

Application No.	Drug	Applicant
NDA 007883	Antabuse (disulfiram) Tablets, 250 milligrams (mg) and 500 mg.	Teva Women's Health, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.
NDA 011324	Sinografin (diatrizoate meglumine and iodipadme meglumine) Injection, 52.7%/26.8%.	Bracco Diagnostic Inc., 259 Prospect Plains Rd., Bldg. H, Monroe Township, NJ 08831.
NDA 018932	ReVia (naltrexone hydrochloride) Tablets, 50 mg	Teva Women's Health, Inc.
NDA 019880	Paraplatin (carboplatin) Injection, 50 mg/vial, 150 mg/vial, and 450 mg/vial.	Corden Pharma Latina S.p.A., c/o Clinipace, Inc., 4840 Pearl East Circle, Suite 201E, Boulder, CO 80301.
NDA 020261	Lescol (fluvastatin sodium) Capsules, 20 mg and 40 mg	Novartis Pharmaceuticals Corp., One Health Plaza, East Hanover, NJ 07936-1080.
NDA 020452	Paraplatin (carboplatin) Injection in multiple dose vials, 50 mg/5 milliliters (mL), 150 mg/15 mL, 450 mg/45 mL, and 600 mg/60 mL.	Corden Pharma Latina S.p.A.
NDA 021431	Campral (acamprosate calcium) Delayed-Release Tablets, 333 mg.	Allergan Sales, LLC., 5 Giralda Farms, Madison, NJ 07940.
NDA 021551	Halflytely and Bisacodyl Tablet Bowel Prep Kit (polyethylene glycol 3350, potassium chloride, sodium bicarbonate, and sodium chloride powder for oral solution, 210 grams (g)/0.74 g/2.86 g/5.6 g; bisacodyl delayed-release tablet, 5 mg).	Braintree Laboratories, Inc., 60 Columbian St. West, P.O. Box 850929, Braintree, MA 02185.
NDA 021823	Actonel with Calcium (risedronate sodium tablets, 35 mg; calcium carbonate tablets USP, equivalent to 500 mg base).	Warner Chilcott Co., LLC., 100 Enterprise Dr., Rockaway, NJ 07866.
NDA 021905	Valtropine (somatropin) for Injection, 5 mg/vial	LG Chem, Ltd., c/o Parexel International, LLC., 4600 East-West Highway, Suite 350, Bethesda, MD 20814.
NDA 022396	Dyloject (diclofenac sodium) Injection, 37.5 mg/mL	Javelin Pharmaceuticals, Inc., c/o Hospira, Inc., 275 North Field Dr., Dept. 0389, HI-3S, Lake Forest, IL 60045.
NDA 050619	Mycostatin (nystatin) Pastilles, 200,000 Units	Delcor Asset Corp., c/o Mylan, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504-4310.
NDA 050739	Omnicef (cefdinir) Capsules, 300 mg	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 050749	Omnicef (cefdinir) Oral Suspension, 125 mg/5 mL and 250 mg/5 mL.	Do.
NDA 050757	PrevPAC (amoxicillin capsules USP, 500 mg; clarithromycin tablets USP, 500 mg; and lansoprazole delayed-release capsules, 30 mg).	Takeda Pharmaceuticals U.S.A., Inc., One Takeda Parkway, Deerfield, IL 60015.
NDA 202356	Docetaxel Injection, 20 mg/2 mL, 80 mg/8 mL, 130 mg/13 mL, and 200 mg/20 mL.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 1, 2019. The drug product strengths listed in the table include all strengths FDA has identified as being previously approved under these NDAs. In each case, approval of the entire application is withdrawn, including any strengths inadvertently missing from the table. 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 May 1, 2019 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: March 26, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-06237 Filed 3-29-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Interdisciplinary, Community-Based Linkages

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

ACTION: Notice.

SUMMARY: The Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL or the Committee) has been rechartered. The effective date of the renewed charter is March 24, 2019.

FOR FURTHER INFORMATION CONTACT: Joan Weis, Ph.D., RN, CRNP, FAAN, Designated Federal Official, at 301-443-0430 or email at jweiss@hrsa.gov. A copy of the current committee membership, charter, and reports can be obtained at <https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html>.

