

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Theresa Wells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5373, Silver Spring, MD 20993-0002, 703-380-3900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Development of Non-Opioid Analgesics for Acute Pain." This draft guidance is written in connection with section 3001 of the SUPPORT Act to provide information that will be useful in the development of non-opioid analgesics for the management of acute pain and, thereby, spur the development of such products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Development of Non-Opioid Analgesics for Acute Pain." 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of

information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001; the collections of information in 21 CFR part 312 for conducting clinical trials and collecting data for such trials have been approved under OMB control number 0910-0014; the collections of information pertaining to Electronic Records and Electronic Signatures have been approved under OMB control number 0910-0303; the collections of information pertaining to the Requirements on Content and Format of Labeling for Human Prescriptions for "opioid-sparing" claims have been approved under OMB control number 0910-0572; and the collections of information found in the Guidance for Industry on Expedited Programs for Serious Condition—Drugs and Biologics for expedited pathways to support the development program for non-opioid analgesics have been approved under OMB control number 0910-0765.

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/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: February 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4853]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar or Interchangeable Biosimilar Applicant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing notice that an applicant for a biologics license application (BLA) for a biosimilar or interchangeable biosimilar product submitted under the Public Health Service Act (PHS Act) (a "subsection (k) applicant") notified FDA that an action for patent infringement was filed in connection

with the applicant's BLA. Under the PHS Act, within 30 days after the subsection (k) applicant is served with a complaint in an action for patent infringement described under the PHS Act, the subsection (k) applicant shall provide the Secretary of HHS with notice and copy of such complaint. FDA is required to publish notice of the complaint in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:

Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993-0002, 301-796-1042, Sandra.Benton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)) sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement to a proposed interchangeable product.

Section 351(l) of the PHS Act (42 U.S.C. 262(l)) describes certain procedures for exchanging patent information and resolving patent disputes between a subsection (k) applicant and the holder of the BLA reference product. If a subsection (k) applicant is served with a complaint in an action for a patent infringement described in section 351(l)(6) of the PHS Act, the subsection (k) applicant is required to provide the Secretary with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

FDA received notice of the following complaint under section 351(l)(6)(C) of the PHS Act: *AbbVie Inc. and AbbVie Biotechnology Ltd. v. Alvotech HF*, 1:21-cv-02258 (N.D. Ill., filed April 27, 2021).

FDA has only a ministerial role in publishing notice of a complaint received under section 351(l)(6)(C) of the PHS Act and does not perform a substantive review of the complaint.

Dated: February 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-02799 Filed 2-9-22; 8:45 am]

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