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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mohamed Ghorab, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3141, Silver Spring, MD, 20993–0002, 240–402–8940; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Field Alert Report Submission: Questions and Answers.'' The FAR regulations found in § 314.81(b)(1) (21 CFR 314.81(b)(1)) and 21 CFR 314.98(b) establish an early warning system to help FDA fulfill its responsibility to protect patient health. Under these regulations, NDA and ANDA applicants must submit certain information to FDA about distributed drug products regulated by the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research.

The guidance addresses the FAR submission requirements and focuses on topics such as the incidents and possible/actual quality issues that require submission of a FAR, the contents of the FAR, who submits the FAR, and when, where, and how they should submit it. The guidance also addresses followup and final FARs, which are not required under § 314.81(b), and recommends their submission to inform FDA of the status of root cause investigations and corrective actions taken, if any.

This guidance finalizes the draft guidance issued on July 19, 2018 (83 FR 34142). In response to public comments, FDA made minor editorial changes and clarified that the FAR requirements apply to all products under an NDA or ANDA, including positron emission tomography drugs, designated medical gases, and combination products containing a drug constituent part. Although not the focus of this guidance, FDA notes that FAR requirements also apply to certain combination products under 21 CFR part 4, subpart B. For additional information about these products, see the guidance for industry and FDA staff ''Postmarketing Safety Reporting for Combination Products,'' available at *https://www.fda.gov/media/111788/download,* and the Postmarketing Safety Reporting for Combination Products web page at *https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.* FDA may consider whether additional adjustments are needed to guidance or FAR-related instructions for biologics license applications or device applications for combination products that contain a drug constituent part as the Agency gains experience with safety reporting for such products.

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 ''Field Report Alert Submission.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no 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 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15645 Filed 7–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0424]

Medical Devices; Exemption From Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport; Extension of Comment Period

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice that appeared in the **Federal Register** of June 15, 2021. In the notice, FDA requested comments by August 16, 2021. The Agency is taking this action in response to a correction to the notice's docket number that appeared in the **Federal Register** of June 30, 2021, to allow interested persons time to submit comments in response to the corrected notice.

DATES: FDA is extending the comment period on the notice published June 15, 2021 (86 FR 31722). Submit either electronic or written comments by August 30, 2021.

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 August 30, 2021. The *https://www.regulations.gov*

electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 30, 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–2021–P–0424 for ''Medical Devices; Exemption from Premarket Notification: Powered Patient Transport, All Other Powered Patient Transport.'' 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 *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: Dan Reed, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1526, Silver Spring, MD 20993–0002, 240–402–4717.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 15, 2021, FDA published a notice with a 60-day comment period requesting comments by August 16, 2021. Comments on the notice will inform FDA's response to a petition requesting exemption from premarket notification requirements for powered patient transport, all other powered patient transport.

In the **Federal Register** of June 30, 2021, FDA corrected the docket number associated with the notice (86 FR 34770). FDA has considered the requirements associated with receipt of a petition requesting exemption from premarket notification requirements under section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)). Due to the correction to the docket number, the Agency is extending the comment period for the notice, until August 30, 2021. The Agency believes that an extension allows adequate time for interested persons to submit comments from the date of the correction to the notice issued June 30, 2021, without delaying our consideration of these important issues.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–15646 Filed 7–22–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1136 and FDA–2020–D–1137]

Guidance Documents Related to Coronavirus Disease 2019; 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 FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on July 23, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: