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	Pentaspan® (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