SUPPLEMENTARY INFORMATION: ACICBL provides advice and recommendations on policy and program development to the Secretary of HHS (Secretary) concerning the activities under Title VII, Part D of the Public Health Service Act, and is responsible for submitting an annual report to the Secretary and Congress describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under Part D of Title VII. ACICBL develops, publishes, and implements performance measures and guidelines for longitudinal evaluations and recommends appropriation levels for programs under this part. The charter renewal for the ACICBL was approved on March 15, 2019 and the filing date is March 24, 2019. Renewal of the ACICBL charter gives authorization for the Committee to operate until March 24, 2021.

A copy of the ACICBL charter is available on the committee website at <https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html>. A copy of the charter can also be obtained by

accessing the Federal Advisory Committee Act (FACA) database that is maintained by the Committee Management Secretariat under the General Services Administration. The website for the FACA database is <http://www.facadatabase.gov/>.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-06162 Filed 3-29-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Training in Primary Care Medicine and Dentistry

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

ACTION: Notice.

SUMMARY: The Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD or the Committee) has been rechartered. The effective date of the renewed charter is March 24, 2019.

FOR FURTHER INFORMATION CONTACT:

Kennita R. Carter, MD, Designated Federal Official, at 301-945-3505 or email at BHWACTPCMD@hrsa.gov. A copy of the current committee membership, charter, and reports can be obtained by accessing the ACTPCMD's website at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html>.

SUPPLEMENTARY INFORMATION:

ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary and Chair and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. The Committee also develops,

publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C, of the PHS Act, and recommends appropriation levels for programs under this Part. Meetings are held not less than twice a year. The recharter for the ACTPCMD was approved on March 20, 2019, and the filing date is March 24, 2019. Recharter of the ACTPCMD gives authorization for the Committee to operate until March 24, 2021.

A copy of the ACTPCMD charter is available on the ACTPCMD website at <https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html>. A copy of the charter can also be obtained by accessing the Federal Advisory Committee Act (FACA) database that is maintained by the Committee Management Secretariat under the General Services Administration. The website for the FACA database is <http://www.facadatabase.gov/>.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-06161 Filed 3-29-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs: Stakeholder Listening Session in Preparation for the 72nd World Health Assembly

Time and date: Monday, May 6, 2019, 10:00 a.m.–11:30 a.m. EST.

Place: Hubert H. Humphrey Building, Auditorium, 200 Independence Ave. SW, Washington, District of Columbia 20201.

Status: Open, but requiring RSVP to OGA.RSVP@hhs.gov by Friday, April 26, 2019.

Purpose: The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 72nd World Health Assembly—will hold an informal Stakeholder Listening Session on *Monday, May 6 from 10:00 a.m. to 11:30 a.m.*, in the Hubert H. Humphrey Building Auditorium, 200 Independence Ave. SW, Washington, DC 20201. The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation for the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all individuals interested in and affected by agenda items to be discussed at the 72nd World Health Assembly.

Time allotted to each attendee who wishes to comment, not to exceed three minutes, will be communicated at the beginning of session, and will depend on the number of comments anticipated. Written comments are welcome and encouraged, even if you are planning on attending in person. Please send your written comments to OGA.RSVP@hhs.gov.

Your input will contribute to informing U.S. positions as we negotiate with our international colleagues at the World Health Assembly on these important health topics.

The draft agenda for the 72nd World Health Assembly can be found at this website: http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_1-en.pdf.

The HHS Office of Global Affairs will organize the listening session by agenda item, and welcomes participation from all individuals, including individuals familiar with the following topics and groups:

- Public health and advocacy activities;
- State, local, and Tribal issues;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

RSVP: Due to security restrictions for entry into the HHS Hubert H. Humphrey Building, RSVPs are required for this event. Please send your full name and organization to OGA.RSVP@hhs.gov. Please RSVP no later than Friday, April 26, 2019.

If you are *not* a U.S. citizen *and* do not have a U.S. government issued form of identification, please note this in the subject line of your RSVP, and our office will contact you to gain additional biographical information required for your clearance. Photo identification for all attendees is required for building access without exception.

We look forward to hearing your comments related to the 72nd World Health Assembly agenda items.

Dated: March 22, 2019.

Glenn Garrett Grigsby,

Director for Global Affairs.

[FR Doc. 2019-06207 Filed 3-29-19; 8:45 am]

BILLING CODE 4150-38-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 against