FEE SCHEDULE FOR EACH VESSEL SIZE—Continued

Vessel size (GT [1])	Operational inspection [2] fee (US$)	Construction and renovation inspection [3] fee (US$)
Tier 4 (>180,001 GT)	64,584	129,168

[1] Gross tonnage in cubic feet, as shown in *Lloyd's Register of Shipping* (*https://www.lr.org/en/*).
[2] Operations inspections and re-inspections involve the same procedures and require the same amount of time, so they are charged at the same rates.
[3] Construction and renovation inspections require at least twice the amount of time as operations inspections, so they are charged double the rates.

[FR Doc. 2024–21786 Filed 9–20–24; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10170 and CMS–10156]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by October 23, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of 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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy Payment Request and Instructions; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR part 423 subpart R plan sponsors (*e.g.,* employers, unions) who offer prescription drug coverage meeting specified criteria to their qualified covered retirees are eligible to receive a 28% subsidy for allowable drug costs, through the Retiree Drug Subsidy (RDS) Program. Section 423.886 describes the payment methods, including the provision of necessary information. The information provided in the payment request provides CMS with the information needed to pay RDS sponsors the subsidy.

The application process for the RDS is a completely electronic process (100%). The basis for the decision for adopting this means of collection was to maximize efficiency. The only instance when hard copy/paper applications can be submitted is when the RDS Center is experiencing technical difficulties. The Plan Sponsor completes and submits the RDS application (including the Plan Sponsor's Authorized Representative's electronic signature) on-line, via the secure RDS Secure website, which is accessed at *https://www.rds.cms.hhs.gov. Form Number:* CMS–10170 (OMB control number: 0938–0977); *Frequency:* Yearly; *Affected Public:* Private; Business or other for-profits, and Not-for Profits; *Number of Respondents:* 1,245; *Number of Responses:* 1,245; *Total Annual Hours:* 187,995. (For questions regarding this collection, contact Ivan Iveljic at 410–786–3312 or *Ivan.iveljic@cms.hhs.gov.*)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy (RDS) Application and Instructions ; *Use:* Under § 1860D–22 of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR part 423 subpart R, Plan Sponsors (*e.g.,* employers or unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% subsidy for allowable drug costs.

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