CMS has contracted with an outside vendor to assist in the administration of the RDS program; this effort is called the RDS Center. Plan Sponsors will apply on-line for the retiree drug subsidy by logging on to the RDS Secure website. 42 CFR 423.844 describes the requirement for qualified retiree prescription drug plans who want to receive the retiree drug subsidy. Once the Plan Sponsor submits the RDS application via the RDS Secure website (and a valid initial retiree list) CMS, using its contractor, will analyze the application to determine whether the Plan Sponsor qualifies for the RDS. To qualify for the subsidy, the Plan Sponsor must show that its coverage is as generous as, or more generous than, the defined standard coverage under the Medicare Part D prescription drug benefit. The information within the application includes sponsor account registration information, plan information, benefit options under the plan, actuary information and actuarial attestation. The RDS center has various checks within each section of the application. Applications can be denied if issues cannot be resolved. *Form Number:* CMS–10170 (OMB control number: 0938–0977); *Frequency:* Yearly; *Affected Public:* Private Sector; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 1,245; *Number of Responses:* 1,245; *Total Annual Hours:* 79,680. (For questions regarding this collection, contact Ivan Iveljic at 410–786–3312 or *Ivan.iveljic@cms.hhs.gov*.)

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2024–21631 Filed 9–20–24; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–2219]**

### Progynon Associates, et al.; Withdrawal of Approval of Four New Drug Applications

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of four new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for the identified NDAs.

**DATES:** Approval is withdrawn as of September 23, 2024.

**FOR FURTHER INFORMATION CONTACT:** Kimberly 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, *Kimberly.Lehrfeld@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of May 28, 2024 (89 FR 46139), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of four NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of those NDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their NDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the four applications listed in table 1 of this document.

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

| Application No. | Drug | Holder |
|---|---|---|
| NDA 004652 ..... | ORETON (testosterone) Pellets for Subcutaneous Implantations, 75 milligrams (mg). | Progynon Associates, 9300 Wilshire Blvd., Beverly Hills, CA 90212. |
| NDA 013268 ..... | WINSTEROID (stanozolol) Tablets, 2 mg ..... | Sterling Winthrop Inc., 90 Park Ave., New York, NY 10016. |
| NDA 017455 ..... | Copper T Model TCu 200B (copper) Intrauterine Device ..... | Duramed Research, Inc., 425 Privet Rd., Horsham, PA 19044. |
| NDA 205003 ..... | PRESTALIA (amlodipine besylate/perindopril arginine) Tablets, equivalent to (EQ) 2.5 mg base/3.5mg, EQ 5 mg base/7 mg, and EQ 10 mg base/14 mg. | Adhera Therapeutics, Inc., 224 Holding Ave., Wake Forest, NC 27588. |

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto are hereby withdrawn as of September 23, 2024.

Dated: September 16, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–21680 Filed 9–20–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2024–N–3112]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Experience Reporting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public