

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 087191 .....	Triamcinolone Acetonide Lotion USP, 0.025% .....	Alpharma U.S. Pharms, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 087398 .....	Spironolactone and Hydrochlorothiazide Tablets USP, 25 mg/25 mg.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088229 .....	Thioridazine HCl Oral Solution USP, 100 mg/mL .....	Actavis Mid Atlantic, LLC, Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088563 .....	Thioridazine HCl Tablets USP, 50 mg .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088567 .....	Thioridazine HCl Tablets USP, 25 mg .....	Do.
ANDA 088733 .....	Meclizine HCl Tablets, 25 mg (Chewable) .....	Pliva, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088869 .....	Thioridazine HCl Tablets USP, 150 mg .....	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 090800 .....	Quinapril Tablets USP, EQ 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base.	Sun Pharmaceutical Industries, Ltd.
ANDA 091177 .....	Anastrozole Tablets, 1 mg .....	Do.
ANDA 091466 .....	Letrozole Tablets USP, 2.5 mg .....	Do.
ANDA 200486 .....	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, and 1 mg/0.035 mg.	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 200488 .....	Norethindrone and Ethinyl Estradiol Tablets USP, 0.5 mg/0.035 mg.	Do.
ANDA 200489 .....	Norethindrone and Ethinyl Estradiol Tablets USP, 1 mg/0.035 mg.	Do.
ANDA 201250 .....	Vancomycin HCl for Injection USP, EQ 5 g base/vial and EQ 10 g base/vial (Pharmacy Bulk Package).	Teva Pharmaceuticals USA, Inc.
ANDA 201251 .....	Vancomycin HCl for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial.	Do.
ANDA 201828 .....	Norgestrel and Ethinyl Estradiol Tablets USP, 0.3 mg/0.03 mg.	Mylan Laboratories, Ltd.
ANDA 202203 .....	Topotecan HCl for Injection, EQ 4 mg base/vial .....	Sun Pharmaceutical Industries, Ltd.
ANDA 202746 .....	Zoledronic Acid Injection, EQ 4 mg base/5 mL .....	Sun Pharma Global FZE, c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 202875 .....	Norgestrel and Ethinyl Estradiol Tablets USP, 0.5 mg/0.05 mg.	Mylan Laboratories, Ltd.
ANDA 203476 .....	Zolmitriptan Tablets, 2.5 mg and 5 mg .....	Sun Pharma Global FZE.
ANDA 203685 .....	Irbesartan Tablets USP, 75 mg, 150 mg, and 300 mg .....	Ajanta Pharma Ltd., c/o Ajanta Pharma USA, Inc., One Grande Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807.
ANDA 203838 .....	Hydrocodone Bitartrate, Chlorpheniramine Maleate, and Pseudoephedrine HCl Oral Solution, 5 mg/4 mg/60 mg per 5 mL.	Tris Pharma, Inc., 2033 Route 130, Monmouth Junction, NJ 08852.
ANDA 203839 .....	Hydrocodone Bitartrate and Pseudoephedrine HCl Oral Solution, 5 mg/60 mg per 5 mL.	Do.

Therefore, approval of the applications listed in table 1 of this document, and all amendments and supplements thereto, is hereby withdrawn as of January 2, 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 table 1 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 become violative, whichever occurs first.

Dated: November 27, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy..*

[FR Doc. 2017-25920 Filed 11-30-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Committee on Vital and Health Statistics: Teleconference

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting.

*Name:* National Committee on Vital and Health Statistics (NCVHS), Full Committee Meeting.

*Dates and Times:*

Tuesday, January 9, 2018: 9:00 a.m.–5:30 p.m. ET

Wednesday, January 10, 2018: 8:45 a.m.–3:00 p.m. ET

*Place:* U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW., Rm. 705A, Washington, DC 20201.

*Status:* Open.

