Page 10 – Dr. Miller, DoD

suggest that this product is safe or effective for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical.

The emergency use of the authorized French FDP as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of FDP for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat (e.g., firearms, projectiles, and explosive devices) when plasma is not available for use or when the use of plasma is not practical is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Rachel E. Sherman, M.D., M.P.H.
Principal Deputy Commissioner of Food and Drugs

Enclosures

Dated: August 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17303 Filed 8–10–18; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2876]

Fougera Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 20 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 20 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of September 12, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 060133	Chloramphenicol Ophthalmic Ointment, 1%	Fougera Pharmaceuticals, Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747.
ANDA 060572	Mycolog II (nystatin and triamcinolone acetonide) Ointment USP, 100,000 units/gram (g) and 0.1%.	Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 061107	Hydrocortisone Acetate and Neomycin Sulfate Ointment, 0.5%/0.5% and 1.5%/0.5%.	Fougera Pharmaceuticals, Inc..
ANDA 061988	Polycillin (ampicillin) Capsules, 250 milligrams (mg) and 500 mg.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.
ANDA 072097	Cap-Profen (ibuprofen) Tablets USP, 200 mg (White)	L. Perrigo Co., 515 Eastern Ave., Allegan, MI 49010.
ANDA 072098	Ibuprofen Tablets, 200 mg (Brown)	Do.
ANDA 074334	Vecuronium Bromide for Injection, 10 mg/vial and 20 mg/vial.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 074874	Pentoxifylline Extended-Release Tablets, 400 mg	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.

Application No.	Drug	Applicant
ANDA 074945	Atracurium Besylate Injection, 10 mg/milliliter (mL)	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 077251	Finasteride Tablets USP, 5 mg	Gedeon Richter Plc., c/o Gedeon Richter USA, Inc., 119 Cherry Hill Rd., Suite 325, Parsippany, NJ 07054.
ANDA 077983	Gemcitabine for Injection USP, Equivalent to (EQ) 200 mg base/vial and EQ 1 g/vial.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 080425	Texacort (hydrocortisone) Topical Solution, 1%	Mission Pharmacal Co., 10999 IH 10 West, Suite 1000, San Antonio, TX 78230.
ANDA 083242	Amen (medroxyprogesterone acetate) Tablets, 10 mg	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 085455	Dexamethasone Tablets USP, 0.25 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc..
ANDA 086308	Homapin-10 (homatropine methylbromide) Tablets USP, 10 mg.	Mission Pharmacal Co.
ANDA 086309	Homapin-5 (homatropine methylbromide) Tablets USP, 5 mg.	Do.
ANDA 086310	Equipin (homatropine methylbromide) Chewable Tablets, 3 mg.	Do.
ANDA 086711	Beta-2 (isoetharine hydrochloride (HCl)) Inhalation Solution, 1%.	Nephron Pharmaceuticals, Corp., 4500 12th St. Extension, West Columbia, SC 20172.
ANDA 087438	Folicet (folic acid) Tablets USP, 1 mg	Mission Pharmacal Co.
ANDA 087939	Trimethobenzamide HCl Injection, 100 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 12, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications 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 September 12, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: August 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17226 Filed 8–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Advisory Committee to the Director, National Institutes of Health.

The meeting will be held as a teleconference call only and is open to the public to dial-in for participation. Individuals who plan to dial-in to the meeting and need special assistance or other reasonable accommodations in order to do so, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Advisory Committee to the Director, National Institutes of Health.

Date: August 24, 2018.

Time: 9:15 a.m. to 9:45 a.m.

Agenda: Updates on ACD Working Groups.

Place: National Institutes of Health, Building 1, One Center Drive, Bethesda, MD 20892 (Telephone Conference Call), 800–369–1915, Access Code: 6496247.

Contact Person: Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *Woodgs@od.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to scheduling difficulties.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://acd.od.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: August 8, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–17345 Filed 8–10–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; National Cancer Institute (NCI) Future Fellows Resume Databank

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institutes of Health, National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Angela Jones, Program