under 21 CFR parts 50 and 56 cumulatively, however we have itemized burden associated with certain of the regulatory provisions for purposes of providing a more detailed estimate. We invite comment on burden associated with these information collection requirements.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
50.25; elements of informed consent	2,520	40	100,800	*0.5	50,400
56.109(d); written statement about minimal risk research when documentation of informed consent is waived	2,520	2	5,040	*0.5	2,520
56.109(e); written notification to approve or disapprove research	2,520	40	100,800	*0.5	50,400
56.109(g) IRB written statement about public disclosures to sponsor of emergency research under 50.24	8	2	16	1	16
Total					103,336

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* (30 minutes).

As discussed above, we have reorganized the table to characterize our estimates of burden associated with 21 CFR 50.25, 56.109(d) and 56.109(e) as disclosure burdens. We estimate that eight IRBs per year will receive a request to review emergency research under § 50.24, thus requiring written notification under 21 CFR 56.109(g) from the IRB to the sponsor. We estimate that it will take an IRB approximately 1 hour to prepare each written statement, for a total of 2 hours per study. The total annual third-party disclosure burden for IRBs to fulfill this requirement is estimated at 16 hours.

Dated: December 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27351 Filed 12–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5585]

Bridging for Drug-Device and Biologic-Device Combination Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Bridging for Drug-Device and Biologic-Device Combination Products.'' This draft guidance, when finalized, will represent the Agency's thinking on how to approach bridging in new drug applications (NDAs) or biologics license applications (BLAs) for drug-device and biologic-device single entity or co-packaged combination products and will help to fulfill the performance goals under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI). For the purposes of this guidance, the term *bridging* refers to the process of establishing the scientific relevance of information developed in an earlier phase of the development program or another development program to support the combination product for which an applicant is seeking approval. Once the applicant has established the relevance of such information to (*i.e.,* bridged to) its product, the applicant may be able to leverage that information to streamline the development program.

DATES: Submit either electronic or written comments on the draft guidance by February 18, 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–2019–D–5585 for ''Bridging for Drug-Device and Biologic-Device 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.

- 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.

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; 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; or the Office of Communication and Education, CDRH-Division of Industry and Consumer Education, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4621, 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: Robert Berlin, Center for Drug Evaluation and Research, Office of New Drugs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6373, Silver Spring, MD 20993, 301–796–8828; Irene Chan, Center for Drug Evaluation and Research, Office of New Drugs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4420, Silver Spring, MD 20993, 301–796–3962; 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; Andrew Yeatts, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002, 301–796–4539; or Patricia Love, Office of Special Medical Programs, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5144, Silver Spring, MD 20993–0002, 301–796–8933.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bridging for Drug-Device and Biologic-Device Combination Products.'' This document is one of several documents FDA is issuing to fulfill the performance goals under PDUFA VI. This document provides guidance to industry and FDA staff on how to approach bridging in NDAs or BLAs for drug-device and biologic-device single entity or co-packaged combination products, including the following:

- Bridging of information related to a combination product that employs a different device constituent part or parts with the same drug or biological product constituent part or parts as the proposed combination product
- Bridging of information related to a combination product that employs a different drug or biological product constituent part or parts as the proposed combination product

For the purposes of this draft guidance, the term *bridging* refers to the process of establishing the scientific relevance of information developed in an earlier phase of the development program or another development program to support the combination product for which an applicant is seeking approval. After the applicant has established the relevance of such information to (*i.e.,* bridged to) its product, the applicant may be able to leverage that information to streamline its development program. From a scientific perspective, an applicant must bridge its current application to information developed in an earlier phase of the development program or another development program if the applicant wishes to leverage that information in its current application. For certain types of applications, the use of information from another development program may require that the applicant own the information or have a right of reference.

This draft guidance seeks to clarify how to bridge to information gathered from another development program to leverage that information in support of an application. To facilitate that process, the draft guidance recommends that an applicant use an analytical framework described in the draft guidance to identify and address information gaps for an application. Although the draft guidance is intended to help applicants consider the type and scope of information that may be leveraged for a combination product development program, the draft guidance does not address all of the issues applicable to any particular combination product.

