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DATES: Approval is withdrawn as of September 23, 2024.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

comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on postmarketing reporting and recordkeeping of adverse experiences for drug and biological products.

DATES: Either electronic or written comments on the collection of information must be submitted by November 22, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 22, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3112 for ''Postmarketing Adverse Experience Reporting.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Postmarketing Adverse Experience Reporting

OMB Control Number 0910–0230—Revision

This information collection helps support provisions found in sections 201, 502, 505, 701, and 760 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 352, 355, 371, and 379aa) governing adverse experience reporting (AER) and associated recordkeeping for FDA-regulated drug products. FDA has

promulgated applicable regulations in part 4 and §§ 310.305, 314.80, 314.81, 314.98, and 329.100 (21 CFR part 4 and 21 CFR 310.305, 314.80, 314.81, 314.98, and 329.100) that implement the statutory requirements, identify specific content and format elements, and establish reporting and retention schedules for the required information. Postmarketing safety data collection and adverse event reporting are critical elements of FDA's monitoring of drugs. For more information, please visit *https://www.fda.gov/drugs/surveillance/postmarketing-adverse-event-reporting-compliance-program.*

Respondents to the information collection are manufacturers, packers, distributors, and applicants of FDA-regulated drug and biologic products marketed with or without an FDA-approved application, including over-the-counter (OTC) drug products marketed without an approved application; OTC drug products marketed under the OTC Drug Monograph Review process (whether subject to a final monograph or not); and drug products marketed outside the monograph system. All reports and followup reports must be submitted to FDA in electronic format, although waivers of the electronic requirements are available for good cause.

Adverse experience reporting for products associated with drug marketing applications are governed by regulations in §§ 314.80, 314.81, and 314.98. The regulations identify required reporting content and format elements, as well as establish followup reporting requirements and mandatory reporting schedules. The regulations also establish associated recordkeeping and require that written procedures be developed for the surveillance, receipt, evaluation, and reporting of postmarketing adverse experiences to FDA. The regulations require reporting in an electronic format that FDA can process, although temporary waivers may be granted on a limited basis for good cause. A final guidance for industry entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports'' (April 2022) is available for general information pertaining to electronic submission of postmarketing safety reports for certain human drugs, biological products, and combination products. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports.*

We have established and maintain the FDA Adverse Event Reporting System (FAERS) at *https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions.* Information may be submitted via FDA's Electronic Submissions Gateway or utilizing the ''Safety Reporting Portal,'' developed by FDA and the National Institutes of Health to streamline reporting and review of adverse events.

The primary purpose of FDA's adverse drug experience reporting system is to enable identification of signals for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed product provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, clinical investigators, and literature. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning), to make decisions about risk evaluation and mitigation strategies; the need for postmarketing studies or clinical trials; and, when necessary, to initiate removal of a product from the market.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2] [3]

21 CFR section or guidance; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5); AERs for prescription products not the subject of a marketing application	36	88.8	3,197	1	3,197
314.80(c)(1); 15-day alerts for approved products	682	1,832.84	1,250,000	1	1,250,000
314.80(c)(2); periodic reports for approved products	682	1,228.73	838,000	60	50,280,000
329.100; AERs for non-prescription drug products	312	62.522	19,507	6	117,042
ICH E2C(R2) Guidance; Periodic safety updates; Applicants w/waiver for an approved application (section III.A.)	471	8.885	4,185	1	4,185
ICH E2C(R2) Guidance; Periodic safety updates; Applicants w/no waiver for an approved application (section III.B.)	1,115	16.254	18,123	2	36,246
AER During Pandemic Guidance; notifying FDA when normal reporting is not feasible (section III.C.)	1	1	1	8	8
4.103, 4.104, 4.105, 310.305, 314.80, 314.98, 329.100(c); Waiver requests from electronic reporting requirements	1	1	1	24	24
Total	[4] 2,618		2,133,014		51,690,702

[1] There are no capital costs associated with this collection. The operating and maintenance costs associated with this collection of information are approximately $25,000 annually.

