drug when ''[a] postmarketing clinical study fails to verify clinical benefit'' or ''[o]ther evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use,'' among other circumstances.

To initiate the process for withdrawing accelerated approval of a drug, the Director of CDER must provide the applicant with notice of an opportunity for a hearing on the proposed grounds for withdrawal under § 314.530(b). To obtain a hearing, the applicant must, pursuant to § 314.530(c), request one within 15 days after receiving CDER's notice and submit ''the data and information upon which [it] intends to rely at the hearing'' within 30 days thereafter.

Pursuant to § 314.530(e)(1), FDA conducts hearings under § 314.530 in accordance with part 15 (21 CFR part 15), with certain modifications. The key modification under § 314.530(e)(1) is that an advisory committee is present at the hearing and provides advice and recommendations to the Commissioner. Under § 314.530(e)(2), the presiding officer, the members of the advisory committee, and up to three representatives from both the applicant and CDER may ask questions of the presenters at the hearing. The presiding officer, as a matter of discretion, may also permit questions of presenters posed by others participating in the hearing upon submission of such questions in writing. After receiving advice and recommendations from the advisory committee, the Commissioner of Food and Drugs makes the final decision on whether to withdraw accelerated approval of the drug product at issue (see § 314.530(f)).

On February 3, 2011, FDA approved the NDA for MAKENA under the accelerated approval pathway to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. As described in CDER's proposal to withdraw approval, the MAKENA NDA ''relied on evidence from the Maternal Fetal Medicine Unit (MFMU) Network trial (referred to as 'Trial 002') for primary support of efficacy and safety.'' CDER granted accelerated approval based on the results for Trial 002. Consistent with section 506(c)(2) of the FD&C Act and § 314.510, CDER's approval letter required, *inter alia,* that the sponsor complete a postmarketing confirmatory study, described as ''a clinical trial of MAKENA in women with a singleton pregnancy who had a previous spontaneous preterm birth (Protocol #17P–ES–003)'' (Trial 003).

On October 5, 2020, CDER proposed withdrawing accelerated approval of MAKENA and provided Covis with an opportunity to request a hearing on the proposal.[1] In the proposal, CDER cited two grounds under section 506(c)(3) of the FD&C Act and § 314.530(a) for withdrawing approval: (1) the confirmatory study failed to verify clinical benefit of the drug and (2) the evidence does not establish that the drug is effective under its conditions of use. CDER's proposal to withdraw approval also provided notice to all holders of approved abbreviated new drug applications (ANDAs) referencing the NDA for MAKENA (NDA 021945) that, if the Agency withdraws

[1] AMAG Pharmaceuticals, Inc. (AMAG), the sponsor of NDA 021945 at the time, received this notice. After AMAG requested a hearing, Covis acquired AMAG, including NDA 021945. For efficiency, this notice refers to AMAG as ''Covis.''

accelerated approval of MAKENA, CDER would proceed to withdraw approval of the ANDAs under 21 CFR 314.151(b)(3).

On October 14, 2020, Covis timely requested a hearing and sought an additional 30 days in which to submit data and information in support. On December 4, 2020, after receiving an extension of time within which to do so, Covis further responded to CDER's proposal to withdraw accelerated approval of MAKENA. The response included data and information and incorporated other data and information in FDA's administrative files by reference.[2]

By letter to CDER and Covis dated August 18, 2021, FDA's Chief Scientist granted Covis's hearing request and appointed Celia M. Witten as presiding officer.

II. Notice of Hearing Under Part 15 and § 314.530

This public hearing will be held in accordance with part 15 and § 314.530. The presiding officer will conduct the hearing, and an advisory committee will be present at the hearing for purposes of considering the data and information presented by CDER and Covis with respect to CDER's proposal to withdraw accelerated approval of MAKENA and providing advice to the Commissioner of Food and Drugs on that proposal (see § 314.530(e)).

Under 21 CFR 15.30(f), the hearing is informal, and the rules of evidence do not apply. In accordance with § 314.530(e)(2), however, only the presiding officer, the members of the advisory committee, and up to three representatives from CDER and Covis may pose questions to the advisory committee at the hearing itself. The presiding officer may nonetheless exercise her discretion under § 314.530(e)(2) to allow others to propose questions by submitting them in writing for her consideration. In the interest of economy and efficiency, particularly given the virtual platform, the presiding officer has determined that only the holders of ANDAs referencing the NDA for MAKENA (ANDA holders) will be permitted to submit questions; that all proposed questions must be submitted to the docket for this proceeding in advance of the hearing; and that the questions selected will be posed to CDER and Covis at the close of their respective presentations (see section IV of this document).

