

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 to 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4132, Silver Spring, MD 20993, 301-796-1697; 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FDA is announcing the availability of a draft guidance for industry entitled “Child-Resistant Packaging Statements in Drug Product Labeling.” In 1970, the Poison Prevention Packaging Act (PPPA) was enacted to protect children (under 5 years of age) from unintentional exposure to household substances including food, drugs, and cosmetics. Under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), a drug that has packaging or labeling that is in violation of a regulation issued pursuant to section 3 or 4 of the PPPA is deemed to be misbranded. FDA was responsible for enforcing the PPPA until 1973, when jurisdiction was transferred to the U.S. Consumer Product Safety Commission (CPSC). Because of FDA’s authority to regulate labeling for prescription and nonprescription drug products, if firms choose to make statements in their labeling for such products about CRP, such statements must comply with FDA’s statutory and regulatory requirements. The draft guidance explains that to ensure that CRP statements on labeling are not false or misleading, such statements should only be used when the drug product packaging has been shown to comply with the applicable CPSC regulatory standards and test procedures for CRP. This guidance is intended to apply to

FDA-regulated drug products that bear CRP statements, regardless of whether CRP is required for such products under 16 CFR 1700. For example, bulk packages of prescription drugs that are shipped to pharmacies for repackaging by a pharmacist are not required to utilize CRP, but a firm may nevertheless choose to use CRP (and a CRP statement) for such drugs.

CPSC’s regulations list “special packaging standards” (also referred to herein as child-resistant packaging, or CRP) for a wide range of household products, including most oral prescription drugs and many nonprescription drug products (see 16 CFR 1700 for substances requiring special packaging and the relevant packaging standards and testing procedures). There are different ways to make packaging child-resistant, with the most common forms being a child-resistant closure (e.g., a “safety cap”) and certain unit-dose blister packaging (e.g., puncture-resistant and peel-push blisters).

Child-resistant packaging is regarded as an important public health safety tool for avoiding harmful outcomes related to unsupervised pediatric ingestions. FDA advocates that all drugs, irrespective of the type of packaging, be stored safely out of reach and sight of children to further the overall public health efforts to address this safety issue.

Because health care professionals and consumers may not be able to determine on visual inspection whether the packaging is child-resistant, a labeling statement may help to identify this attribute. Therefore, in this guidance, we recommend text that may be appropriate to consider when including CRP statements on the containers and packaging of 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 child-resistant packaging statements in drug product labeling. 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. Because FDA’s guidance documents do not bind the public or FDA to any requirements, this guidance is not considered to be subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by

the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information for submitting labeling in original and supplemental new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs) in 21 CFR 314.50(e) and (l), 314.94(a)(8), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910-0001 and 0910-0338, respectively. The collection of information for preparing prescription drug product labeling under 21 CFR 201.56 and 201.57 has been approved under OMB control number 0910-0572. The collection of information for Drug Facts labeling under 21 CFR 201.66 has been approved under OMB control number 0910-0340. The collection of information for Medication Guides has been approved under OMB control number 0910-0393. The collection of information for submitting chemistry, manufacturing, and controls information in original and supplemental NDAs, ANDAs, and BLAs in 21 CFR 314.50(d)(1), 314.94(a)(9), 314.70, and 314.97, and 21 CFR 601.2 and 601.12 has been approved under OMB control number 0910-0001 and 0910-0338, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: July 31, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-16379 Filed 8-2-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2489]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a 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 proposed biosimilar product notified FDA that a patent infringement action was filed in connection with the applicant's biologics license application (BLA). Under the Public Health Service Act (PHS Act), an applicant for a proposed biosimilar product or interchangeable product must notify FDA within 30 days after the applicant was served with a complaint in a patent infringement action described under the PHS Act. FDA is required to publish notice of the complaint in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993-0002, 240-402-0979, daniel.orr@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)), added by the BPCI Act, describes the requirements for a BLA for a proposed biosimilar product or a proposed interchangeable product (351(k) BLA). Section 351(l) of the PHS Act, also added by the BPCI Act, describes certain procedures for exchanging patent information and

resolving patent disputes between a 351(k) BLA applicant and the holder of the BLA reference product. If a 351(k) applicant is served with a complaint for a patent infringement described in section 351(l)(6) of the PHS Act, the applicant is required to provide FDA 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: *Amgen, Inc., et al. v. Coherus Biosciences, Inc.*, 17-cv-00546 (D. Del., filed May 10, 2017).

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: July 31, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-16380 Filed 8-2-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0002]

B. Braun Medical, Inc.; Withdrawal of Approval of Three New Drug Applications and One Abbreviated New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three new drug applications (NDAs) and one abbreviated new drug application (ANDA) held by B. Braun Medical, Inc. B. Braun Medical, Inc., notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Effective September 5, 2017.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, 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: B. Braun Medical, Inc., 901 Marcon Blvd., Allentown, PA 18109, has informed FDA that the following three NDAs and one ANDA are no longer marketed and has requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). By its request, B. Braun Medical, Inc., has also waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

NDA/ANDA	Proprietary name
BN 090024	Dextran 70, 6% Dextran 70 in 0.9% NaCl Injection.
BN 160767	Dextran 40, 10% Dextran 40 in 0.9% NaCl Injection and 10% Dextran 40 in 5% Dextrose.
BN 890104	Pentaspán® (10% Pentastarch in 0.9% NaCl Injection in EXCEL Containers).
BA 740283	Hespan® (6% Hetastarch in 0.9% NaCl in EXCEL Containers).

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn, effective September 5, 2017. Introduction or delivery for introduction into interstate commerce for products without an approved NDA or ANDA violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the

drug products have reached their expiration dates or otherwise becomes violative, whichever occurs first.

Dated: July 31, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-16377 Filed 8-2-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Nasser Chegini, Ph.D., University of Florida: Based on the report of an investigation conducted by the University of Florida (UF), the prior