[2] The reporting burdens for § 310.305(c)(1), (2), and (3), and voluntary reports by healthcare providers received under § 314.80(c)(1)(i) and (ii) are covered under OMB control number 0910–0291.

[3] Totals may not sum due to rounding.

[4] Total of unique respondents.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section or guidance section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305; AER records—prescription product not the subject of a marketing application.	36	88.8	3,197	16	51,152
314.80(j); AER records—product associated w/marketing application	841	1,814.0606	1,525,625	16	24,410,000

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]—Continued

21 CFR section or guidance section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Postmarket AER for Nonprescription Drug Products Guidance; (§ 329.100).	312	62.5224	19,507	8	156,056
AERs During Pandemic Guidance; Continuity of operations planning (section III.B.).	100	1	100	50	5,000
AERs During Pandemic Guidance; documenting conditions and resultant high absenteeism (section III.C.2).	350	1	350	8	2,800
AERs During Pandemic Guidance; documenting AER process (section III.C.1.).	350	1	350	8	2,800
4.105; Postmarketing safety recordkeeping for combination products and constituent parts.	11	18	198	0.1 (6 minutes)	19.8
Total	[3] 1,650		1,549,327		24,627,827.8

[1] There are no capital costs associated with this collection of information. There are operating and maintenance costs associated with this collection of information of approximately $22,000 annually.
[2] Totals may not sum due to rounding.
[3] Total of unique respondents.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.103; Postmarketing Safety reporting for Combination products—Sharing information with other constituent part applicants.	11	18	198	0.35 (21 minutes)	69.3

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

All applicants who have received marketing approval for drug products (including combination products that are administered as drug products) are required to report serious, unexpected adverse drug experiences (15-day ''Alert reports'') (§ 314.80(c)(1)(i)), as well as followup reports (§ 314.80(c)(1)(ii)) to FDA. These include all foreign or domestic AERs as well as AERs based on information from applicable scientific literature and certain reports from post marketing studies. Section 314.80(c)(1)(iii) pertains to AERs submitted by nonapplicants. For operational efficiency, we have adjusted this information collection and burden table to include all 15-day alert reports submitted by applicants, manufacturers, packers, and distributors. Voluntary reports from healthcare providers are included under OMB control number 0910–0291.

Under § 314.80(c)(2), applicants (including combination products that are administered as drug products) must also provide periodic reports of adverse drug experiences. For the reporting interval, a periodic report includes reports of serious, expected adverse drug experiences, all nonserious adverse drug experiences, and an index of these reports; a narrative summary and analysis of adverse drug experiences; an analysis of the 15-day Alert reports submitted during the reporting interval; and a history of actions taken because of adverse drug experiences. Under § 314.80(j), applicants must keep records of all adverse drug experience reports known to the applicant for 10 years.

For marketed prescription drug products without approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs), manufacturers, packers, and distributors of these products are required to report to FDA serious, unexpected adverse drug experiences as well as followup reports (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded to the manufacturers, packers, and distributors by FDA. Under § 310.305(g), each manufacturer, packer, and distributor shall maintain records of all adverse drug experiences required to be reported for 10 years. All 15-day Alert reports and followup reports must be submitted to FDA in electronic format.

Section 760 of the FD&C Act also provides for mandatory safety reporting for over-the-counter human drug products not subject to applications approved under section 505 of the FD&C Act (NDAs or ANDAs). These requirements apply to all OTC drug products marketed without an approved application, including those marketed under the OTC Drug Monograph Review process (whether or not subject to a final monograph), those marketed outside the monograph system, and including those that have been discontinued from marketing but for which a report of an adverse event was received. Under § 329.100, respondents must submit reports according to section 760 of the FD&C Act in an electronic format.

