

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

#### Proposed Project

Fire Fighter Fatality Investigation and Prevention Program (FFFIPP) Survey—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

The FFFIPP conducts independent investigations of fire fighter (FF) line-of-duty deaths and recommends ways to prevent deaths and injuries. In 2003, an evaluation was conducted to determine

the extent to which recommendations from NIOSH investigations of FF fatalities are being implemented by fire departments (FDs). Since then, there have been changes to the FFFIPP recommendations and methods of disseminating FFFIPP reports. For example, there have been changes to: (1) The details and types of recommendations for preventing FF fatalities, and (2) the method to disseminate the FFFIPP reports to FDs (driven in large part by cost). Dissemination methods have evolved from hardcopy mailings to FDs to internet-based, with notifications of new FFFIPP reports by the fire service media and if FDs sign-up at the NIOSH website for notifications of new reports.

Understanding how or if NIOSH recommendations are used by various types of FDs will allow a better understanding of barriers to the use of proven prevention recommendations and help identify approaches to improve the delivery of services to FDs. Additionally, we will gain insight into whether changes to the communication and dissemination have impacted the reach of these recommendations. Knowing if different types of FDs are aware of and willing to access FFFIPP reports and recommendations in non-print formats is critical, as these recommendations cannot have the intended impact of saving FF lives if large numbers of FDs do not know where to find NIOSH reports or have the resources to access them.

This data collection will assess FD implementation of the NIOSH FFFIPP recommendations and identify barriers to implementation of recommendations. Results will provide an understanding of current FD operational procedures, insight into motor vehicle-related activities and related policies and identify whether FFFIPP recommendations are being utilized by FDs. Findings will inform strategies for communication of future recommendations and identify areas for potential intervention projects in order to improve the delivery of services and help ensure an effective and efficient stakeholder experience with the FFFIPP.

The estimate for burden hours is based on a pilot test of the survey instrument by eight FD personnel. In the pilot test, the average time to complete the survey including time for reviewing instructions, gathering needed information, and completing the survey was 10–25 minutes. For the purposes of estimating burden hours, the upper limit of this range is used. There are screening questions at the beginning of the survey so all respondents may not actually participate.

The respondent universe is based on: (1) 4,500 FDs, (2) eight strata (region, department type), and (3) position (FF, chief, company officer). An estimated 13,500 respondents are anticipated to participate in the survey. The annual respondent burden is estimated to be 4,050 hours.

#### ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Fire Fighters .....	Survey .....	4,500	1	18/60	1,350
Fire Chiefs .....	Survey .....	4,500	1	18/60	1,350
Company Officers .....	Survey .....	4,500	1	18/60	1,350
Total .....	.....	.....	.....	.....	4,050

Jeffrey M. Zirger,

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Centers for Disease Control and Prevention.

[FR Doc. 2022-01825 Filed 1-28-22; 8:45 am]

BILLING CODE 4163-18-P

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Food and Drug Administration

[Docket No. FDA-2019-D-0078]

#### Principles of Premarket Pathways for Combination Products; 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 a final guidance for industry and FDA staff entitled “Principles of Premarket Pathways for Combination Products.” This guidance presents FDA’s current thinking on principles for premarket review of combination products. This guidance includes general, high-level information regarding what combination products are, coordination within FDA and interaction between FDA and sponsors regarding combination product regulation, and how combination products are reviewed by FDA before

they are marketed. The guidance also includes recommendations on how to determine which type of premarket submissions may be appropriate for combination products. FDA is publishing this guidance as part of its efforts to implement the 21st Century Cures Act (Cures Act) and in keeping with the Agency's long-standing commitment to transparency, efficiency, and regulatory consistency to facilitate development of safe and effective combination products. This guidance finalizes the draft guidance of the same title that published on February 6, 2019.

**DATES:** The announcement of the guidance is published in the **Federal Register** on January 31, 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-2019-D-0078 for "Principles of Premarket Pathways for Combination 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 this guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, 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:** John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, 301-796-8930, [john.weiner@fda.hhs.gov](mailto:john.weiner@fda.hhs.gov) or [combination@fda.gov](mailto:combination@fda.gov).

#### **SUPPLEMENTARY INFORMATION:**

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

FDA is announcing the availability of a guidance for industry and FDA staff entitled "Principles of Premarket Pathways for Combination Products." This guidance presents FDA's current thinking on principles for premarket review of combination products. This guidance includes general, high-level information regarding what combination products are, coordination within FDA and interaction between FDA and sponsors regarding combination product regulation, and how combination products are reviewed by FDA before they are marketed. The guidance also includes recommendations on how to determine which type of premarket submissions may be appropriate for combination products, as well as illustrative examples.

Section 3038 of the Cures Act (Pub. L. 114-255), enacted in December 2016, substantially amended section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)), the principal section of the FD&C Act expressly addressing combination products. General themes of these amendments include enhancing clarity, predictability, efficiency, and consistency of premarket regulatory expectations for combination products, including by ensuring that Agency components and staff coordinate appropriately on premarket review of these products, and that Agency thinking is aligned in conducting these reviews. This guidance is part of FDA's efforts to implement section 3038 of the Cures Act.

In the **Federal Register** of February 6, 2019 (84 FR 2236), FDA announced the availability of the draft guidance of the same title. FDA received comments and considered those comments as the guidance was finalized. The final guidance clarifies the guidance including its applicability across combination product types and additional detail regarding processes for interacting with the Agency.

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 "Principles of Premarket Pathways for Combination Products." 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 3 and in the guidance "How to Prepare a Pre-Request for Designation (Pre-RFD)" have been approved under OMB control number 0910–0523. The collections of information for applications for FDA approval to market a new drug (certain provisions of 21 CFR part 314) have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under 0910–0338; and the collections of information in section 351(k) of the Public Health Service Act (42 U.S.C. 262) have been approved under 0910–0719. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 860, subparts A through C, have been approved under OMB control number 0910–0138; the collections of information in the guidance document "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" have been approved under OMB control number 0910–0756; and the collections of information in 21 CFR part 860, subpart D, for De Novo classifications have been approved under OMB control number 0910–0844.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/combo-combination-products-guidance-regulatory-information/combo-combination-products-guidance->

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

Dated: January 26, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–01925 Filed 1–28–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2022–N–0008]

#### Advisory Committee; Vaccines and Related Biological Products Advisory Committee; Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Vaccines and Related Biological Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the December 31, 2023, expiration date.

**DATES:** Authority for the Vaccines and Related Biological Products Advisory Committee will expire on December 31, 2023, unless the Commissioner formally determines that renewal is in the public interest.

#### FOR FURTHER INFORMATION CONTACT:

Prabhakara Atreya, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 240–402–8006, [Prabhakara.Atreya@fda.hhs.gov](mailto:Prabhakara.Atreya@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Vaccines and Related Biological Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in

discharging responsibilities as they relate to helping to ensure safe and effective vaccines and related biological products for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, and, as required, any other products for which FDA has regulatory responsibility. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 15 voting members, including the Chairperson (the Chair). Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, vaccine policy, vaccine safety science, federal immunization activities, vaccine development including translational and clinical evaluation programs, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Ex Officio voting members, one each from the Department of Health and Human Services, the Centers for Disease Control and Prevention, and the National Institutes of Health may be included. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) Expertise is required that is not available among current voting standing