Contains Nonbinding Recommendations

Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency

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Guidance for Industry

June 2020

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA web page titled "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 from the FDA web page titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to druginfo@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number FDA-2020-D-1136 and complete title of the guidance in the request.

Questions

For questions about this document, contact the Division of Supply Chain Integrity at drugsupplychainintegrity@fda.hhs.gov, 301-796-3130.

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Guidance for Industry

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to address questions FDA has received asking for clarification regarding FDA's enforcement of certain requirements relating to the distribution of drug samples[1] under the Prescription Drug Marketing Act of 1987 (PDMA) during the COVID-19 public health emergency (PHE). PDMA is part of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the relevant implementing regulations regarding drug samples are in 21 CFR part 203 (part 203), subpart D.

Except as noted below, this policy is intended to remain in effect only for the duration of the PHE related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January

[1] *Drug sample* is defined in 21 CFR 203.3(i) to mean a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this PHE, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2" and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a PHE related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3]

The Prescription Drug Marketing Act (PDMA) (Public Law 100-293) was signed into law on April 22, 1988, and was modified by the Prescription Drug Amendments of 1992 (PDA) (Public Law 102-353) and the FDA Modernization Act of 1997 (FDAMA) (Public Law 105-115). FDA published final regulations implementing PDMA, as modified by PDA and FDAMA, in part 203 in a 1999 final rule.[4] Among other things, PDMA and these implementing regulations established requirements related to the distribution of prescription drug samples by mail or common carrier.[5]

[2] Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.
[3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.
[4] See 64 FR 67720 (Dec. 3, 1999). The final rule implementing PDMA regarding state licensing requirements (21 CFR part 205) was published in 1990. See 55 FR 38023 (Sept. 14, 1990).
[5] See FD&C Act § 503(d) (21 U.S.C. 353(d)); 21 CFR part 203, subpart D.

PDMA requires in part that licensed practitioners[6] who request drug samples do so in writing and mandates storage, handling, and recordkeeping requirements for drug samples.[7]

During the COVID-19 PHE, manufacturers that use drug samples as part of their marketing programs have been relying more on mail and common carriers, rather than sales representatives, to deliver drug samples. In this guidance, we are addressing our current policy regarding drug sample requirements in PDMA and part 203 related to the collection of physical signatures upon delivery of drug samples and the ability of licensed healthcare providers to request that drug samples be delivered to various locations during the COVID-19 PHE.

III. Discussion

This guidance outlines FDA's temporary policy regarding certain requirements under PDMA for distribution of drug samples during the COVID-19 PHE. FDA is also clarifying our interpretation of sample delivery directly to a licensed health care practitioner, and is confirming that drug samples may not be distributed to a retail pharmacy. This guidance does not address any other requirements in PDMA and FDA regulations in part 203 related to drug samples.

A. Physical Collection of Signatures upon Receipt of Drug Samples

Under PDMA and implementing regulations, drug samples may be distributed by a manufacturer or its authorized distributor of record[8] to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity,[9] by mail or common carrier, provided that certain conditions are met.[10] Among other conditions, before such drug samples can be delivered, a licensed practitioner must submit a written request for drug samples to the manufacturer or authorized distributor of record that contains the name, address, professional title, and signature of the practitioner making the request.[11] The requirements concerning drug sample requests under PMDA and part 203, subpart D are not the subject of this guidance.

In addition, the recipient of a prescription drug sample must execute a written receipt of the drug

[6] *Licensed practitioner* is defined in 21 CFR 203.3(r) to mean any person licensed or authorized by State law to prescribe drugs.
[7] FD&C Act § 503(d) (21 U.S.C. 353(d)); *see also* 21 CFR part 203, subpart D.
[8] *Authorized distributor of record* is defined in section 503(d)(4) of the FD&C Act (21 U.S.C. 353(d)(4)) and in 21 CFR 203.3(b) to mean a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.
[9] See 21 CFR 203.3(q).
[10] See FD&C Act § 503(d)(2)(A) (21 U.S.C. 353(d)(2)(A)); 21 CFR 203.30(a).
[11] See 21 CFR 203.30(a), (b).

sample upon delivery, and such receipt must be returned to the manufacturer or authorized distributor of record from which the drug sample was received.[12] In addition to regulating the required contents of the written request from a licensed practitioner for delivery of a drug sample by mail or common carrier, PDMA regulates the content of the receipt to be completed by the recipient of a drug sample upon delivery of the drug sample.[13] If the drug samples are delivered to the licensed practitioner who requested them, the receipt is required to contain, among other things, the name, address, professional title, and signature of the practitioner or the practitioner's designee who acknowledges receipt.[14] If the drug samples are delivered to the pharmacy of a hospital or other health care entity at the request of a licensed practitioner, the receipt is required to contain, among other things, the name, address, professional title, and signature of the person acknowledging delivery of the drug samples.[15]

