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# Bridging for Drug-Device and Biologic-Device Combination Products; Draft Guidance for Industry; Availability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**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Bridging for Drug-Device and Biologic-Device Combination Products." This draft guidance, when finalized, will represent the Agency's thinking on how to approach bridging in new drug applications (NDAs) or biologics license applications (BLAs) for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**DATES:** Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to

ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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,**

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