Pharmacy, Vol. 11, Issue 6, pp. 891–900, 2015.
3. *PhRMA, ''PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines,'' *Pharmaceutical Research and Manufacturers of America,* Washington, DC, *https://www.phrma.org,* revised October 2018, available at *https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Guiding_Principles_2018.pdf* (accessed May 18, 2022).
4. *Schouten, A. P., L. Janssen, and M. Verspaget, ''Celebrity vs. Influencer Endorsements in Advertising: The Role of Identification, Credibility, and Product-Endorser Fit,'' *International Journal of Advertising,* Vol. 39, Issue 2, pp. 258–281, 2020, *https://doi.org/10.1080/02650487.2019.1634898.*
5. *Bulik, B.S., ''Merck Adds Real Patient to 'TRU' Keytruda TV Ad,'' Fierce Pharma, September 27, 2017, available at *https://www.fiercepharma.com/marketing/new-merck-tv-ad-for-keytruda-continues-tru-theme-but-now-features-real-patient* (accessed May 18, 2022).

Dated: September 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20617 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1847]

Exemption and Exclusion From Certain Requirements of the Drug Supply Chain Security Act for the Distribution of Food and Drug Administration-Approved Naloxone Products During the Opioid Public Health Emergency; 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 ''Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency.'' Combating the opioid overdose epidemic is an urgent public health priority for FDA. Naloxone hydrochloride (''naloxone'') is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. FDA understands that naloxone is being made available to underserved communities through entities such as harm reduction programs and is aware of concerns that harm reduction programs are having difficulty acquiring naloxone. FDA is issuing this guidance to clarify the scope of the public health emergency exclusion and exemption under the Drug Supply Chain Security Act as they apply to the distribution of FDA-approved naloxone products indicated for the emergency treatment of opioid overdose to harm reduction programs during the opioid public health emergency. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 23, 2022.

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–2022–D–1847 for ''Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency.'' 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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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: Elizabeth Pepinsky, CDER/Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4258, Silver Spring, MD 20993–0002, 301–796–8763.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency.'' We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because the guidance requires immediate implementation for public health reasons. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

Combating the opioid overdose epidemic is an urgent public health priority for FDA. Naloxone is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. FDA understands that naloxone is being made available to underserved communities through entities such as harm reduction programs. FDA is aware of concerns that harm reduction programs are having difficulty acquiring naloxone. The Agency is aware that some stakeholders have viewed as a contributing factor the current availability of approved naloxone products only as prescription drugs and FDA has recently become aware that some stakeholders have viewed as a contributing factor certain requirements under the Drug Supply Chain Security Act (DSCSA) for distribution of FDA-approved prescription drug products., *e.g.,* being an authorized trading partner. FDA is issuing this guidance to clarify the scope of the public health emergency exclusion and exemption under the DSCSA as they apply to the distribution of FDA-approved naloxone products indicated for the emergency treatment of opioid overdose to harm reduction programs during the opioid public health emergency.

The guidance represents the current thinking of FDA on ''Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency.'' 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

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20552 Filed 9–22–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1874]

Agency Information Collection Activities; Proposed Collection; Comment Request; Perceptions of Prescription Drug Products With Medication Tracking Capabilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed study entitled ''Perceptions of Prescription Drug Products With Medication Tracking Capabilities.''

DATES: Either electronic or written comments on the collection of information must be submitted by November 22, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 22, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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