DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10858]

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice, correction.

SUMMARY: On November 13, 2026, CMS published a notice in the **Federal Register** that sought comment on a collection of information concerning CMS–10858 (OMB control number 0938–1474) entitled ''Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (IRA).'' The OMB control number is incorrectly listed in 35th line within the left column of the notice. This document corrects the error.

FOR FURTHER INFORMATION CONTACT: William N. Parham, III, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the November 13. 2026, issue of the **Federal Register** (91 FR 73250), we published a Paperwork Reduction Act notice requesting a 30-day public comment period for the information collection request identified under CMS–10858, OMB control number 0938–1474, and titled ''Rebate Reduction Requests under Sections 11101 and 11102 of the Inflation Reduction Act (IRA).''

II. Explanation of Error

In the November 13. 2026 (91 FR 73250) notice, the OMB control number is incorrect. The incorrect language is located in the 35th line of the left column of page 73251, ''control number: 0938–1471'' All of the other information contained in the November 13, 2026, notice is correct and remains unchanged. The related public comment period remains in effect and ends December 14, 2026.

III. Correction of Error

In FR Doc. 2026–23146 of November 13, 2026 (91 FR 73250), page 73251, the language in the 35th line of the left column, ''control number: 0938–1471'', is corrected to read as follows: (control number: 0938–1474)

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; 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 additional draft and revised draft product-specific guidances. The draft guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry titled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The draft guidances identified in this notice were developed using the process described in that guidance.

DATES: Submit either electronic or written comments on these draft guidances by January 19, 2027 to ensure that the Agency considers your comment on these draft guidances before it begins work on the final version of these guidances.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2007–D–0369 for ''Product-Specific Guidances; Draft and Revised Draft Guidances for Industry.'' Received comments 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