*Purpose:* At the January 9–10, 2018 full meeting, the Committee will hear presentations, hold discussions on several health data policy topics and begin work on activities outlined in the NCVHS 2018 workplan. An environmental scan report will be reviewed and discussed by the full Committee as part of the Health Information Privacy and Security Beyond HIPAA project. This effort includes an exploration of challenges that extend beyond HIPAA and the range of policy options that may be available to the Department related to privacy, security and access measures to

protect individually identifiable health information in an environment of electronic networking and multiple uses of data. The Population Health Subcommittee will focus on Next Generation Vital Statistics in follow up to the hearing held September 11–12, 2017 and subsequent analyses conducted following the hearing. The purpose of the hearing was to assess the current state of the national vital statistics system (NVSS) to address concerns regarding sustainability and viability of the system infrastructure. Also addressed was the system's capacity to provide timely, high quality, secure vital administrative and statistical data for identity establishment and protection, identification of trends in disease and epidemics, *e.g.*, the recent surge in opioid-related deaths, and a host of critical uses for research, finance, planning, public records and services. The Committee will discuss concerns regarding decreased access to county and community-level data and potential plans to conduct work to address the issue. The Committee will also discuss the Predictability Roadmap as part of the Standards Subcommittee's project to identify possible approaches to improve the predictability and improvements in the adoption and processes related to updating standards and operating rules for electronic administrative transactions (*e.g.* claims, eligibility, electronic funds transfer); health terminology & vocabulary development, maintenance, and dissemination processes; and mapping out activities and timelines for the Committee's 2018 work.

The times and topics are subject to change. Please refer to the posted agenda for any updates.

**Contact Person for More Information:** Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS Web site: <http://www.ncvhs.hhs.gov/>, where further information including an agenda and instructions to access the audio broadcast of the meetings will also be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Dated: November 27, 2017.

**Laina Bush,**

*Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2017–25895 Filed 11–30–17; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Nominations to the Presidential Advisory Council on HIV/AIDS

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

**ACTION:** Notice.

**SUMMARY:** The Office of the Assistant Secretary for Health (OASH) is seeking nominations of qualified individuals to be considered for appointment as members of the Presidential Advisory Council on HIV/AIDS (PACHA). The PACHA is a federal advisory committee within the Department of Health and Human Services (HHS). Management support for the activities of this Council is the responsibility of the Office of HIV/AIDS and Infectious Disease Policy in the OASH. The qualified individuals will be nominated to the Secretary of Health and Human Services for consideration for appointment as members of the PACHA. Members of the Council, including the Chair, are appointed by the Secretary. Members are invited to serve on the Council for up to four-year terms. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

**DATES:** All nominations must be received no later than 5:00 p.m. (ET) on January 2, 2018 to the address listed below.

**ADDRESSES:** All nominations should be mailed or delivered to Ms. B. Kaye Hayes, Executive Director, PACHA, Department of Health and Human Services, Office of HIV/AIDS and Infectious Disease Policy, 330 C Street SW., Room L100B, Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Ms. Caroline Talev, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW., Room L106B, Washington, DC 20024; (202) 795–7622 or [Caroline.Talev@hhs.gov](mailto:Caroline.Talev@hhs.gov). More detailed information about PACHA can

be obtained by accessing the Council's page on the HIV.gov site at <https://www.hiv.gov/federal-response/pacha/about-pacha>.

**SUPPLEMENTARY INFORMATION:** PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996, and is currently operating under the authority given in Executive Order 13811, dated September 29, 2017. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House. Pursuant to advance written agreement, Council members shall receive no stipend for the advisory service they render as members of PACHA. However, as authorized by law and in accordance with federal travel regulations, PACHA members may receive per diem and reimbursement for travel expenses incurred in relation to performing duties for the Council.

This announcement is to solicit nominations of qualified candidates to fill vacancies on the PACHA.

**Nominations:** In accordance with the PACHA charter, persons nominated for appointment as members of the PACHA should be among prominent community leaders and authorities with particular expertise in, of knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. The following information should be included in the package of material submitted for each individual being nominated for consideration of appointment:

- Name, return address, and daytime telephone number and affiliation(s) of the individual being nominated, the basis for the individual's nomination, and a statement bearing an original signature of the nominated individual that, if appointed, he or she is willing to serve as a member of the Council;