**FOR FURTHER INFORMATION CONTACT:** Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The holder of an approved NDA to market a new drug for human use is required to submit annual reports to FDA concerning its approved NDA under §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). The holders of the approved NDAs listed in Table 1 have repeatedly failed to submit the required annual reports and have not responded to the Agency's request for submission of the reports.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

| Application No. | Drug | NDA holder |
|---|---|---|
| NDA 008284 | Cortisone Acetate Tablets, 5 milligrams (mg) and 25 mg | Panray Corp. Sub Ormont Drug and Chemical Co., Inc., 520 South Dean St., Englewood, NJ 07631. |
| NDA 009659 | Hydrocortisone Tablets, 10 mg and 20 mg | Do. |
| NDA 019503 | Triamcinolone Acetonide Suspension, 3 mg/milliliters (mL) | Parnell Pharmaceuticals Inc., 111 Francisco Blvd., San Rafael, CA 94901. |

Therefore, notice is given to the holders of the approved NDAs listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the NDAs and all amendments and supplements thereto on the grounds that the NDA holders have failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and 21 CFR part 314, the NDA holders are hereby provided an opportunity for a hearing to show why the approval of the NDAs listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these NDAs.

An NDA holder who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an NDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the NDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the NDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All paper submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: December 20, 2021.

**Jacqueline Corrigan-Curay,**

*Principal Deputy Center Director, Center for Drug Evaluation and Research.*

[FR Doc. 2021–27946 Filed 12–23–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–D–1118]**

### Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia; 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 ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' This guidance identifies the key features of non-clinical and clinical investigational plans used to support investigational device exemption applications, premarket approval applications, De Novo classification requests, and some premarket notification submissions for devices used in the treatment of BPH.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 27, 2021.

**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–2020–D–1118 for ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH).'' 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 ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' to the Office of Policy, Guidance and Policy Development, 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:** Charles Viviano, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2680, Silver Spring, MD 20993–0002, 240–402–2975.

**SUPPLEMENTARY INFORMATION:**

## I. Background

As men age, the prostate enlarges over time, obstructing the prostatic urethra and resulting in anatomic and functional changes in the bladder. The resulting condition, known as benign prostatic hyperplasia (BPH), can be associated with decreased peak urinary flow rate and increased post void residual urine. Men with BPH experience bothersome lower urinary tract symptoms that affect their quality of life by disrupting sleep patterns or interfering with daily activities.

This guidance revises the guidance entitled ''Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) [1],'' issued on August 17, 2010 (''2010 BPH guidance''). This guidance identifies the key features of non-clinical and clinical investigational plans used to support investigational device exemption applications, premarket approval applications, De Novo classification requests, and some premarket notification submissions for devices used in the treatment of BPH. Some recommendations in this document may not apply to a particular device, and additional recommendations may be appropriate for novel device types or technologies. FDA will consider alternative non-clinical and clinical testing when the proposed alternatives are supported by an adequate scientific rationale.

FDA issued a draft guidance entitled ''Select Updates for Guidance for the Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH) [2],'' which proposed to add new devices within scope and updates to the animal and clinical studies sections of the 2010 BPH guidance. A notice of availability of the draft guidance appeared in the **Federal Register** of July 14, 2020 (85 FR 42406). FDA considered comments received and revised the guidance as appropriate in response to the comments, including the following technical changes: Suggested examination of surrounding anatomy during animal studies for embolic devices; clarification of sexual function; additional specificity around the primary safety endpoint; inclusion of secondary endpoints such as return to normal activities; measuring prostate volume according to current clinical guidelines; additional post-treatment evaluation; and consideration of the addition or increase in medications or other modalities as treatment failure. The remainder of the content of the 2010 BPH guidance remains largely unchanged.

This guidance is being issued consistent with FDA's good guidance

[1] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign-prostatic-hyperplasia.*

[2] Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/select-updates-guidance-non-clinical-and-clinical-investigation-devices-used-treatment-benign.*

practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on non-clinical and clinical investigation of devices used for the treatment of BPH. 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 at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Non-Clinical and Clinical Investigation of Devices Used for the Treatment of Benign Prostatic Hyperplasia (BPH)'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1724 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 guidance 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 |
| 814, subparts A through E | Premarket approval | 0910–0231 |
| 812 | Investigational Device Exemption | 0910–0078 |
| ''De Novo Classification Process (Evaluation of Automatic Class III Designation)''. | De Novo classification process | 0910–0844 |
| ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''. | Q-submissions | 0910–0756 |
| 800, 801, and 809 | Medical Device Labeling Regulations | 0910–0485 |
| 50, 56 | Protection of Human Subjects: Informed Consent; Institutional Review Boards. | 0910–0755 |
| 58 | Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies. | 0910–0119 |

Dated: December 20, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021–27919 Filed 12–23–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–D–2330]**

### Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers; 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 ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers.'' This guidance represents FDA's current thinking on the management and conduct of pathology peer review performed during good laboratory practice (GLP)-compliant toxicology studies. This guidance finalizes the draft guidance ''Pathology Peer Review in Nonclinical Toxicology Studies: Questions and Answers'' issued on September 30, 2019. This revision includes editorial changes to improve the clarity of the document.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 27, 2021.

**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–2330 for ''Pathology Peer Review in Nonclinical Toxicology