• The form is available through the CMS Forms website at: *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms20017.pdf.*

• We encourage submitters to make efforts to ensure that their presentations and comment letters are 508 compliant.

IV. Formal Presentations

In addition to formal presentations (limited to 5 minutes total per presentation), there will be an opportunity during the meeting for public comments as time permits (limited to 1 minute for each individual and a total of 3 minutes per organization).

V. Panel Recommendations and Discussions

The Panel's recommendations at any Panel meeting generally are not final until they have been reviewed and approved by the Panel on the last day of the meeting, before the final adjournment. These recommendations will be posted to our website after the meeting.

VI. Membership Appointments to the Advisory Panel on Hospital Outpatient Payment

The Panel Charter provides that the Panel shall meet up to 3 times annually. We consider the technical advice provided by the Panel as we prepare the proposed and final rules to update the OPPS for the following calendar year.

The Panel shall consist of a chair and up to 15 members who are full-time employees of hospitals, hospital systems, or other Medicare providers that are subject to the OPPS. The panel may also include a representative of the provider with ASC expertise, who shall advise CMS only on OPPS APC rates, as appropriate, impacting ASC covered procedures within the context and purview of the panel's scope. The Secretary or a designee selects the Panel membership based upon either self-nominations or nominations submitted by Medicare providers and other interested organizations of candidates determined to have the required expertise. For supervision deliberations, the Panel shall also include members that represent the interests of Critical Access Hospitals, who advice CMS only regarding the level of supervision for hospital outpatient therapeutic services. New appointments are made in a manner that ensures a balanced membership under the Federal Advisory Committee Act guidelines.

This notice also announces four new membership appointments to the Panel. The four new members will each serve a 4-year period, with terms that begin in Calendar Year (CY) 2020 and end in CY 2024. The Secretary rechartered the Panel in 2018 for a 2-year period effective through November 20, 2020. The current charter is available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2018-HOP-Panel-Charter.pdf.* The Panel presently consists of members and a Chair named below. The panel members whose names are annotated with a single asterisk (*) are members that had terms that otherwise would have expired but are continuing to serve temporarily in accordance with the charter while we search for new members. The panel members whose names are annotated with a double asterisk (**) are new members and have a 4 year term beginning on July 16, 2020 and continuing through July 15, 2024.

- E.L. Hambrick, M.D., J.D., CMS Chairperson
- Terry Bohlke, C.P.A., C.M.A, M.H.A., C.A.S.C
- Carmen Cooper-Oguz, P.T., D.P.T, M.B.A, C.W.S, W.C.C
- Paul Courtney, M.D.
- Peter Duffy, M.D.
- Shelly Dunham, R.N. (*)
- Lisa Gangarosa, M.D.
- Erika Hardy, R.H.I.A., C.D.I.P, C.C.S. (*)
- Michael Kuettel, M.D., M.B.A, Ph.D.
- Karen A. Lambert (*)
- Scott Manaker, M.D., Ph.D.**
- Brian Nester, D.O., M.B.A. **
- Bo Gately, M.B.A. **
- Matthew Wheatley, M.D., F.A.C.E.P. **

VII. Provisions of the Notice

We published a notice in the **Federal Register** on January 26, 2018, entitled ''Medicare Program; Request for Nominations to the Advisory Panel on Hospital Outpatient Payment'' (83 FR 3715). The notice solicited nominations for the Panel members on a continuous basis to fill the vacancies on the Panel. As published in this notice, CMS is accepting nominations on a continuous basis and encourages additional submissions. Any interested person or organization may nominate qualified individuals. Self-nominations from qualified individuals are also accepted. Additional information including criteria for nominees as well as submission requirements are available in the notice, which is accessible from the CMS website at: *https://www.govinfo.gov/content/pkg/FR-2018-01-26/pdf/2018-01474.pdf.*

VIII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: August 4, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–17398 Filed 8–5–20; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1480]

Drug-Drug Interaction Assessment for Therapeutic Proteins; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (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 ''Drug-Drug Interaction Assessment for Therapeutic Proteins.'' The purpose of this guidance is to provide a systematic, risk-based approach to help sponsors of investigational new drug applications (INDs) and applicants of biologic license applications (BLAs) determine the need for drug-drug interaction (DDI) studies for a therapeutic protein (TP).

DATES: Submit either electronic or written comments on the draft guidance by November 9, 2020 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–2020–D–1480 for ''Drug-Drug Interaction Assessment for Therapeutic Proteins.'' 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. 240–420–7500.

