Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than August 26, 2020.

A. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *First Holding Company of Park River, Inc., Park River, North Dakota*; to indirectly retain voting shares of AccuData Services, Inc., through its subsidiary bank, First United Bank, both of Park River, North Dakota, pursuant to section 225.28(b)(14)(i) of Regulation Y.

Board of Governors of the Federal Reserve System, August 6, 2020.

**Yao-Chin Chao,**

*Assistant Secretary of the Board.*

[FR Doc. 2020–17530 Filed 8–10–20; 8:45 am]

**BILLING CODE P**

## GENERAL SERVICES ADMINISTRATION

**[OMB Control No. 3090–0118; Docket No. 2020–0001; Sequence No. 4]**

### Submission for OMB Review; Federal Management Regulation; Standard Form 94, Statement of Witness

**AGENCY:** Office of Government-wide Policy (OGP), General Services Administration (GSA).

**ACTION:** Notice; request for comments.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an existing information collection requirement regarding OMB Control No: 3090–0118; Standard Form 94, Statement of Witness.

**DATES:** Submit comments on or before September 10, 2020.

**ADDRESSES:** Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. If your comment cannot be submitted using *www.reginfo.gov/public/do/PRAMain,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ray Wynter, GSA, Office of Government-wide Policy (MAG), Office of Asset and Transportation Management, at telephone 202–501–3802 or via email to *ray.wynter@gsa.gov.*

**SUPPLEMENTARY INFORMATION:**

#### A. Purpose

GSA's Office of Government-wide Policy is announcing the availability of Standard Form 94, Statement of Witness that is publicly available on *http://www.gsa.gov/forms.* This form will be used to collect information from witnesses reporting accidents and/or damage to Federal Fleet Vehicles. Standard Form (SF) 94 provides additional accounts of motor vehicle accidents that supplement statements made by a motor vehicle operator. Use of the SF 94 is prescribed in Federal Management Regulation, 41 CFR 102–34.290(b) and Federal Property Management Regulations, 41 CFR 101–39.401(b). The SF 94 is usually completed at the time of an accident involving a motor vehicle owned or leased by the Government.

The SF 94 is an essential part of the investigation of motor vehicle accidents, especially those involving the public with a potential for claims against the United States. It is a vital piece of information in lawsuits and provides the Assistant United States Attorneys with a written statement to refresh recollection of accidents, as necessary.

#### B. Annual Reporting Burden

*Respondents:* 290.
*Responses per Respondent:* 1.
*Total Annual Responses:* 290.
*Hours Per Response:* 0.333.
*Total Burden Hours:* 97.

#### C. Public Comments

A 60-day notice was published in the **Federal Register** at 85 FR 34631 on June 5, 2020. No comments were received.

*Obtaining Copies of Proposals:* Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division, at *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0118, Standard Form 94, Statement of Witness, in all correspondence.

**Beth Anne Killoran,**

*Deputy Chief Information Officer.*

[FR Doc. 2020–17474 Filed 8–10–20; 8:45 am]

**BILLING CODE 6820–14–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–N–0626]**

### Pulmonary-Allergy 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 Pulmonary-Allergy 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 take place virtually on August 31, 2020, from 10 a.m. Eastern Time to 4 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–2020–N–0626. The docket will close on August 28, 2020. Submit either electronic or written comments on this public meeting by August 28, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 28, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 28, 2020. 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 August 17, 2020, 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–2020–N–0626 for ''Pulmonary-Allergy 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. Eastern Time and 4 p.m. Eastern Time, 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:** Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *PADAC@fda.hhs.gov,* 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 the 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 will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On August 31, 2020, the committee will discuss supplemental new drug application 209482/S–008, for TRELEGY ELLIPTA, a fixed-dose combination (fluticasone furoate, umeclidinium, and vilanterol inhalation powder oral inhalation), submitted by GlaxoSmithKline, for the following proposed labeling claim: Reduction in all-cause mortality in patients with chronic obstructive pulmonary disease (COPD). The focus of the discussion will be on the efficacy data submitted to support the proposed labeling claim, including the results from the Informing the Pathway of COPD Treatment trial and the influence of inhaled corticosteroids withdrawal on the results.

FDA intends to make the meeting's background material and pre-recorded presentations available to the public no later than 2 business days before the meeting. The pre-recorded presentations will be viewed by the committee prior to the meeting and will not be replayed on meeting day. If FDA is unable to post the background material and/or pre-recorded presentations on its website prior to the meeting, the background material and/or pre-recorded presentations will be made publicly available on FDA's website at the time of the advisory committee meeting. The meeting will include brief summaries of the pre-recorded presentations. 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.

*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 August 17, 2020, will be provided to the

committee. Oral presentations from the public will be scheduled on August 31, 2020, between approximately 12:50 p.m. Eastern Time and 1:50 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include 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 August 14, 2020. 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 August 17, 2020.

For press inquiries, please contact the Office of Media Affairs at *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 Philip Bautista (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: August 5, 2020.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2020–17533 Filed 8–10–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–4615]**

### Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format; 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 ''Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format.'' This guidance is intended to assist holders of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) with their submission of required marketing status notifications. This guidance finalizes the draft guidance of the same title issued on January 31, 2019.

**DATES:** The announcement of the guidance is published in the **Federal Register** on August 11, 2020.

**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–4615 for ''Marketing Status Notifications Under Section 506I of the Federal Food, Drug, and Cosmetic Act; Content and Format.'' 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.

- 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*