information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Survey of Retail Prices; *Use:* This information collection request provides for a survey of the average acquisition costs of all covered outpatient drugs purchased by retail community pharmacies. CMS may contract with a vendor to conduct monthly surveys of retail prices for covered outpatient drugs. Such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The contractor shall provide notification when a drug product becomes generally available and that the contract includes such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. CMS has developed a National Average Drug Acquisition Cost (NADAC) for states to consider when developing reimbursement methodology. The NADAC is a pricing benchmark that is based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark is based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey is conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date. *Form Number:* CMS–10241 (OMB control number 0938–1041); *Frequency:* Monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 72,000; *Total Annual Responses: 72,000; Total Annual Hours:* 36,000. (For policy questions regarding this collection contact: Robert Giles at 667–290–8626.)

Dated: July 27, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–16281 Filed 7–31–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare and Medicaid Services, Center for Medicare and Medicaid Innovation (CMMI), has modified its organizational structure.

DATES: These new organizational structures were approved by the Secretary of Health and Human Services and took effect on July 27, 2023.

FOR FURTHER INFORMATION CONTACT: Joe Kane at (410) 786–0655; 7500 Security Blvd., Baltimore, MD.

SUPPLEMENTARY INFORMATION: Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) (last amended at **Federal Register**, Vol. 88, No. 107, pp. 36586–36587, dated June 5, 2023) is further amended to reflect the establishment of the Division of Drug Innovation within the Center for Medicare and Medicaid Innovation (CMMI). Part F, Section FC. 10 (Organization) is revised as follows:

Center for Medicare and Medicaid Innovation (CMMI), Seamless Care Models Group, Seamless Care Models Group, Division of Health Plan Innovations

Part F, Section FC. 20 (Functions) for the new organization is as follows:

Centers for Medicare & Medicaid Services

Office of the Administrator

Center for Medicare and Medicaid Innovation

Seamless Care Models Group

Division of Drug Innovation

- Directs, designs and implements models to test alternative approaches to payment for drugs in Medicare Part B, Part D, and Medicaid to optimize access to high quality, affordable drugs.
- Seeks and develop opportunities to include Part B and Part D drugs in alternative payment models, including accountable care models, and addresses regulatory and operational issues that arise when trying to develop a model crossing different parts of the Medicare program.
- Builds relationships within CMS and HHS, with States and Medicaid agencies, and with both governmental and non-governmental entities to develop, implement, and operate innovative Medicare Part B, Part D, and Medicaid models.
- Meets with model participants and other interested parties, including relevant Government officials, representatives from the pharmaceutical industry, payers, providers, academia, and consumer advocates regarding their perspectives on innovative models, research, and ideas for new models.
- Conducts formative research studies to inform innovative payment models.
- Provides technical expertise to various CMS and non-Governmental entities on innovative Medicare Part B, Part D, and Medicaid payment and service delivery models to optimize access to affordable drugs.

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–16280 Filed 7–31–23; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–1574]

Determination That Progesterone Injection, USP, 50 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Progesterone Injection, USP, 50 milligrams/milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Iris Masucci, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–3600, *Iris.Masucci@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and

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.