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.

Therefore, notice is given to the holders of the approved NDAs listed in table 1 and to all other interested persons that the Director of CDER proposes to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of the NDAs and all amendments and supplements thereto on the grounds that the NDA holders have failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the NDA holders are hereby provided an opportunity for a hearing to show why the approval of the NDAs listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these NDAs.

An NDA holder who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an NDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that NDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the NDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the NDAs, and the drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: May 17, 2024.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Implement Maternal, Infant, and Early Childhood Home Visiting Program 2022 Legislative Changes: Assessment of Administrative Burden

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than June 27, 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 Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Implement Maternal, Infant, and Early Childhood Home Visiting Program 2022 Legislative Changes: Assessment of Administrative Burden

OMB No. 0915-xxxx—[NEW]

Abstract: The Consolidated Appropriations Act, 2023, Public Law 117–328, section 6101, the Jackie Walorski Maternal and Child Home Visiting Reauthorization Act of 2022 (Section 6101 of the Consolidated Appropriations Act, 2023) extended funding for the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program for an additional 5 years and adopted new program requirements. This included a new requirement for the Secretary of Health and Human Services to assess and reduce burden on MIECHV funding recipients in administering the program by: (1) eliminating duplication and streamlining reporting requirements; (2) analyzing ways, in consultation with administering agencies (*i.e.,* MIECHV funding recipients) to reduce the number of hours spent on complying with paperwork requirements by at least 15 percent; (3) reviewing paperwork and data collection requirements for tribal MIECHV funding recipients and exploring, in consultation with tribes and tribal organizations, ways to reduce administrative burden, respect sovereignty, and acknowledge the different focus points for tribal funding recipients; (4) collecting input from relevant state fiscal officials to align fiscal requirements and oversight for states and eligible entities to ensure consistency with standards and guidelines for other federal formula grant programs; and (5) consulting with administering agencies and service delivery model representatives on needed and unneeded data elements regarding the dashboards provided for in newly added Social Security Act subsection 511(d)(1)(B), consistent with the data requirements of such subsection.

Through this ICR, HRSA aims to survey state, jurisdiction, and tribal MIECHV funding recipients to obtain feedback regarding potential ways to reduce administrative burden, as described above.

A 60-day notice was published in the **Federal Register** on December 20, 2023, vol. 88, No. 243; pp. 88084–88085. HRSA received four comments and the information collection tools have been revised in response. These changes addressed concerns with the burden estimate and to modify items for clarity and increase the burden estimates for respondents to more accurately reflect the time it will reasonably take respondents to respond to this information collection. HRSA also considered additional feedback from certain home visiting model developers and is removing from this ICR the proposed plan to survey home visiting model developers.

Need and Proposed Use of the Information: Section 511(h)(6)(A) of the Social Security Act requires the Secretary of Health and Human Services to assess and reduce administrative burden on MIECHV funding recipients in specified ways. Information gained from this information collection will inform recommendations to reduce administrative burden.

Likely Respondents: State and jurisdiction MIECHV Program funding recipients that are states, territories, and, where applicable, nonprofit organizations receiving MIECHV funding to provide home visiting services within states; and tribal MIECHV Program funding recipients that are tribes and tribal organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
State and Jurisdiction MIECHV Funding Recipient Survey	56	1	56	27	1,512
Tribal MIECHV Funding Recipient Survey	29	1	29	4	116
Total	85		85		1,628

Maria G. Button,

Director, Executive Secretariat.

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