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 ''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 established in the last few decades; however, FDA had become aware of an increase in the number of adverse event reports related to the misuse of these products. These reports led FDA to convene a meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee and the Risk Communication Advisory Committee on March 17, 2017, to discuss additional measures to mitigate the potential risk for misuse of these devices. The meeting covered a range of important issues, including appropriate labeling and packaging of these products and the importance of clearly communicating these concerns to the consumer public, which were incorporated into this guidance. This guidance is intended to provide recommendations concerning the content and format of labeling for HPCPs. FDA believes that the labeling recommendations in this guidance may help manufacturers develop labeling with information about specific risks and directions for use of the HPCPs in conjunction with a user's prescribed contact lenses.

A notice of availability of the draft guidance appeared in the **Federal Register** of August 17, 2022 (87 FR 50629). FDA considered the comments received and revised the guidance as appropriate in response to the comments, including clarifying examples and language included in the guidance recommendations.

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 ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions.'' 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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00018041 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 have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910–0485

Dated: July 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15879 Filed 7–26–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2857]

Diana Daffin: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Diana Daffin from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Daffin was convicted of a felony under Federal law for conduct that relates to the regulation of any drug product under the FD&C Act. Ms. Daffin was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of April 2, 2023 (30 days after receipt of the notice), Ms. Daffin has not responded to the notice. Ms. Daffin's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable July 27, 2023.

ADDRESSES: Any application by Ms. Daffin for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically,

including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 application, that information will be posted on *https://www.regulations.gov.*

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2022–N–2857. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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 application 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, 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, between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On November 2, 2022, Ms. Daffin was convicted in the U.S. District Court for the District of New Hampshire, when the court entered a judgment of conviction, after her plea of guilty, to one count of introduction into interstate commerce of unapproved drugs in violation of 21 U.S.C. 331(d), 333(a)(2), and 355(a), a felony offense under Federal law.

As described in the plea agreement in Ms. Daffin's case, filed on June 22, 2022; the factual basis for this conviction is as follows: Ms. Daffin operated a business, Savvy Holistic Health d/b/a Holistic Healthy Pet, from Ms. Daffin's home, which primarily sold holistic pet remedies on its website *holistichealthypet.com.* On or about March 9, 2020, during routine internet surveillance, FDA personnel noticed that Ms. Daffin's website was offering for sale AN330, a ''HAMPL'' branded product marketed to treat COVID–19 in humans. Later investigation showed that Ms. Daffin also offered for sale another HAMPL product, Respiratory Immune 331, intended to cure mitigate, treat, and prevent COVID–19 in humans. AN330 and Respiratory Immune 331 were new drugs and were not approved by FDA. On April 7, 2020, and on August 25, 2020, FDA issued warning letters advising Ms. Daffin that products offered for sale on her website were unapproved new drugs and their distribution violated the FD&C Act. After receiving the warning letters, Ms. Daffin represented to FDA that she would remove violative products from her website and cease distributing them; however, she continued distributing these products and took steps to defraud and mislead FDA. For example, Ms. Daffin told customers seeking her HAMPL products to place orders on weekends when she stated that she would open her password protected website to customers because Ms. Daffin assumed FDA employees were not checking her website on weekends. Ms. Daffin stated that she would then close her website to search engines during the week.

Although Ms. Daffin told FDA that she would be closing the HAMPL product line, instead, in February 2021, Ms. Daffin sold to an undercover law enforcement officer Respiratory Immune 331, a HAMPL product intended to cure, mitigate, treat, and prevent COVID–19 in humans. In an email leading up to the sale, Ms. Daffin told the undercover officer, ''This stuff does work for COVID, but FDA shut it down.'' In another email, Ms. Daffin admitted to the undercover officer that Ms. Daffin had been warned that ''these all natural homeopathy and herbs,'' appearing to refer to the HAMPL products Ms. Daffin sold, were unapproved drugs. Ms. Daffin nevertheless sold the HAMPL to the undercover officer.

Based on this conviction, FDA sent Ms. Daffin by certified mail on February 24, 2023, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), that Ms. Daffin was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Ms. Daffin an opportunity to request a hearing, providing her 30 days

from the date of receipt of the letter in which to file the request, and advised her that failure to file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Daffin received the proposal on March 3, 2023. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), under authority delegated to the Assistant Commissioner, finds that Diana Daffin has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Daffin is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 335a(a)(2)(B) and 335a(c)(2)(A)(ii))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Ms. Daffin during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Daffin provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Daffin during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B))). Note that, for purposes of sections 306 and 307 of the FD&C Act (21 U.S.C. 335a and 335b), a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: July 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15944 Filed 7–26–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2608]

Cellular, Tissue, and Gene Therapies Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. On September 27, 2023, the committee will discuss and make recommendations on biologics license application (BLA) 125782 from BrainStorm Therapeutics, Inc. for debamestrocel (autologous bone marrow-derived mesenchymal stromal cells induced to secrete neurotrophic factors). The applicant has requested an indication for the treatment of amyotrophic lateral sclerosis (ALS). The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 27, 2023, from 10 a.m. to 6 p.m. Eastern Time.

ADDRESSES: All meeting participants will be heard, viewed, captioned, and recorded for this advisory committee meeting via an online teleconferencing and/or video conferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

The online web conference meeting will be available at the following link on the day of the meeting: *https://youtube.com/live/c-2-33ipSbk.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–2608. The docket will close on September 26, 2023. 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 at the end of September 26, 2023. 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 September 20, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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.''