

gear that may not be protective against all hazards is being used by fire fighters.

Intuitively, the use conditions to which turnout gear would be exposed to when used by a large or medium metropolitan fire department would be very different than those of a smaller department. However, the absence of scientific data to link performance to use conditions (*e.g.*, number and type of washings, number of fire-related calls) provides a barrier to transitioning to an alternative approach to retirement.

This study will obtain a statistically meaningful sample of turnout gear from three fire departments. The use

conditions for the sampled turnout gear will be determined, and the gear will be subjected to established performance requirements. For each set of gear, its performance will be directly linked to its use condition history. This combined lab and field data will help determine if there is a relationship between turnout gear use conditions and the ability for turnout gear to effectively protect the user.

The use conditions for each set of sampled gear will be determined by:

(1) Reviewing fire department records, practices, and policies;

(2) surveying the fire fighters assigned to each set of sampled gear to obtain one-month of retrospective information about the use conditions to which it was likely exposed; and

(3) a 6-month prospective data collection where the fire fighters assigned to each set of sampled gear provide information about their shift-specific exposures.

The estimated annualized Burden Hours for this information collection is 1,050. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individual Fire Fighter	Turnout Gear Safety Survey—Retrospective Exposures for past month.	100	1	30/60
	Turnout Gear Safety Survey—Prospective Exposures for six months.	100	60	10/60

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3305]

Allergenic Products Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Allergenic Products Advisory Committee scheduled for November 7, 2018, is cancelled. This meeting was announced in the **Federal Register** of September 26, 2018.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6338, Silver Spring, MD 20993-0002, 240-402-5771, serina.hunter-thomas@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the

prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-22942 Filed 10-19-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3728]

Agency Information Collection Activities; Proposed Collection; Comment Request; Collection of Conflict of Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

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, including each proposed extension of an existing collection of information, and

to allow 60 days for public comment in response to the notice. This notice solicits comments on the "Collection of Conflict of Interest Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs."

DATES: Submit either electronic or written comments on the collection of information by December 21, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 21, 2018]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 21, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 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-2018-N-3728 for "Collection of Conflict of Interest Information for Participation in FDA Fellowship and Traineeship Programs." Received comments, those filed in a timely manner (see

ADDRESSES), 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.

- **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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's

estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Collection of Conflict of Interest Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs; OMB Control Number 0910—NEW

In compliance with 44 U.S.C. 3507, FDA will submit to the Office of Management and Budget a request to review and approve a new collection of information: "Collection of Conflict of Interest Information for Participation in FDA Non-Employee Fellowship and Traineeship Programs." Section 742 (b) of the Food, Drug and Cosmetic Act (21 U.S.C. 379l) allows FDA to conduct and support intramural training programs through fellowship and traineeship programs. These new forms provide the FDA with information about financial investments and relationships from non-employee scientists who participate in FDA fellowship and traineeship programs. Participants in FDA fellowship and traineeship programs will be asked for certain information about financial interests and current relationships: (1) Description of the financial interest; (2) the type of financial interest (e.g. stocks, bonds, stock options); (3) if the financial interest is an employee benefit from prior employment; (4) value of financial interest; (5) who owns the financial interest (e.g. self, spouse minor children); (6) employment relationship with an FDA significantly regulated organization (SRO); (7) and service as a consultant to an FDA SRO, and/or proprietary interest(s) in one of more product(s) regulated by FDA, including patent, trademark, copyright, or licensing agreement. The purpose of the financial information is for FDA to determine if there is a conflict of interest between the Fellow's or Trainee's financial and relationship interests and their activities at FDA. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Collection Form—Report of Financial Interests and Other Relationships for Non-Employee Scientists at FDA					
Oak Ridge Institute for Science and Education Fellowship	500	1	500	1	500
Traineeship Program	500	1	500	1	500
Reagan-Udall Fellowship at FDA	50	1	50	1	50
Total					1,050

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22960 Filed 10–19–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–3916]

Determination of Regulatory Review Period for Purposes of Patent Extension; TECENTRIQ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for TECENTRIQ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 21, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 22, 2019. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 21,

2018. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 21, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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 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–2016–E–3916 for “Determination of Regulatory Review Period for Purposes of Patent Extension; TECENTRIQ.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- **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 § 10.20 (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