

**SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** Please note that due to the impact of the COVID-19 pandemic, all participants will be joining this public workshop via an online teleconferencing platform.

**FOR FURTHER INFORMATION CONTACT:** Rokhsareh Shahidzadeh, Office of Scientific Professional Development, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2383, Silver Spring, MD 20993, 301-796-8740, [FDASciProDev@fda.hhs.gov](mailto:FDASciProDev@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

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

The FDA Science Forum is held biennially to inform the public about the groundbreaking science conducted at the Agency and to show how scientific research is used in FDA's regulatory decisions to protect and promote public health. Open to the public, industry, academia, patient advocates, government agencies, and current and potential collaborators, the 2-day event offers an opportunity to hear FDA scientific experts and nationally renowned scientists speak on a range of topics associated with regulatory science.

##### **II. Topics for Discussion at the Public Workshop**

The theme for the 2021 FDA Science Forum, "Science as the Foundation for Protecting and Promoting Public Health", will highlight areas of FDA research, including: (1) Improving clinical and postmarket evaluation; (2) substance use, misuse, and addiction; (3) product development and manufacturing; and (4) medical countermeasures, infectious disease, and pathogen-reduction technologies.

##### **III. Participating in the Public Workshop**

**Registration:** To register for the public workshop, please visit the following website: <https://www.fda.gov/scienceforum>. Registration is free. Persons interested in attending this public workshop must register by May 21, 2021, by 5 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Rokhsareh Shahidzadeh (see **FOR FURTHER INFORMATION CONTACT**) no later than May 21, 2021, by 5 p.m. Eastern Time.

**Streaming Webcast of the Public Workshop:** This public workshop will

be streamed via a webcast only. To register for the webcast, please visit the following website: <https://www.fda.gov/scienceforum>. Participants interested in viewing via webcast must register by May 21, 2021, by 5 p.m. Eastern Time.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: March 24, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-06705 Filed 3-31-21; 8:45 am]

**BILLING CODE 4164-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-2020-N-2306]

##### **TG United, Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of January 15, 2021. The document announced the withdrawal of approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants as of February 16, 2021. The document indicated that FDA was withdrawing approval of the following three ANDAs after receiving a withdrawal request from Upsher-Smith Laboratories, LLC., 6701 Evenstad Dr., Maple Grove, MN 55369: ANDA 084041, Chlordiazepoxide Hydrochloride (HCl) Capsules, 10 milligrams (mg); ANDA 084678, Chlordiazepoxide HCl Capsules, 5 mg; and ANDA 084679, Chlordiazepoxide HCl Capsules, 25 mg. Before FDA withdrew the approval of these ANDAs, Upsher-Smith Laboratories, LLC., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Upsher-Smith Laboratories, LLC., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 084041, 084678, and 084679 is still in effect. In addition, the document indicated that FDA was

withdrawing approval of ANDA 206061, Pravastatin Sodium Tablets, 20 mg, 40 mg, and 80 mg, after receiving a request from Hisun Pharmaceutical (Hangzhou) Co., Ltd. However, the document published with the incorrect applicant name for ANDA 206061. This document corrects that error. All other information for ANDA 206061 remains the same.

#### **FOR FURTHER INFORMATION CONTACT:**

Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Friday, January 15, 2021 (86 FR 4081), appearing on page 4081 in FR Doc. 2021-00833, the following corrections are made on page 4082 in the table:

1. The entries for ANDAs 084041, 084678, and 084679 are removed.
2. In the third column, third item from the bottom, the applicant name "Hisun Pharmaceuticals USA, Inc." is corrected to read "Hisun Pharmaceuticals USA, Inc., U.S. Agent for Hisun Pharmaceutical (Hangzhou) Co., Ltd." for ANDA 206061.

Dated: March 29, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-06745 Filed 3-31-21; 8:45 am]

**BILLING CODE 4164-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Food and Drug Administration**

[Docket No. FDA-2021-N-0270]

##### **Endocrinologic and Metabolic Drugs 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 Endocrinologic and Metabolic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. 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 May 27, 2021, from 9 a.m. to 5:30 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0270. The docket will close on May 26, 2021. Submit either electronic or written comments on this public meeting by May 26, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 26, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 26, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before May 13, 2021, 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."

**Instructions:** All submissions received must include the Docket No. FDA-2021-N-0270 for "Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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." FDA 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 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 the 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:**

LaToya Bonner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, email: [EMDAC@fda.hhs.gov](mailto:EMDAC@fda.hhs.gov), 301-796-2855, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

#### **SUPPLEMENTARY INFORMATION:**

**Agenda:** The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss the safety and efficacy of biologics license application (BLA) 761183, for teplizumab intravenous infusion, submitted by Provention Bio, Inc. The proposed indication is for the delay or prevention of clinical type 1 diabetes mellitus in at-risk (Stage 2) individuals.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the

appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before May 13, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 5, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 6, 2021.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact LaToya Bonner (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 26, 2021.

**Lauren K. Roth,**  
*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-06708 Filed 3-31-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-N-3023]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; BIOMIMICS 3D VASCULAR STENT SYSTEM

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for BIOMIMICS 3D VASCULAR STENT SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by June 1, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 28, 2021. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 1, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 1, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### 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-N-3023 for "Determination of Regulatory Review Period for Purposes of Patent Extension; BIOMIMICS 3D VASCULAR STENT SYSTEM." 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 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