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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of March 26, 2018.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 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 040398	MiCort-HC (hydrocortisone acetate) Cream USP, 2%	Sebela Ireland, Ltd., c/o Sebela Pharmaceuticals, Inc., 645 Hembree Parkway, Suite 1, Roswell, GA 30076.
ANDA 071893	Acetohexamide Tablets, 250 milligrams (mg)	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 071894	Acetohexamide Tablets, 500 mg	Do.
ANDA 073143	Cyclobenzaprine Hydrochloride (HCl) Tablets USP, 10 mg	Do.
ANDA 074576	Captopril Tablets USP, 12.5 mg, 25 mg, 50 mg, and 100 mg	Do.
ANDA 076607	Quinapril Tablets USP, Equivalent to (EQ) 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 076786	Donepezil HCl Tablets USP, 5 mg and 10 mg	Do.
ANDA 077483	Benazepril HCl and Hydrochlorothiazide Tablets, 5 mg/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg.	Do.
ANDA 078502	Eliphos (calcium acetate) Tablets USP, 667 mg	Cypress Pharmaceutical, Inc., 10 North Park Pl., Suite 201, Morristown, NJ 07960.
ANDA 081019	Chlorzoxazone Tablets USP, 500 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083821	Brompheniramine Maleate Injection, 10 mg/milliliter (mL)	Do.
ANDA 084408	Bethanechol Chloride Tablets USP, 10 mg	Do.
ANDA 084441	Bethanechol Chloride Tablets USP, 25 mg	Do.
ANDA 085283	Theolair (theophylline) Tablets, 125 mg and 250 mg	3M Drug Delivery Systems, 3M Center, Bldg. 275–3E–02, 2510 Conway Ave., St. Paul, MN 55144.
ANDA 085738	Betamethasone Sodium Phosphate Injection, EQ 3 mg base/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087444	Bethanechol Chloride Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087792	Fluorouracil Injection USP, 50 mg/mL	Spectrum Pharmaceuticals, Inc., 157 Technology Dr., Irvine, CA 92618.
ANDA 087978	Diphenhydramine HCl Capsules, 50 mg	LNK International, Inc., 145 Ricefield Ln., Hauppauge, NY 11788.
ANDA 090417	Carbinoxamine Maleate Tablets USP, 4 mg	Cypress Pharmaceutical, Inc.
ANDA 090418	Carbinoxamine Maleate Oral Solution, 4 mg/5 mL	Do.
ANDA 090468	Zyfrel (acetaminophen and hydrocodone bitartrate) Oral Solution, 325 mg/7.5 mg per 15 mL.	Do.
ANDA 091034	Dorzolamide HCl Ophthalmic Solution USP, EQ 2% base	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242.
ANDA 200794	Pantoprazole Sodium Delayed-Release Tablets USP, EQ 20 mg base and EQ 40 mg base.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc.
ANDA 206438	Hydrocodone Bitartrate and Chlorpheniramine Maleate Oral Solution, 5 mg/4 mg per 5 mL.	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 26, 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 March 26, 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: February 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03700 Filed 2–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on

Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Tuesday, March 13, 2018, from 8:30 a.m. until 5:00 p.m., and Wednesday, March 14, 2018, from 8:30 a.m. until 4:00 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services (HHS), through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 8:30 a.m., on Tuesday, March 13, 2018, followed by opening remarks from Dr. Jerry Menikoff, Director of the Office for Human Research Protections and Dr. Stephen Rosenfeld, SACHRP Chair.

The SAS and SOH subcommittees will present their recommendations regarding the description of ''key information,'' as required by the revised Common Rule's § 46.116(a)(5)(i). This will be followed by a discussion of SOH recommendations on the research use of repositories and registries under various consent models, under both the current and the revised Common Rule. The Tuesday, March 13, meeting will adjourn at approximately 5:00 p.m.

The Wednesday, March 14, meeting will begin at 8:30 a.m. The SOH will present and discuss recommendations on the European Union's General Data Protection Regulation and its impact on U.S. human subjects research. Modifications to the previous day's work will be discussed and finalized. The meeting will adjourn at approximately 4:00 p.m.

Time for public comment sessions will be allotted both days. On-site registration is required for participation in the live public comment session. Note that public comment must be relevant to issues currently being addressed by the SACHRP. Individuals submitting written statements as public comment should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated SACHRP point of contact at the address/phone number listed above at least one week prior to the meeting.

Dated: February 16, 2018.

Julia G. Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2018–03768 Filed 2–22–18; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made on the part of Colleen T. Skau, Ph.D., former postdoctoral fellow in the Cell Biology and Physiology Center, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH). Dr. Skau engaged in research misconduct in research supported by NHLBI, NIH. The administrative actions, including three (3) years of supervision, were implemented beginning on January 25, 2018, and are detailed below.

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

SUPPLEMENTARY INFORMATION:

Colleen T. Skau, Ph.D., National Institutes of Health: Based on Respondent's admission, an assessment conducted by NIH, and analysis conducted by ORI in its oversight review, ORI found that Dr. Colleen T. Skau, former postdoctoral fellow in the Cell Biology and Physiology Center, NHLBI, NIH, engaged in research misconduct in research supported by NHLBI, NIH.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly reporting falsified and/or fabricated data and/or falsifying and/or fabricating data in the following two (2) papers:

- *Cell* 167(6):1571–1585, 2016 (hereafter referred to as ''Paper 1'')
- *Proceedings of the National Academy of Sciences* 112(19):E2447–E2456, 2015 (hereafter referred to as ''Paper 2'')

ORI found that Respondent engaged in research misconduct by intentional, knowing, or reckless falsification and/or fabrication of the research record by selectively reporting by inappropriate inclusion/omission or alteration of data points in ten (10) figures and falsely reporting the statistical significance based on falsified data in ten (10) figures across the two (2) papers and supplementary material. Specifically, ORI found that:

- In Paper 1, Respondent falsified and/or fabricated the research record in:

—Figure 3B, by selectively omitting/including data points in the Rescue condition

—Figure 5B, by reporting a significant difference between conditions by performing statistical calculations based on fabricated primary data

—Figure 5C (bottom), by selectively omitting images and conditions from the analysis

—Figure 6I (bottom left), by reporting data from the same data set as Figure 6B (top)

—Figure S5B, by reporting statistical significance despite performing a T test calculation that returned an insignificant p-value

—Figure 7F, by reporting that error bars represented standard deviation, when they actually represented standard error of the mean (SEM.)

—Figure S4D, by performing different normalizing calculations in the Rescue condition than performed in other conditions and by omitting three data points from the Rescue conditions calculated average

- In Paper 2, Respondent falsified and/or fabricated the research record in: