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.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CMS HCPCS Modification to Code Set Form; *Use:* The Healthcare Common Procedure Coding System (HCPCS) Level II code set is one of the standard code sets used for this purpose. The HCPCS Level II code set, also referred to as alpha-numeric codes, is a standardized coding system that is used primarily to identify items, supplies, and services not included in the HCPCS Level I Current Procedural Terminology (CPT®) codes, such as ambulatory services and durable medical equipment, prosthetics, orthotics, and supplies when used in the home or outpatient setting as well as certain drugs and biologicals. Because Medicare and other insurers cover a variety of these services and supplies, HCPCS Level II codes were established for assignment by insurers to identify items on claims. HCPCS Level II classifies similar items or services that are medical in nature into categories for the purpose of efficient claims processing. For each alpha-numeric HCPCS code, there is descriptive terminology that identifies a category of like items.

As stated in 42 CFR Sec. 414.40(a) CMS establishes uniform national definitions of services, codes to represent services, and payment modifiers to the codes. The HCPCS code set has been maintained and distributed via modifications of codes, modifiers and descriptions, as a direct result of data received from applicants. Thus, information collected in the application is significant to code set maintenance. The HCPCS code set maintenance is an ongoing process, as changes are implemented and updated quarterly (for drug and biological products) and biannual (for non-drug and non-biological items or services); therefore, the process requires continual collection of information from applicants on a quarterly and bi-annual basis. As new technology evolves and new devices, drugs and supplies are introduced to the market, applicants submit applications to CMS requesting modifications to the HCPCS Level II code set. *Form Number:* CMS–10244 (OMB control number: 0938–1042); *Frequency:* Annually; *Affected Public:* Private sector, Business or other for-profit; Number of Respondents: 250; Total Annual Responses: 250; Total Annual Hours: 2,500. (For policy questions regarding this collection contact Sundus Ashar at 410–786–0750.)

2. Type of Information Collection Request: Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation for Comprehensive Outpatient Rehabilitation Facilities (CORFs); *Use:* The purpose of this package is to request approval from the Office of Management and Budget (OMB) to reinstate, with change, the information collection request. CORFs provide coordinated outpatient diagnostic, therapeutic, and restorative services to rehabilitate individuals who are injured, disabled or ill. Physical, occupational and speech-language therapy may be provided at a single, off-site location. CORFs must provide the following core services:

- Physician consultation and supervision of staff, oversight of treatment plans, and facility administration;
- Physical therapy and social or psychological services.

The information collections (ICs) described herein enable the Centers for Medicare & Medicaid Services (CMS) to ensure CORFs comply with the initial and ongoing Medicare Conditions of Participation (CoPs) specified at Title 42 Code for Regulations (CFR) Section 485, Subpart B. These CoPs help assure a minimal level of patient health and safety in participating facilities and help ensure that Medicare requirements are being met. The only CoP with ICs is 42 CFR 485.66 and the burden estimates are designated as: IC–1a: § 485.66(a)—for Newly Certified CORFs to Develop Utilization Review Plan and IC–1b: § 485.66—for Currently Certified CORFs to Conduct Annual Utilization Reviews.

The previous iteration of this package included an estimated annual burden of 1,504 hours and an annual cost of $103,776. For this reinstatement, the total annual hourly burden is revised to 1,260 hours, with an annual burden cost of $108,190. The 16% decrease in burden hours (from 1,504 to 1,260) is primarily due to the decrease in number of certified CORFs from 188 in the prior iteration to 155 in this reinstatement and the addition of IC–1a for newly certified CORFs to develop a utilization review plan which was unintentionally omitted in prior request but is not a new requirement. *Form Number:* CMS–10282 (OMB control number: 0938–1091); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 158; *Total Annual Responses:* 158; *Total Annual Hours:* 1,260. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

William N. Parham, III,

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

[FR Doc. 2026–08025 Filed 4–23–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–2026–N–3334]

Report on the Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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.'' 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.

[FR Doc. 2026–08084 Filed 4–23–26; 8:45 am]

BILLING CODE 4164–01–P

[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