In addition, the draft guidance presents three hypothetical case examples to illustrate how an applicant might appropriately apply the recommended framework and associated analyses to determine the bridging strategy and informational needs in a development program. These considerations and recommendations are not intended to apply to any particular development program. The draft guidance also encourages applicants to discuss their particular development program and bridging strategy with FDA.

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 ''Bridging for Drug-Device and Biologic-Device 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

This draft guidance refers to currently 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 in 21 CFR part 312 for investigational new drug applications and 21 CFR part 314 for new drug applications have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR part 601 for biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 814, subparts A through E, for premarket approval applications have been approved under OMB control number 0910–0231. The collections of information in section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), subpart E for 510(k) notifications, have been approved under OMB control number 0910–0120. The collections of information in the guidance for industry and FDA staff entitled ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844. The collection of information in 21 CFR part 4 has been approved under the underlying current good manufacturing process regulations for drugs, devices, and biological products, including current good tissue practices for human cells, tissues, and cellular and tissue-based products, found at parts 211, 820, 600 through 680, and 1271 (21 CFR parts 211, 820, 600 through 680, and 1271), which have already been approved and are in effect. The provisions of part 211 are approved under OMB control number 0910–0139. The provisions of part 820 are approved under OMB control number 0910–0073. The provisions of parts 606, 640, and 660 are approved under OMB control number 0910–0116. The provisions of part 610 are approved under OMB control numbers 0910–0116 and 0910–0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910–0543.

III. 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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products,* or *https://www.regulations.gov.*

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27354 Filed 12–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: National Practitioner Data Bank Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, Health Centers, and Other Eligible Entities

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 18, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: National Practitioner Data Bank (NPDB) Attestation of Reports by Hospitals, Medical Malpractice Payers, Health Plans, Health Centers, and Other Eligible Entities, OMB No. 0906–0028—Revision.

Abstract: NPDB proposes to continue collecting data from entities, such as hospitals, medical malpractice payers, health plans, and health centers that are subject to NPDB reporting requirements during registration renewal.[1] This will allow the NPDB to continue to assist these entities in understanding and meeting their reporting requirements.

NPDB plans to expand its population of focus to include other eligible entities,[2] including ambulatory surgery centers, group medical practices, skilled nursing facilities, mental health centers, and other registered entities. Beyond attesting to meeting NPDB reporting requirements, entities will also attest to querying and confidentiality compliance.

NPDB began operation on September 1, 1990. The statutory authorities establishing and governing the NPDB are Title IV of Public Law (Pub. L.) 99–660, the Health Care Quality Improvement Act of 1986, as amended, Section 5 of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100–93, codified as Section 1921 of the Social Security Act, and Section 221(a) of the Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, codified as Section 1128E of the Social Security Act. Final regulations governing the NPDB are codified at 45 CFR part 60. Responsibility of the NPDB implementation and operation resides in the Bureau of Health Workforce, HRSA, HHS.

[1] Unless otherwise noted, the term ''health centers'' refers to health centers whose access and reporting obligations are addressed in the NPDB statutory and regulatory requirements for health care entities. In this document, ''health center'' refers to organizations that receive grants under the HRSA Health Center Program as authorized under section 330 of the Public Health Service Act, as amended (referred to as ''grantees'') and FQHC Look-Alike organizations, which meet all the Health Center Program requirements but do not receive Health Center Program grants. It does not refer to FQHCs that are sponsored by tribal or Urban Indian Health Organizations, except for those that receive Health Center Program grants.

[2] ''Other eligible entities'' that participate in the NPDB are defined in the provisions of Title IV, Section 1921, Section 1128E, and implementing regulations. In addition, a few federal agencies also participate with the NPDB through federal memorandums of understanding. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity. Each eligible entity must certify its eligibility in order to report to the NPDB, query the NPDB, or both. Information from the NPDB is available only to those entities specified as eligible in the statutes and regulations. Not all entities have the same reporting requirements or level of query access.