FDA recognizes that the business practices of some manufacturers involve the use of other parties, such as mail delivery or common carriers, to assist in the distribution of their drug samples as described in PDMA and 21 CFR 203.30. In such cases, where the delivery is to the licensed practitioner who requested the drug samples, the mail or common carrier captures the signature of the licensed practitioner who requested drug samples (or the signature of a person designated by the practitioner to sign on their behalf).[16] Similarly, in cases where the delivery is to the pharmacy of a hospital or other health care entity, the mail or common carrier captures the signature of the person acknowledging delivery.[17]

In the interest of employee and patient safety during the COVID-19 PHE, some mail and common carriers may be considering alternate ways of verifying deliveries and receipt of deliveries that normally require an adult signature, including deliveries of drug samples. During the COVID-19 PHE, FDA does not intend to take action against a manufacturer or authorized distributor of record that accepts alternate ways of verifying delivery and receipt of drug samples instead of obtaining the signature of the person acknowledging delivery, provided, however, the receipt obtained by the manufacturer or authorized distributor of record complies with all other receipt requirements in PDMA and 21 CFR 203.30(c).

B. Place of Delivery of Prescription Drug Samples

Under PDMA and implementing regulations, manufacturers or authorized distributors of record may deliver a drug sample to the licensed practitioner who requested it, or, at the written request of the licensed practitioner, to the pharmacy of a hospital or other health care entity.[18] During the COVID-19 PHE, state or local stay-at-home orders and social distancing recommendations have

[12] See *id.* § 203.30(a)(3), (4).
[13] See *id.* § 203.30(a), (c).
[14] See *id.* § 203.30(c)(1).
[15] See *id.* § 203.30(c)(2).
[16] See *id.* § 203.30(c)(1).
[17] See *id.* § 203.30(c)(2).
[18] See *id.* § 203.30(a).

impacted how licensed practitioners are providing care and consultation. In response to these changes during the COVID-19 PHE, FDA is announcing a temporary policy regarding enforcement of the requirement for drug samples to be sent to the requesting health care practitioner licensed to prescribe the drug, or to a designee at the pharmacy of a hospital or other health care entity.[19] FDA is also a clarifying our interpretation of sample delivery directly to a licensed health care practitioner, and is confirming that drug samples may not be distributed to a retail pharmacy.

1. Delivery to Patient's Home

FDA understands that during the COVID-19 PHE, many licensed practitioners are not meeting face-to-face with patients, and these licensed practitioners would like to be able to request that a manufacturer or authorized distributor of record send drug samples directly to the identified patient's home. We understand that this is due to social distancing and for the protection of patients and healthcare providers during the COVID-19 PHE. At this time, FDA does not intend to take action against a manufacturer or authorized distributor of record that delivers drug samples by mail or common carrier directly to the identified patient's home during the COVID-19 PHE, provided that: (1) the written request executed by the licensed practitioner in accordance with 21 CFR 203.30(a)(1), in addition to information required by the regulation, is for an identified patient of that licensed practitioner who has been designated to accept the delivery of the drug samples as the licensed practitioner's designee; (2) the receipt of the drug samples is documented in accordance with 21 CFR 203.30(a)(3) and (4); and (3) the recordkeeping and other applicable requirements under PDMA and FDA regulations under part 203 are met by the manufacturer or authorized distributor of record.

2. Delivery to Licensed Practitioner's Home

FDA understands that during the COVID-19 PHE, licensed practitioners may be practicing telemedicine from their homes. Neither PDMA nor part 203 specifies where a licensed practitioner may receive delivery of requested drug samples. Therefore, neither PDMA nor part 203 prohibits the delivery of drug samples to the licensed practitioner's home, provided that the licensed practitioner executes and submits a written request to the manufacturer or authorized distributor of record for the delivery of the drug samples to their home being used as an office, and all other applicable provisions in part 203 are met. This interpretation of PDMA and part 203 reflects FDA's current thinking and is not anticipated to change following termination of the COVID-19 PHE. Therefore, following the termination of the PHE, FDA intends to address this issue in future guidance with any appropriate changes based on comments received on this guidance and the Agency's experience with implementation.

[19] See *id.* § 203.30.

3. Delivery to Pharmacies

Under PDMA and implementing regulations, drug samples cannot be distributed to a retail pharmacy.[20] There are no changes in policy regarding these requirements during the COVID-19 PHE. Under 21 CFR 203.30, a drug sample may be distributed to a pharmacy of a hospital or other health care entity at the written request of a licensed practitioner.

[20] See FD&C Act 503(d)(1), (2)(A) (21 U.S.C. 353(d)(1)); *see also* 21 CFR 203.30(a). Pursuant to 21 CFR 203.30(a), a manufacturer or authorized distributor of record may distribute a drug sample to a practitioner licensed to prescribe the drug that is to be sampled or, at the written request of a licensed practitioner, to the pharmacy of a hospital or other health care entity. *Health care entity* is defined in 21 CFR 203.3(q) to mean any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or any wholesale distributor.