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

corrections in the scientific record noted below, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Nasser Chegini, retired as a Professor in the Department of Obstetrics and Gynecology, UF, engaged in research misconduct in research supported by National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), grant 2 R01 HD037432.

ORI acknowledges that the following papers were retracted as a result of the institution's investigation:

1. *J Clin Endocrinol Metab* 88(10):4967–4976, 2003. Retraction in: *J Clin Endocrinol Metab* 100(1):318, 2015 Jan.
2. *Reprod Biol Endocrinol* 1:125, 2003. Retraction in: *Reprod Biol Endocrinol* 13:25, 2015 Apr 3.
3. *J Clin Endocrinol Metab* 88(3):1350–1361, 2003. Retraction in: *J Clin Endocrinol Metab* 100(1):318, 2015 Jan.
4. *Hum Reprod* 21(10):2555–2563, 2006. Retraction in: *Hum Reprod* 30(1):249, 2015 Jan (Epub 2014 Nov 6).
5. *Mol Hum Reprod* 12(4):245–256, 2006. Retraction in: *Mol Hum Reprod* 20(12):1258, 2014 Dec (Epub 2014 Nov 13).
6. *Mol Hum Reprod* 13(11):797–806, 2007. Retraction in: *Mol Hum Reprod* 20(12):1259, 2014 Dec (Epub 2014 Nov 13).
7. *Reprod Sci* 15(10):993–1001, 2007. Retraction in: *Reprod Sci* 21(10):1326, 2014 Oct.
8. *J Cell Mol Med* 12(1):227–240, 2008. Retraction in: *J Cell Mol Med* 19(10):2512, 2015 Oct.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying data that were included in: *J Reprod Immunol* 73(2):118–29, 2007 (hereafter referred to as ''*JRI* 2007''). Specifically, ORI found that Respondent falsified data points and standard errors of the mean in bar graphs plotting matrix metalloprotease expression or activity in the following figures of *JRI* 2007:

- Figures 2A, 2B, 2C
- Figures 3A, 3B, 3C
- Figure 4B
- Figure 5C
- Figure 6B
- Figures 7A, 7B, 7C
- Figure 8, middle left panel and lower right panel

Dr. Chegini entered into a Voluntary Settlement Agreement with ORI, in which he voluntarily agreed to the following, beginning on July 12, 2017:

(1) Respondent has not applied for or engaged in U.S. Public Health Service (PHS)-supported research since 2012; Respondent has no intention of applying for or engaging in PHS-supported research or otherwise working with PHS; however, if within five (5) years of the effective date of the Agreement, the Respondent receives or applies for PHS support, the Respondent agreed to have his research supervised for a period of five (5) years from the date of his employment in a position in which he receives or applies for PHS support and agreed to notify his employer(s)/institution(s) of the terms of this supervision; Respondent agreed that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan;

(2) Respondent agreed that for a period of five (5) years beginning on the date on which the Respondent receives or applies for PHS support, any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of five (5) years, beginning with the effective date of the Agreement; and

(4) as a condition of the Agreement, Respondent will request that *J Reprod Immunol* 73(2):118–29, 2007 be retracted.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

Kathryn M. Partin,

Director, Office of Research Integrity.

[FR Doc. 2017–16311 Filed 8–2–17; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel NIAID Clinical Trial Implementation Grant (R01).

Date: August 28, 2017.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Program, Division of Extramural Activities, Room 3F40B National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5036, *poeky@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 28, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–16314 Filed 8–2–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the