Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
ANDA 080472.	HYTONE	Hydrocortisone	1%, 2.5%	Cream; Topical	Valeant Pharmaceuticals North America, LLC.
ANDA 080473.	HYTONE	Hydrocortisone	1%; 2.5%	Lotion; Topical	Valeant Pharmaceuticals North America, LLC.
ANDA 080474.	HYTONE	Hydrocortisone	1%, 2.5%	Ointment; Topical	Dermik Laboratories, Inc.
NDA 202088.	SUPRENZA	Phentermine HCl	15 mg; 30 mg; 37.5 mg	Orally Disintegrating Tablet; Oral.	Citius Pharmaceuticals, LLC.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25187 Filed 11–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants have agreed to, or are required to, conduct is on the FDA's ''Postmarketing Requirements and Commitments: Reports'' web page (*https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Post-marketing PhaseIVCommitments/ucm064436.htm*).

FOR FURTHER INFORMATION CONTACT: Cathryn C. Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 301–796–0700; 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

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing study commitments that applicants have committed to, or are required to conduct, and for which annual status reports have been submitted.

Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drugs and licensed biologics are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval[1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2017 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application, and summarizes the status of PMRs/PMCs in fiscal year (FY) 2017 (*i.e.,* as of September 30, 2017). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) The number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports

[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

(ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year of establishment [2] (FY2011 to FY2017) for PMRs and PMCs open at the end of FY2017, or those closed within FY2017. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Post-marketing PhaseIVCommitments/default.htm.*

Dated: November 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25128 Filed 11–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

SUPPLEMENTARY INFORMATION: Section 100.2 of VICP's implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of HHS (the Secretary), is effective upon its delivery by the Secretary to the United States Court of Federal Claims (the Court), and will be published periodically in a notice in the **Federal Register**. This figure is calculated using the most recent Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation (KFF) Employer Health Benefits Survey or other authoritative source that may be more accurate or appropriate.

In 2018, MEPS–IC, available at *www.meps.ahrq.gov,* published the annual 2017 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was $6,368. This figure is divided by 12 months to determine the cost per month of $530.67. The $530.67 figure is increased or decreased by the percentage change reported by the most recent KFF Employer Health Benefits Survey, available at *www.kff.org.* The percentage increase from 2017 to 2018 was 3.0 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is $546.59.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is $546.59 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on November 13, 2018.

Dated: November 13, 2018.

George Sigounas,

Administrator.

[FR Doc. 2018–25087 Filed 11–16–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Meeting of the Advisory Committee on Infant Mortality

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Advisory Committee on Infant Mortality (ACIM) has scheduled a public meeting.

DATES: December 4, 2018, 9:00 a.m.–5:00 p.m. ET and December 5, 2018, 9:00 a.m.–3:30 p.m. ET.

ADDRESSES: This meeting will be held in-person and by webinar. The address for the meeting is 5600 Fishers Lane, Room 5W11, Rockville, Maryland 20857. Instructions on how to access the meeting via webcast will be provided upon registration.

Information about ACIM and the agenda for this meeting can be found on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.* While this meeting is open to the public, advance registration is required. Registration information and information about the ACIM can be obtained by accessing: *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: David S. de la Cruz, Ph.D., MPH, Designated Federal Official (DFO), at HRSA, Maternal and Child Health Bureau (MCHB), 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0543; or *dcruz@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIM provides advice and recommendations to the Secretary of HHS (Secretary) on HHS programs and activities that focus on reducing infant mortality and improving the health status of infants and pregnant women and factors affecting the continuum of care with respect to maternal and child health care. ACIM focuses on outcomes before, during, and following pregnancy and childbirth, strategies to coordinate a myriad of federal, state, local, and private programs, efforts that are designed to deal with the health and social problems impacting infant mortality, and the implementation of the federal Healthy Start Program.

The meeting agenda is being finalized and tentatively includes updates on HRSA, MCHB, and the Healthy Start Program, an introduction of members, a briefing on infant mortality and health disparity data in the U.S., and future topic areas for ACIM to discuss. Agenda items are subject to changes as priorities dictate. The final meeting agenda will be available 2 days prior to the meeting on the ACIM website: *https://www.hrsa.gov/advisory-committees/Infant-Mortality/index.html.* Refer to the ACIM website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments on the afternoon of December 5, 2018. Written comments must be submitted via email to the DFO, David S. de la Cruz, by 12:00 p.m. ET on Tuesday, November 20, 2018, at *dcruz@hrsa.gov.* Please indicate if your comments will be written only or if you are requesting to present your comments in person during the meeting. All comments (oral and written) will be part of the official meeting record. To ensure all individuals who have requested time for oral comments are accommodated, the allocated time for each comment will be limited to no more than 3 minutes. More complete/longer comments should be submitted in writing. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or -requested (PMC) postmarketing study or clinical trial.