

information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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**

Assessing Fatigue and Fatigue Management in U.S. Onshore Oil and Gas Extraction Industry—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Oil and gas extraction (OGE) workers play an important role in supporting the United States economy and help fulfill the energy needs of Americans and American businesses. OGE workers have significant risks for a variety of exposures at oil and gas well sites. There has been no significant fatigue research in the United States onshore upstream OGE sector. This proposed project will characterize relationships

between sleep, fatigue, fatigue management, and related factors, within the onshore OGE industry.

Primary data will be collected using three approaches. First, researchers will collect direct measurements of sleep and alertness among OGE workers. Second, researchers will use questionnaires to collect information on OGE worker demographics, occupation, general health, normal working hours, commute times, home life, physical sleeping environment, and typical sleep quality. Third, researchers will collect qualitative information through interviews with workers, front-line supervisors, health and safety leaders, as well as subject matter experts, to understand challenges and opportunities related to fatigue management in the OGE industry.

CDC requests OMB approval for an estimated 305 annual burden hours. There is no cost to respondents other than their time to participate.

**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)
Land-based OGE workers .....	Baseline Questionnaire .....	80	1	12/60	16
Land-based OGE workers .....	Daily Pre-Shift Questionnaires .....	80	14	3/60	56
Land-based OGE workers .....	Daily Post-Shift Questionnaires .....	80	14	3/60	56
Land-based OGE workers .....	Psychomotor Vigilance Test (PVT) ..	80	28	3/60	112
Land-based OGE workers .....	Worker Interview Guide .....	30	1	90/60	45
Field-level Supervisors .....	Manager Interview Guide .....	10	1	1	10
Health and Safety Leaders .....	HSE Interview Guide .....	7	1	1	7
Subject Matter Experts .....	SME Interview Guide .....	3	1	1	3
<b>Total .....</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>305</b>

**Jeffrey M. Zirger,**

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2007-D-0369]

**Product-Specific Guidances; Draft and Revised Draft Guidances 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 additional draft and revised draft product-specific guidances. The guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website. The guidances identified in this notice were developed using the process described in that guidance.

**DATES:** Submit either electronic or written comments on the draft guidance by October 3, 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-2007-D-0369 for “Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.” 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993-0002, 301-796-2398, [PSG-Questions@fda.hhs.gov](mailto:PSG-Questions@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products” that explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA’s website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days

of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on May 20, 2022 (87 FR 30962). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA’s website.

**II. Drug Products for Which New Draft Product-Specific Guidances Are Available**

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

**TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS**

Active Ingredient(s)
Acetaminophen; Ibuprofen
Amphetamine; Amphetamine aspartate/Dextroamphetamine sulfate
Ampicillin/Ampicillin trihydrate
Azelastine hydrochloride
Berotrastat hydrochloride
Cabotegravir sodium
Carbamazepine
Casopofungin acetate
Cobicistat; Darunavir; Emtricitabine; Tenofovir alafenamide fumarate
Cyclosporine
Cytarabine; Daunorubicin
Dasiglucagon hydrochloride
Doxycycline hyclate
Etonogestrel
Famotidine
Gallium Ga-68 gozetotide
Ibuprofen
Ketoprofen
Lonafarnib
Loperamide hydrochloride; Simethicone
Loteprednol etabonate
Mometasone furoate; Olopatadine hydrochloride
Nifurtimox
Pafolacianine sodium
Relugolix
Setmelanotide acetate
Technetium Tc-99m sodium pertechnetate generator
Vericiguat
Vibegron

**III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available**

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

Active Ingredient(s)
Amoxicillin; Clavulanate potassium
Azelastine hydrochloride

Active Ingredient(s)
Cetirizine hydrochloride
Dantrolene sodium
Ethinyl estradiol; Norethindrone
Ethinyl estradiol; Norethindrone acetate
Lamotrigine
Lanthanum carbonate
Loratadine
Medroxyprogesterone acetate (multiple reference listed drugs)
Meloxicam
Methylphenidate hydrochloride
Nicotine
Olopatadine hydrochloride
Oxymetazone hydrochloride; Tetracaine hydrochloride
Prednisone
Tacrolimus
Upadacitinib

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

#### IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### V. Electronic Access

Persons with access to the internet may obtain the draft 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: July 27, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0008]

#### Advisory Committee; Blood Products Advisory Committee; Renewal

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

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

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Blood 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 Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2024, expiration date.

**DATES:** Authority for the Blood Products Advisory Committee will expire on May 13, 2024, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993-0002, 240-402-8054, [Christina.Vert@fda.hhs.gov](mailto:Christina.Vert@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 Blood 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 drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and, as required, any other product for which the Food and Drug Administration has regulatory responsibility. The Committee also

advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses, and on the quality and relevance of FDA's research program which provides the scientific support for regulating these agents. The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee: (1) recommends classification of devices subject to its review into regulatory categories; (2) recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; (3) advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; (4) recommends exemption of certain devices from the application of portions of the Medical Device Amendments of 1976; (5) advises on the necessity to ban a device; and (6) responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

The Committee shall consist of a core of 17 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and other related professions. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. 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 representative member who is identified with industry