• 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 INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elimika Pfuma Fletcher, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2162, Silver Spring, MD 20993, 301–796–3473; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Drug-Drug Interaction Assessment for Therapeutic Proteins.'' With the continued market growth and increased clinical use of TPs, it is important to understand the nature of and the potential for DDIs with these products. This guidance supplements the final FDA guidances for industry entitled ''In Vitro Drug Interaction Studies—Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions'' and ''Clinical Drug Interaction Studies—Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions'' (January 2020) by providing a systematic, risk-based approach to determining the need for DDI studies for TPs. This guidance discusses considerations for assessing DDIs for TPs, including situations where determining the DDI potential of a TP is warranted. The guidance also discusses various types of DDI assessments, considerations for study design, and recommendations for labeling.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Drug-Drug Interaction Assessment for Therapeutic Proteins.'' 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 draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information for submissions of investigational new drug applications, new drug applications, and biologic license applications in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338, respectively. In addition, the submission of prescription drug labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: August 4, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–17412 Filed 8–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[OMB Control Number 1010–0057; Docket ID: BOEM–2017–0016]

Agency Information Collection Activities; Pollution Prevention and Control

AGENCY: Bureau of Ocean Energy Management, Interior

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Bureau of Ocean Energy Management (BOEM) is proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before October 9, 2020.

ADDRESSES: Send your comments on this information collection request (ICR) to the BOEM Information Collection Clearance Officer, Anna Atkinson, Bureau of Ocean Energy Management, 45600 Woodland Road, VAM–DIR, Sterling, Virginia 20166 (mail); or by email to *anna.atkinson@boem.gov.* Please reference OMB Control Number 1010–0057 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Anna Atkinson, 703–787–1205, or by email at *anna.atkinson@boem.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

BOEM is soliciting comments on the proposed ICR that is described below. BOEM is especially interested in public comment addressing the following issues: (1) Is the collection necessary to the proper functions of BOEM; (2) what can BOEM do to ensure this information will be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might BOEM enhance the quality, utility, and clarity of the information to be collected; and (5) how might BOEM minimize the burden of this collection on the respondents, including minimizing the burden through the use of information technology?

Comments that you submit in response to this notice are a matter of public record. BOEM will include or summarize each comment in our request to Office of Management and Budget (OMB) for approval of this ICR. Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. In order for BOEM to withhold from disclosure your personally identifiable information, you must identify any information contained in the submittal of your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequences of the disclosure of information, such as embarrassment, injury, or other harm. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Abstract: Section 5(a) of the Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1334(a)), authorizes the Secretary of the Interior (Secretary) to prescribe rules and regulations to manage the mineral resources of the OCS. Such rules and regulations apply to all operations conducted under a lease, right-of-use and easement, and pipeline right-of-way.

Section 5(a)(8) of the OCS Lands Act (43 U.S.C. 1334(a)(8)) requires that regulations prescribed by the Secretary include provisions ''for compliance with the national ambient air quality standards pursuant to the Clean Air Act (42 U.S.C. 7401 *et seq.*), to the extent that activities authorized under this subchapter significantly affect the air quality of any State.'' This information collection renewal with revisions concerns information that is submitted in response to regulatory requirements, such as the regulations at 30 CFR part 550, subpart C, Pollution Prevention and Control that implement section 5(a)(8) and related Notices to Lessees and Operators (NTLs) that clarify and provide additional guidance on some aspects of these regulations. BOEM uses the information to inform its decisions on plan approval, to ensure operations are conducted according to all applicable regulations and plan conditions of approval, and to inform State and regional planning organizations' modeling efforts.

BOEM prepares an Emissions Inventory every three years to help ensure that its regulations comply with section 5(a)(8) of OCS Lands Act, 43 U.S.C. 1334(a)(8), and to implement the requirement at 30 CFR 550.303(k) and 550.304(g). BOEM begins this effort by issuing an NTL with instructions about how lessees can submit basic information about their operations that are subject to sec. 5(a)(8) regulations, from which BOEM's software calculates emissions information. BOEM is planning to issue the next such guidance in the Fall for a collection period in calendar year 2021. These emission inventories provide BOEM with the essential input needed to assess offshore OCS oil and gas activity impacts to the states as mandated by the OCSLA. They also provide the states the essential tools needed to perform their State Implementation Plan demonstrations to the U.S. Environmental Protection Agency (USEPA), and they provide the operators essential data for their mandatory reporting of greenhouse gases to the USEPA.

BOEM is developing and planning to implement a web-based solution that will allow operators to submit their platform and non-platform activity data electronically, instantaneously calculate monthly and annual emissions, quality assure and control data, and generate reports, such as emission inventory reports, and data graphics to the operators and to BOEM. To collect the necessary emissions data from companies, BOEM currently uses the Gulfwide Offshore Activity Data System (GOADS) software. This software is out of date and resides on a platform that BOEM is no longer able to utilize satisfactorily. Therefore, BOEM plans to implement a new web-based solution that would allow users to input their information directly into the system, which in turn will allow BOEM to access the data and create reports needed to assess oil and gas source impacts to States. Unlike the existing tool, the new solution will make it easy for users to enter activity data, calculate emissions data in real-time for users, and leverage built-in validation features to quality check the calculations prior to submission.

BOEM protects proprietary information according to the Freedom of Information Act (FOIA) (5 U.S.C. 552) and the Department of the Interior's