as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kimberly S. Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The NDA holders listed in table 1 have failed to submit the required annual reports and have not responded to the Agency's request for submission of the reports.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	NDA holder
NDA 014217	MAOLATE (chlorphenesin carbamate) Tablet, 400 milligrams (mg).	Pan American Laboratories, LLC, 4099 Highway 190, Covington, LA 70433.
NDA 018663	CHYMODIACTIN (chymopapain) for Injection, 4,000 Units/vial and 10,000 Units/vial.	Chart Medical, Inc., c/o Renascent Medical, Inc., 9600 Great Hills Trail, Suite 150 West, Austin, TX 78759.
NDA 020530	IONTOCAINE (epinephrine and lidocaine hydrochloride (HCl)) Topical Solution, 0.01 mg/milliliter; 2%.	Iomed, Inc., 2441 South 3850 West, Suite A, Salt Lake City, UT 84120–9941.
NDA 021504	LIDOSITE TOPICAL SYSTEM: LidoSite Patch (lidocaine HCl and epinephrine topical iontophoretic patch) 10%/0.1% and LidoSite Controller.	Vyteris, Inc., 13–01 Pollitt Dr., Fair Lawn, NJ 07410.

Therefore, notice is given to the NDA holders listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the applications and all amendments and supplements thereto on the grounds that the NDA holders have failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and 21 CFR part 314, the NDA holders are hereby provided an opportunity for a hearing to show why the approval of the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An NDA holder who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an NDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: November 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24921 Filed 11–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2649]

Advisory Committee; Nonprescription Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Nonprescription Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Nonprescription Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until August 27, 2021.

DATES: Authority for the Nonprescription Drugs Advisory Committee will expire on August 27, 2021, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *NDAC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3, FDA is announcing the renewal of the Nonprescription Drugs Advisory Committee (the Committee). The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

Pursuant to its charter, the Committee consists of a core of 10 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. Members are invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/nonprescription-drugs-advisory-committee/nonprescription-drugs-advisory-committee-charter* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check *https://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: November 12, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24917 Filed 11–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–xxxx—NEW

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than December 18, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *paperwork@hrsa.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ryan White HIV/AIDS Program Parts A and B Unobligated Balances and Rebate Addendum Tables, OMB No. 0906–xxxx—NEW.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, territories, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people diagnosed with HIV. Nearly two-thirds of RWHAP clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial and ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of HIV service providers who deliver high quality direct health care and support services to over half a million people diagnosed with HIV—more than 50 percent of all people diagnosed with HIV in the United States.

Grant recipients funded under Parts A, B, C, and D of the RWHAP (codified under Title XXVI of the Public Health Service Act) are required to report financial data to HRSA at the beginning (Allocations Report) and at the end of each grant budget period (Expenditures Report) using the HRSA Electronic Handbooks (EHBs).[i] HRSA RWHAP Parts A and B collect unobligated balances (UOB) of federal funds and rebate addendum information by subprogram from their grant recipients. Parts A and B use the UOB and rebate addendum financial information to determine formula funding as directed by the RWHAP statute. These data were collected when grant recipients submitted their annual Federal Financial Report (FFR SF–425) in hard copy only, and were submitted to the individual HHS Operating Divisions. HRSA added UOB and rebate addendum tables after the FFR SF–425, using a suggested format through the HRSA EHBs. This financial information is collected in the same location to

[i] The Allocations Report and the Expenditures Report were approved by OMB under the 0915–0318 control number.