To assist respondents with implementation of section 760 of the FD&C Act, FDA developed the guidance for industry entitled ''Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application,'' (July, 2009) available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-nonprescription-human-drug-products-marketed-without-approved.* The guidance document discusses what should be included in a serious adverse drug event report submitted under section 760(b)(1) of the FD&C Act, including how to submit these reports and followup reports under section 760(c)(2) of the FD&C Act. Section 760(e) of the FD&C Act also requires that responsible persons maintain records of nonprescription drug adverse event reports, whether the event is serious or not, for a period of 6 years. FDA's guidance recommends that respondents maintain records of efforts to obtain the minimum data elements for a report of a serious adverse drug event and any followup reports.

In addition, this information collection includes an International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance for industry entitled ''Providing Postmarketing Periodic Safety Reports in the ICH

E2C(R2) Format (Periodic Benefit-Risk Evaluation Report), (November 2016)'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-postmarket-periodic-safety-reports-ich-e2cr2-format-periodic-benefit-risk-evaluation.* The ICH E2C(R2) guidance describes the conditions under which applicants may use the ICH E2C(R2) Periodic Benefit-Risk Evaluation Report format for certain types of adverse event reporting.

FDA regulations in §§ 314.80(c)(2) and 600.80(c)(2) require applicants to submit postmarketing periodic safety reports for each approved application. The reports must be submitted quarterly for the first 3 years following the U.S. approval date and annually thereafter and must contain the information described in §§ 314.80(c)(2)(ii) and 600.80(c)(2)(ii) (the information collection associated with 21 CFR part 600—Biological Products, is approved under OMB control number 0910–0308). The Agency guidance assists respondents with satisfying the regulatory requirements in an alternative format, noting that the process differs depending on whether an applicable periodic safety update report waiver is in place.

Similarly, this information collection accounts for burden that may be applicable to the guidance document, ''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (May 2020),'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-adverse-event-reporting-medical-products-and-dietary-supplements-during-pandemic.* In response to the Coronavirus Disease 2019 public health emergency, we revised the Agency guidance document to provide recommendations for recordkeeping applicable to any pandemic, not just influenza, including recommendations for planning, notification, and documentation for continuity of operations for firms that report postmarketing adverse events during any pandemic.

For operational efficiency, on March 20, 2023, OMB approved the addition of burden attributable to provisions related to postmarketing safety reporting for combination products as outlined in part 4, subpart B, and previously included in OMB control number 0910–0834. When information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of a combination product that includes a drug product, is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt under § 4.103 (21 CFR 4.103). Relatedly, 21 CFR 4.104 explains how and where to submit reports for combination products, and 21 CFR 4.105 provides for associated recordkeeping. For combination products that are administered as drug products with a constituent part, adverse event reports are submitted to the drug application under 21 CFR part 314, and constituent applicants are notified of the AER under § 4.103. These provisions are also described in the guidance document ''Postmarketing Safety Reporting for Combination Products'' (July 2019), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-safety-reporting-combination-products.*

Our estimates of the number of respondents and the total annual responses are based on reports submitted to the Agency. This information collection incorporates revisions to include the two guidances for industry regarding submission of adverse event reports (''Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic'' and ''Providing Submissions in Electronic Format—Postmarketing Safety Reports'') and adjustments to include 15-day alert reports from applicants, manufacturers, distributors, and packers that were not recorded previously in this information collection. We also believe adjustments in the information collection reflect anticipated fluctuations in burden after pandemic conditions, adjustments by reporters' and changes in electronic reporting methodologies use of updated technology including updates and redefinitions of reporting software, and changes of company business practices over time. All reports and followup reports must be submitted to FDA in electronic format. Waivers of the electronic requirements are available. As a result of these revisions and adjustments, including the additional reports, the inclusion of guidance document recommendations and the consolidation of the burden from OMB control number 0910–0834 (previously added to this information collection March 2023), the total burden hours of the information collection have increased by 61,615,010.1 hours and 2,546,310 responses as compared to the previous renewal. We invite comment on our assumptions.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21675 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–N–2030 and FDA–2024–N–0972]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.