Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA is required to report annually on the status of postmarketing requirements (PMRs) and postmarketing commitments (PMCs) required of, or agreed upon by, application holders of approved drug and biological products. The report on the status of the studies and clinical trials that applicants are required to, or have agreed to, conduct is on the FDA's website entitled ''Postmarketing Requirements and Commitments: Reports'' (*https://www.fda.gov/drugs/postmarketing-requirements-and-commitments-introduction/postmarketing-requirements-and-commitments-reports*).

FOR FURTHER INFORMATION CONTACT: Lauren Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6300, Silver Spring, MD 20993–0002, 301–796–0700; or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7217, Silver Spring, MD 20993–0002, 240–402–0467.

SUPPLEMENTARY INFORMATION:

I. Background

Section 506B(c) of the FD&C Act (21 U.S.C. 356b(c)) requires FDA to publish an annual report on the status of postmarketing studies that applicants are required to, or have committed to, conduct and for which annual status reports have been submitted. Under §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70), applicants of approved drug products and licensed biological products are required to submit annually a report on the status of each clinical safety, clinical efficacy, clinical pharmacology, and nonclinical toxicology study or clinical trial either required by FDA (PMRs) or that they have committed to conduct (PMCs), either at the time of approval or after approval of their new drug application, abbreviated new drug application, or biologics license application, as applicable. The status of PMCs concerning chemistry, manufacturing, and production controls and the status of other studies or clinical trials conducted on an applicant's own initiative are not required to be reported under §§ 314.81(b)(2)(vii) and 601.70 and are not addressed in this report. Furthermore, section 505(o)(3)(E) of the FD&C Act (21 U.S.C. 355(o)(3)(E)) requires that applicants report periodically on the status of each required study or clinical trial and each study or clinical trial ''otherwise undertaken . . . to investigate a safety issue . . .''

An applicant must report on the progress of the PMR/PMC on the anniversary of the drug product's approval [1] until the PMR/PMC is completed or terminated and FDA determines that the PMR/PMC has been fulfilled or that the PMR/PMC is either no longer feasible or would no longer provide useful information.

II. Fiscal Year 2024 Report

With this notice, FDA is announcing the availability of the Agency's annual report entitled ''Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments.'' Information in this report covers any PMR/PMC that was established, in writing, at the time of approval or after approval of an application or a supplement to an application and summarizes the status of PMRs/PMCs in fiscal year 2024 (*i.e.,* as of September 30, 2024). Information summarized in the report reflects combined data from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and includes the following: (1) the number of applicants with open PMRs/PMCs; (2) the number of open PMRs/PMCs; (3) the timeliness of applicant submission of the annual status reports (ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year (FY) of establishment [2] (FY2018 to FY2024) for PMRs and PMCs open at the end of FY2024, or those closed within FY2024. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarketing-requirements-and-commitments-introduction.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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[1] An applicant must submit an annual status report on the progress of each open PMR/PMC within 60 days of the anniversary date of U.S. approval of the original application or on an alternate reporting date that was granted by FDA in writing. Some applicants have requested and been granted by FDA alternate annual reporting dates to facilitate harmonized reporting across multiple applications.

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or requested (PMC) postmarketing study or clinical trial.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–2026–N–3445]

Egis Pharmaceuticals Limited, et al.; Withdrawal of Approval of Three Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of three abbreviated new drug applications (ANDAs) from the holders of those ANDAs. The basis for the withdrawal is that the ANDA holders have repeatedly failed to file required annual reports for those ANDAs.

DATES: Approval is withdrawn as of April 24, 2026.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@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 and 314.98 (21 CFR 314.81 and 314.98).

In the **Federal Register** of December 29, 2025 (90 FR 60724), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of three ANDAs because the holders of these ANDAs had repeatedly failed to submit the required annual reports for these ANDAs. The holders of these ANDAs 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 a waiver of the opportunity for hearing by the holders of the ANDAs concerning the proposal to withdraw approval of the ANDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval

of the three applications listed in Table 1 of this document.

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

Application No.	Drug	Applicant
ANDA 060453	Bacitracin-neomycin sulfate-polymyxin B sulfate ointment with diperodon hydrochloride.	Ambix Laboratories, 55 West End Rd., Totowa, NJ 07512.
ANDA 074748	Captopril tablet, 12.5 milligrams (mg), 25 mg, 50 mg, and 100 mg.	Egis Pharmaceuticals Ltd., 1475 Budapest 10 Pf. 100 Hungary.
ANDA 074808	Piroxicam capsule, 10 mg and 20 mg	Do.

FDA finds that the holders of the ANDAs listed in Table 1 have repeatedly failed to submit reports required by §§ 314.81 and 314.98. In addition, under § 314.200, FDA finds that the holders of the ANDAs have waived the opportunity for a hearing and any contentions concerning the legal status of the drug products. Therefore, based on these findings and pursuant to the authority under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), approval of the ANDAs listed in Table 1 and all amendments and supplements thereto, is hereby withdrawn as of April 24, 2026.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–08020 Filed 4–23–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Data Collection Tool for State Offices of Rural Health Program, OMB No. 0915–0322—Revision

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 May 26, 2026.

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 Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Data Collection Tool for State Offices of Rural Health Program, OMB No. 0915–0322—Revision.

Abstract: HRSA is requesting OMB approval to continue use of a Technical Assistance (TA) Data Form (Technical Assistance Report) for the State Offices of Rural Health (SORH) program established by section 338J of the Public Health Service Act (42 U.S.C. 254r). In its authorizing language (sec. 711 of the Social Security Act [42 U.S.C. 912]), Congress charged HRSA's Federal Office of Rural Health Policy with administering grants, cooperative agreements, and contracts to provide TA and other activities as necessary to support activities related to improving health care in rural areas. The mission of FORHP is to sustain and improve access to quality health care services for rural communities. This electronic form is used to collect information from SORH grantees on the amount of direct TA they provide to clients within their state.

A 60-day notice published in the **Federal Register** on January 29, 2026, vol. 91, No. 19; pp. 3897–3898. There were no public comments.

Need and Proposed Use of the Information: FORHP seeks to continue gathering information from grantees on their efforts to provide TA to clients within their states. SORH grantees submit a TA Report that includes: (1) the total number of TA encounters provided directly by the grantee; and, (2) the total number of unduplicated clients that received direct TA from the grantee. These measures will continue in these three categories: (1) information disseminated, (2) information created, and (3) collaborative efforts by (a) topic area and (b) type of audience.

After the 60-day FRN comment period, FORHP made minor revisions to the form to align with administration priorities. FORHP proposes the following minor revisions: removal of ''*Type of audience collaborated with*'' section, an edit to response categories under ''*Topic area collaborations*'' section, and adding two responses under the ''*Types of Clients that Received TA*'' to capture the number of new and returning organizations receiving TA during the reporting period. These measures are used to obtain an accurate depiction of the breadth of SORH work, based on recommendations from the grantees.

Submission of the TA Report is submitted via FORHP's Data Collection Platform no later than 60 days after the end of each 12-month budget period. Grant dollars are awarded annually; therefore, this information is needed annually by the program in order to measure effective use of grant dollars consistently among all the grantees.

Likely Respondents: Fifty SORH award recipients.

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