III. Questions To Be Addressed at the Public Hearing

The questions to be posed to the advisory committee at the hearing are as follows:

1. For discussion and vote:

Do the findings from Trial 003 verify the clinical benefit of MAKENA on neonatal morbidity and mortality from complications of preterm birth?

2. For discussion and vote:

Does the available evidence demonstrate that MAKENA is effective for its approved indication of reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth?

3. For discussion:

Should FDA allow MAKENA to remain on the market? As part of that discussion, you may discuss:

- whether the benefit-risk profile supports retaining the product on the market;
- what types of studies could provide confirmatory evidence to verify the clinical benefit of MAKENA on neonatal morbidity and mortality from complications of preterm birth?

For vote:

Considering your responses to the previous questions both in the discussions and votes, should FDA allow MAKENA to remain on the market while an appropriate confirmatory study is designed and conducted?

IV. Participating in the Public Hearing

Persons wishing to view the hearing may access the webcast at the following separate links on the respective days of the hearing:

Day 1: *https://youtu.be/EEm7pM_LgsM.*

Day 2: *https://youtu.be/Nt2bcDVgpag.*

Day 3: *https://youtu.be/Dal27hktzcg.*

Request for Oral Presentations: We currently expect public participation to occur from 2 p.m. to 4 p.m. Eastern Time on the first day of the hearing and from 8 a.m. to 10 a.m. on the second day. Persons interested in participating in the hearing by making an oral presentation during the 4 hours currently reserved for such presentations must submit requests by 11:59 p.m. Eastern Time on September 6, 2022, as further described below.

If you wish to make a formal presentation or present oral comments during the session for public participation, you must register at the following link by 5 p.m. Eastern Time on September 6, 2022: *https://www.surveymonkey.com/r/B72THCF.* When registering, please provide complete contact information, including name, title, affiliation, address, email, and telephone number. To complete your request for an opportunity to make a presentation at the hearing, you must also submit a comment to the docket for this hearing matter (see **ADDRESSES**) by 11:59 p.m. Eastern Time on September 6, 2022, and clearly indicate in the heading and/or cover page that your comment is a ''Request for Oral Presentation.''

In the ''Request for Oral Presentation'' submitted to the public docket, you must identify yourself and others who will join you for your presentation, list the affiliation (if any) of each individual participating in your presentation (including your own), and request a specific amount of time for your presentation. You must also include a summary of what you plan to present at the hearing and a copy of any slide deck, along with any data or information on which you intend to rely at the hearing that is not already referenced or included in the public docket for this hearing matter. No commercial or promotional material will be permitted to be presented or distributed at the public hearing.

We urge organizations with common interests to consolidate or coordinate their presentations. In accordance with 21 CFR 15.21(c), the presiding officer may require joint presentations by persons with common interests.

The presiding officer will determine the amount of time allotted to each presenter and the approximate time each presentation is to begin and will select and notify participants by September 30, 2022. If you are notified that you will be a presenter, we encourage you to be online well in advance of the approximate time provided in the notice. Actual presentation times may vary based on how the hearing progresses.

Proposed Questions: To propose a question to either CDER or Covis, an ANDA holder must submit a comment to the docket for this hearing matter (see **ADDRESSES**) by 11:59 p.m. Eastern Time on September 30, 2022; indicate in the heading and/or cover page that the comment includes ''Proposed Question(s)''; and state in the submission that the question or questions are being proposed by a specific ANDA holder or someone authorized to do so on that specific ANDA holder's behalf. The comment should also indicate whether each proposed question is intended for CDER, Covis, or both.

[2] The presiding officer has subsequently granted requests by Covis to submit additional data and information that were not included in its December 4, 2020, submission and may do so again based on a showing of good cause.

Transcripts: Please be advised that as soon as a transcript of the public hearing is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the address where Dockets Management Staff is located (see **ADDRESSES**). A link to the transcript will also be available on the Agency's website.

Dated: August 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17715 Filed 8–16–22; 8:45 am]

BILLING CODE 4164–01–P

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; Draft 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 the draft guidance entitled ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions.'' FDA is issuing this draft 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 draft guidance are intended to promote the safe and effective use of HPCPs and ensure that consumers receive and understand information regarding the benefits and risks associated with the use of the device. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by October 17, 2022 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–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 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 draft guidance document entitled ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions'' 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: Angelo Green, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1306, Silver Spring, MD 20993–0002, 301–796–6860.

SUPPLEMENTARY INFORMATION:

I. Background

The safety and effectiveness of HPCPs when used as directed has been well