Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Progesterone Injection, USP, 50 mg/mL, is the subject of NDA 017362, held by Actavis Laboratories UT, Inc., and initially approved on May 11, 1978. Progesterone Injection, USP, 50 mg/mL, is indicated in amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer. Progesterone Injection, USP, 50 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Daré Bioscience, Inc., submitted a citizen petition dated April 19, 2023 (Docket No. FDA–2023–P–1574), under 21 CFR 10.30, requesting that the Agency determine whether Progesterone Injection, USP, 50 mg/mL (NDA 017362), was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that Progesterone Injection, USP, 50 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Progesterone Injection, USP, 50 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Progesterone Injection, USP, 50 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list Progesterone Injection, USP, 50 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16228 Filed 7–31–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Office of Long COVID Research and Practice

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

ACTION: Notice.

SUMMARY: Statement of Organization, Functions, and Delegations of Authority Part A, Office of the Secretary, Statement of Organization, Function, and Delegation of Authority for the U.S. Department of Health and Human Services (HHS) is being amended at Chapter AC, Office of the Assistant Secretary for Health (OASH), as last amended June 1, 2022. This notice establishes the Office of Long COVID Research and Practice in OASH.

SUPPLEMENTARY INFORMATION: The April 5, 2022, Presidential Memorandum (at *https://www.whitehouse.gov/briefing-room/presidential-actions/2022/04/05/memorandum-on-addressing-the-long-term-effects-of-covid-19/*) on Addressing the Long-term Effects of COVID–19 charged the Secretary of the Department of Health and Human Services (the Secretary) with coordinating a government-wide response to the longer-term effects of COVID–19 and associated conditions. The Secretary in turn directed the Assistant Secretary for Health to serve as the Long COVID Coordinator. The Memorandum specified development and publication of two reports. The two reports were drafted under the leadership of OASH and with the input of 14 federal agencies and published on August 3, 2022. One of the reports, the National Research Action Plan on Long COVID (at *https://www.covid.gov/assets/files/National-Research-Action-Plan-on-Long-COVID-08012022.pdf*), called for the establishment of the Office of Long COVID Research and Practice (the ''Office,'' abbreviated as OLC) given the widespread effects of Long COVID. The Office will be charged with the implementation of the National Research Action Plan on Long COVID (*https://www.covid.gov/assets/files/National-Research-Action-Plan-on-Long-COVID-08012022.pdf*), promotion of the Services and Supports for Longer-Term Impacts of COVID–19 (*https://www.covid.gov/assets/files/Services-and-Supports-for-Longer-Term-Impacts-of-COVID-19-08012022.pdf*), and coordinating the whole-of-government response to the longer-term effects of COVID–19, including Long COVID and associated conditions. Currently 14 federal departments engage on Long COVID, including over a dozen HHS Operating and Staff Divisions. The coordination by the Office will strengthen current work and identify and fill needs in areas such as clinical guidance, partner engagement, public education and communications, and services and supports.

Specifically, the changes to Part A, Chapter AC are as follows:

A. Under Part A, Chapter AC, under Office of the Assistant Secretary for Health, add the following:

1. The Office of Long COVID Research and Practice (OLC) is headed by a Director, who reports to the Assistant Secretary for Health.

2. OLC will focus on

• Leading government-wide coordination of Long COVID strategy, planning, and activities to address the consequences of the COVID–19 pandemic, integrated into the HHS mission to improve health in disadvantaged communities and vulnerable populations across the nation.

• Supporting senior leadership at OASH and HHS on Long COVID.

• Developing implementation plans on Long COVID to drive strategy and communicate to the public.

• Establish, support, and manage a Federal Advisory Committee on Long COVID and associated conditions to facilitate perspectives from outside the government to inform federal actions.

• Providing expertise and support to federal agencies related to Long COVID deliverables and activities.

Xavier Becerra,

Secretary.

[FR Doc. 2023–16251 Filed 7–31–23; 8:45 am]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Proposed Purchased/Referred Care Delivery Area Redesignation for the Mid-Atlantic Tribes

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This Notice advises the public that the Indian Health Service (IHS) proposes to view the seven Mid-Atlantic Tribes in the Commonwealth of Virginia collectively and to expand the geographic boundaries of their current Purchased/Referred Care Delivery Areas (PRCDA). The seven Mid-Atlantic Tribes include the Pamunkey Indian Tribe, Chickahominy Indian Tribe, Chickahominy Indian Tribe—Eastern Division, Upper Mattaponi Tribe, Rappahannock Tribe, Monacan Indian Nation, and Nansemond Indian Tribe. The IHS previously designated a PRCDA for each of the seven Tribes, which include counties and/or independent cities in the Commonwealth of Virginia. The IHS is now proposing to expand those individual PRCDAs by creating a collective PRCDA for the seven Tribes. The collective PRCDA will include all of the counties and independent cities in each of the current PRCDAs, plus additional contiguous counties and independent cities in the Commonwealth of Virginia, the State of Maryland, and the State of North Carolina.

