

Page 9 – Janssen Biotech, Inc.

Conditions Related to Printed Matter, Advertising, and Promotion

- X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Janssen COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.
- Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Janssen COVID-19 Vaccine clearly and conspicuously shall state that:
- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older; and
  - The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

**IV. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

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 RADM Denise M. Hinton  
 Chief Scientist  
 Food and Drug Administration

Enclosures

Dated: May 21, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-11234 Filed 5-26-21; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2020-D-1136]

**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 May 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 name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) 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 § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of these guidances to the address noted in table 1. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Thomas, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993-0002, 301-796-2357.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On January 31, 2020, as a result of confirmed cases of COVID-19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.<sup>1</sup> On March 13, 2020, there was a Presidential declaration that the COVID-19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.<sup>2</sup>

<sup>1</sup> Secretary of Health and Human Services, “Determination that a Public Health Emergency Exists” (originally issued on January 31, 2020, and subsequently renewed), available at: <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>2</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (March 13, 2020), available at: <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>. On February 24, 2021,

In the **Federal Register** of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>), FDA announced procedures for making available FDA guidances related to the COVID-19 PHE. These procedures, which operate within FDA’s established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID-19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID-19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA implements COVID-19-related guidances. Therefore, FDA will issue COVID-19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA’s web pages entitled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders” (available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>) and “Search for FDA Guidance Documents” (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>).

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID-19-related guidance, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID-19-related guidances that FDA issued during the relevant period, as included in table 1. This notice announces COVID-19-related guidances that are posted on FDA’s website.

there was a Presidential Declaration continuing the national emergency concerning the COVID-19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Pandemic (February 24, 2021), available at <https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic>.

**II. Availability of COVID-19-Related Guidance Documents**

announcing the availability of the following COVID-19-related guidances:

Pursuant to the process described in the March 25, 2020, notice, FDA is

**TABLE 1—GUIDANCES RELATED TO THE COVID-19 PUBLIC HEALTH EMERGENCY**

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA-2020-D-1136 .....	CDER	Development of Abbreviated New Drug Applications During the COVID-19 Pandemic—Questions and Answers Guidance for Industry (April 2021).	<i>druginfo@fda.hhs.gov</i> . Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.
FDA-2020-D-1136 .....	CDER	Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency Guidance for Industry (April 2021).	<i>druginfo@fda.hhs.gov</i> . Please include the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA’s good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not establish any rights

for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**  
*CDER Guidances*

While these guidances contain no collection of information, they do refer to previously approved FDA collections

of information (listed in table 2). Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for these guidances. 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 guidances have been approved by OMB as listed in the following table:

**TABLE 2—CDER GUIDANCES AND COLLECTIONS**

COVID-19 guidance title	CFR cite referenced in COVID-19 guidance	Another guidance title referenced in COVID-19 guidance	OMB control No(s).
Development of Abbreviated New Drug Applications During the COVID-19 Pandemic—Questions and Answers Guidance for Industry (April 2021).	.....	—Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers. —Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.	0910-0001, 0910-0338, 0910-0139.
Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency Guidance for Industry (April 2021).	21 CFR 211.170, 21 CFR 314.3, 21 CFR 314.50, 21 CFR 314.94, 21 CFR 314.101, 21 CFR 314.105, 21 CFR 314.107, 21 CFR 320.25, 21 CFR 320.31, 21 CFR 320.38, 21 CFR 320.63.	—ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers. —Referencing Approved Drug Products in ANDA Submissions. —Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID-19 Public Health Emergency. —Safety Reporting Requirements for INDs and BA/BE Studies. —Controlled Correspondence Related to Generic Drug Development. —Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA. —Conduct of Clinical Trials of Medical Products During the COVID-19 Pandemic. —ANDAs: Stability Testing of Drug Substances and Products. —ANDAs: Stability Testing of Drug Substances and Products, Questions and Answers.	0910-0001, 0910-0014, 0910-0797, 0910-0119 0910-0581, 0910-0733, 0910-0672.

**IV. Electronic Access**

Persons with access to the internet may obtain COVID-19-related guidances at:

- FDA web page entitled “COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other

Stakeholders,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>;

- FDA web page entitled “Search for FDA Guidance Documents” available at

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>; or

- <https://www.regulations.gov>.

Dated: May 21, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-11217 Filed 5-26-21; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2005-D-0027]

#### Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order; Draft 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 the draft guidance entitled “Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order.” The existing post-approval studies final guidance, entitled “Procedures for Handling Post-Approval Studies Imposed by PMA Order,” was issued in June 2009. This draft guidance is intended to update the 2009 guidance to assist stakeholders with understanding post-approval study requirements imposed as a condition of approval of a premarket approval application (PMA). This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by July 26, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance 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-2005-D-0027 for “Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order.” 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 draft guidance document entitled “Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order” 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:** Nilsa Loyo-Berrios, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G114, Silver Spring, MD 20993-0002, 301-796-6065.

#### **SUPPLEMENTARY INFORMATION:**

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

To provide reasonable assurance, or the continued assurance, of safety and effectiveness of an approved device, FDA may require a post-approval study (PAS) as a condition of approval under 21 CFR 814.82(a)(2) and (a)(9). A PAS is usually a clinical or non-clinical study, as specified in the PMA approval order, and is typically intended to gather specific data to address questions about the postmarket performance of or experience with an approved medical device. As described in “Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval,” FDA may