4. What are the context and implementation factors of studies with effective EMS/911 workforce practices to prevent, recognize and treat occupationally-acquired infectious diseases? This description might include distinguishing factors such as workforce training, surveillance, protective equipment, pre- and post-exposure prophylaxis, occupational health services, preparedness for emerging infectious diseases, and program funding.

5. What future research is needed to close existing evidence gaps regarding preventing, recognizing, and treating occupationally-acquired infectious diseases in the EMS/911 workforce?

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTINGS)

	Inclusion criteria	Exclusion criteria
Population	• Emergency medical service workforce including 911 dispatchers exposed to or at risk of exposure to an occupationally-acquired infectious disease as contact exposure, respiratory exposure, or blood-borne exposure.*	• Fire fighters and police personnel not involved in medical care.
Intervention	• One or more of the following types of interventions: ○ Training or education. ○ PPE protocols. ○ Personnel policies. ○ Budget allocations. ○ Vaccines. ○ Equipment.	• NA.
Comparison	• Any comparison group (for studies that evaluate the effectiveness of an EMS/911 workforce practice).	• Studies without a comparison group (for studies that evaluate the effectiveness of an EMS/911 workforce practice).
Outcomes	• Incidence • Prevalence. • Duration. • Severity. • Missed work. • Healthcare utilization. • Separation from the workforce. • Disability. • Death from infections.	• NA.
Timing	• Published after 2006 and includes data after 2006.	
Setting	• Conducted in the United States	• Military exercises and drills. • Live evacuations from another country.
Study design	• Experimental and non-experimental studies with comparison groups, including pre-post studies. • Relevant systematic reviews.	• No original data (Narrative reviews, commentaries, simulation studies).

* Organisms of interest included but are not limited to SARS–COV2, influenza, tuberculosis, HIV, and Hepatitis B and C.

Dated: December 3, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–26630 Filed 12–8–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0373]

Tobacco Product User Fees: Responses to Frequently Asked Questions; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Tobacco Product User Fees: Responses to Frequently Asked Questions.'' This guidance provides information in response to frequently asked questions related to tobacco product user fees assessed and collected under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on December 9, 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 Docket No. FDA–2021–D–0373 for ''Tobacco Product User Fees: Responses to Frequently Asked Questions.'' 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 Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993–0002, 1–877–287–1373, email: *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Tobacco Product User Fees: Responses to Frequently Asked Questions.'' This guidance provides information in response to frequently asked questions related to tobacco product user fees assessed and collected under section 919 of the FD&C Act (21 U.S.C. 387s). In particular, this guidance provides information regarding the submission of information needed to assess user fees owed by each domestic manufacturer or importer of tobacco products and how FDA determines whether a company owes user fees in each quarterly assessment.

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was enacted on June 22, 2009 (Pub. L. 111–31), amending the FD&C Act and providing FDA with the authority to regulate tobacco products. Included in the Tobacco Control Act is the requirement that FDA assess and collect user fees. Section 919(a) of the FD&C Act requires FDA, in accordance with that section, to ''assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of the FD&C Act (chapter IX of the FD&C Act). Under the calculations required by section 919 of the FD&C Act, the tobacco products that are subject to user fee assessments are cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco. The total amount of user fees for each fiscal year is specified in section 919(b)(1) of the FD&C Act, and, under section 919(a), FDA is to assess and collect one-fourth of that total each quarter of the fiscal year. The FD&C Act provides for the total quarterly assessment to be allocated among specified classes of tobacco products. The class allocation is based on each tobacco product class' volume of tobacco products removed into commerce. Within each class of tobacco products, an individual domestic manufacturer or importer is assessed a user fee based on its market share for that tobacco product class.

In the **Federal Register** of May 31, 2013 (78 FR 32581), FDA issued a notice of proposed rulemaking to add 21 CFR part 1150 to require domestic tobacco product manufacturers and importers to submit to FDA information needed to calculate the amount of user fees to assess each domestic manufacturer and importer under the FD&C Act. In the **Federal Register** of July 10, 2014 (79 FR 39302), FDA finalized portions of the User Fee proposed rule related to cigarettes, snuff, chewing tobacco, and roll-your-own tobacco, which is codified at 21 CFR part 1150. In the **Federal Register** of May 10, 2016 (81 FR 28707), FDA finalized a rule that requires domestic manufacturers and importers of cigars and pipe tobacco to submit information needed to calculate the amount of user fees assessed under the FD&C Act. In the **Federal Register** of May 27, 2021 (86 FR 28604), we published the notice of availability for the draft guidance ''Tobacco Product User Fees: Responses to Frequently Asked Questions.'' On July 26, 2021, the comment period closed with no comments having been received. We are now finalizing the guidance with no substantive changes.

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 frequently asked questions about tobacco product user fees set forth in the guidance. 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 1150 have been approved under 0910–0749.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm,* or *https://www.regulations.gov.*

Dated: December 3, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26651 Filed 12–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1214]

Considerations for the Use of Real-World Data and Real-World Evidence To Support Regulatory Decision-Making for Drug and Biological Products; Draft 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 draft guidance for industry entitled ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' FDA is issuing this guidance as part of its Real-World Evidence (RWE) Program and to satisfy, in part, the mandate under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue guidance about the use of RWE in regulatory decision making. FDA created a framework to evaluate the potential use of RWE to help support the approval of a new indication for a drug already approved under the FD&C Act or to help to support or satisfy postapproval study requirements. This guidance discusses the applicability of FDA's investigational new drug application (IND) regulations to various clinical study designs that utilize real-world data (RWD), and clarifies the Agency's expectations regarding clinical studies using RWD submitted to FDA in support of a regulatory decision regarding the effectiveness or safety of a drug (*e.g.,* as part of a new drug application or a biologics license application) that are not subject to the IND regulations.

DATES: Submit either electronic or written comments on the draft guidance by March 9, 2022 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–2021–D–1214 for ''Considerations for the Use of Real-World Data and Real-World Evidence to Support Regulatory Decision-Making for Drug and Biological Products.'' 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 the draft 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 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**