DATES: Comments must be submitted August 31, 2023.

ADDRESSES: In commenting, please refer to file code [**Federal Register** insert file code number]. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a Comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Carl Mitchell, Director, Division of Regulatory and Policy Coordination Indian Health Service, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, Maryland 20857.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the above address.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the address above.

If you intend to deliver your comments to the Rockville address, please call telephone number (301) 443–1116 in advance to schedule your arrival with a staff member.

SUPPLEMENTARY INFORMATION: The current PRCDAs for the seven Mid-Atlantic Tribes are:

Pamunkey Indian Tribe—Caroline, Hanover, Henrico, King William, King and Queen, and New Kent Counties; and the independent city of Richmond in the Commonwealth of Virginia.

Chickahominy Indian Tribe—New Kent, James City, Charles City, and Henrico Counties in the Commonwealth of Virginia.

Chickahominy Indian Tribe—Eastern Division—New Kent, James City, Charles City, and Henrico Counties in the Commonwealth of Virginia.

Upper Mattaponi Tribe—Richmond, Middlesex, Essex, King and Queen, King William, New Kent, Hanover, Caroline, Henrico, Charles City, and James City Counties; and the independent city of Richmond in the Commonwealth of Virginia.

Rappahannock Tribe, Inc.—King and Queen, Caroline, Essex, and King William Counties in the Commonwealth of Virginia.

Monacan Indian Nation—Amherst, Nelson, Albemarle, Buckingham, Appomattox, Campbell, Bedford, Botetourt, Rockbridge, and Augusta Counties; and the independent cities of Lynchburg, Lexington, Buena Vista, Staunton, Waynesboro, and Charlottesville in the Commonwealth of Virginia.

Nansemond Indian Tribe—the independent cities of Chesapeake, Hampton, Newport News, Norfolk, Portsmouth, Suffolk, and Virginia Beach in the Commonwealth of Virginia.

The IHS is proposing to create a collective PRCDA for the seven Mid-Atlantic Tribes that will include the following counties and independent cities:

Counties in the Commonwealth of Virginia: Accomack, Albemarle, Alleghany, Amelia, Amherst, Appomattox, Arlington, Augusta, Bath, Bedford, Botetourt, Buckingham, Campbell, Caroline, Charlotte, Chesterfield, Clarke, Cumberland, Culpeper, Dinwiddie, Essex, Fauquier, Floyd, Fluvanna, Gloucester, Greene, Greensville, Goochland, Hanover, Henrico, Isle of Wight, James City, King and Queen, King George, King William, Lancaster, Loudoun, Louisa, Lunenburg, Mathews, Mecklenburg, Middlesex, Montgomery, Nelson, New Kent, Newport News, Norfolk, Nottoway, Orange, Page, Patrick, Pittsylvania, Powhatan, Prince Edward, Prince George, Prince William, Pulaski, Richmond, Rockbridge, Rockingham, Southampton, Spotsylvania, Stafford, Warren, Westmoreland, and York.

Independent Cities in the Commonwealth of Virginia: Alexandria, Buena Vista, Charlottesville, Chesapeake, Colonial Heights, Covington, Emporia, Fairfax, Falls Church, Franklin, Fredericksburg, Hampton, Harrisonburg, Hopewell, Lexington, Lynchburg, Manassas, Manassas Park, Newport News, Norfolk, Petersburg, Poquoson, Portsmouth, Radford, Richmond, Roanoke, Salem, Staunton, Suffolk, Virginia Beach, Waynesboro, and Williamsburg.

Counties in the State of Maryland: Allegany, Anne Arundel, Baltimore, Calvert, Carroll, Cecil, Charles, Frederick, Harford, Howard, Kent, Montgomery, Prince George's, Queen Anne's, St. Mary's, and Washington.

Independent Cities in the State of Maryland: Baltimore City.

Counties in the State of North Carolina: Alexander, Camden, Catawba, Chowan, Currituck, Davidson, Davie, Durham, Forsyth, Franklin, Gates, Granville, Guilford, Johnston, Orange, Pasquotank, Randolph, Rowan, Stanly, Stokes, and Wake.