importation of any drug or controlled substance into the United States because Mr. Lamberty illegally imported the unapproved drug etizolam and sold it to customers in the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that the Agency considered applicable to Mr. Lamberty's offense and concluded that the offense warranted the imposition of a 10-year period of debarment.

The proposal informed Mr. Lamberty of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Lamberty received the proposal and notice of opportunity for a hearing on August 8, 2025. Mr. Lamberty failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Paul Zachary Lamberty has been convicted of felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses should be accorded a debarment period of 10 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Lamberty is debarred for a period of 10 years from importing or offering for import any drug into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Lamberty is a prohibited act.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–02337 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2033]

Agency Information Collection Activities; Proposed Collection; Comment Request; Expedited Programs for Serious Conditions—Accelerated Approval of Drugs and Biologics

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 information collection relating to the draft guidance, ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.''

DATES: Either electronic or written comments on the collection of information must be submitted by April 7, 2026.

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 April 7, 2026. 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–D–2033 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Expedited Programs for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' 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: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5683, *PRABranch@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.

Expedited Programs for Serious Conditions—Accelerated Approval of Drugs and Biologics

OMB Control Number 0910–0765—Revision

This information collection supports the implementation of section 506 of the FD&C Act (21 U.S.C. 356) and agency guidance. In the Consolidated Appropriations Act, 2023 (CAA), Congress amended section 506(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356(c)), to provide FDA additional authorities and to impose on FDA additional obligations regarding the accelerated approval pathway.

In the **Federal Register** of December 6, 2024 (89 FR 97011), FDA announced the availability of a draft guidance for industry entitled ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics.'' The guidance is available from our website at *https://www.fda.gov/media/184120/download.* The guidance provides information on FDA's policies and procedures for the accelerated approval program. FDA issued this guidance to satisfy a mandate under the CAA. This guidance discusses which products may be candidates for accelerated approval, the standards for granting accelerated approval, and the procedures for withdrawing accelerated approval. Statutory requirements in section 506(c) of the FD&C Act are discussed in the draft guidance document, including the recently added procedures for the expedited withdrawal of approval of a product approved under accelerated approval (guidance Section V).

The expedited procedures for withdrawing accelerated approval require FDA to provide the sponsor with (1) due notice, (2) an explanation for the proposed withdrawal, (3) an opportunity to meet with the Commissioner or a designee of the Commissioner (Commissioner/designee), (4) an opportunity for written appeal to the Commissioner, or to a designee who has not participated in the proposed withdrawal of approval and is not a subordinate of an individual (other than the Commissioner) who participated in such proposed withdrawal, and (5) the opportunity for an advisory committee meeting on issues related to the proposed withdrawal if requested by the sponsor and an advisory committee has not previously advised FDA on such issues with respect to the withdrawal of the product prior to the sponsor's request. In addition, FDA must provide an opportunity for public comment on the proposal to withdraw approval and publish on FDA's website a summary of public comments received and FDA's response to such comments. We anticipate there will be information collection burdens associated with participating in an advisory committee meeting or submitting a written appeal.

If FDA is considering whether to propose withdrawing approval of a drug that has been granted accelerated approval, in general, FDA should convene an advisory committee to request the committee's advice on whether one or more of the criteria for withdrawal in section 506(c) of the FD&C Act has been met and any other issues that may be relevant to whether approval should be withdrawn. The guidance recommends that a sponsor submit, if it had not already, any data and evidence and any objections to withdrawal that the sponsor considers relevant so that they may be considered at this stage (guidance Section V.C). Sponsors should follow the submission requirements specified in the meeting notice for the advisory committee using the appropriate docket number, or submit via email or postal mail if specified in the **Federal Register** notice.

In the event that FDA utilizes the expedited procedures for withdrawing accelerated approval and the sponsor seeks to submit a written appeal of the proposed withdrawal of approval, the guidance recommends that the sponsor should present its objections to the proposal to withdraw approval and may submit any supporting data, information, or evidence on which the sponsor relies for its appeal. With respect to such information, the guidance notes that the sponsor may seek to incorporate by reference any data, information, or evidence submitted to the new drug application (NDA) or biologics license application (BLA) file or presented in briefing materials to an advisory committee convened to provide advice to the Agency on whether to withdraw the accelerated approval (guidance Section V.C.3.a). The appeal and any other response, including supporting materials, should be submitted to the docket opened for the written notice, with a copy provided to the Center. Additional instructions, for example, on submitting redacted materials, will

come from the Commissioner/designee should the sponsor elect to pursue its opportunity for an appeal or meeting.

The information that respondents submit to us in preparation for an Advisory Committee meeting and in a written appeal is needed to allow us to efficiently administer the expedited withdrawal procedures in section 506(c)(3) of the FD&C Act and to support our efforts to protect the health of users of drugs approved under accelerated approval. We use the information collected in preparation for an Advisory Committee meeting to facilitate discussion among the advisory committee members. We use the information collected in a written appeal to evaluate whether the Center's proposal to withdraw approval should be finalized. We are requesting approval to revise the statutory authority reference in approved OMB control number 0910–0765 to include section 3210 of the CAA and to revise the burden estimates approved in that control number to include the following burden hours.

Description of Respondents: Respondents to this information collection are sponsors of drugs and biologics that have been granted accelerated approval designations.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Advisory Committee meeting; Draft Guidance, section V.B	2	1	2	400	800
Appeal to the Commissioner; Draft Guidance, section V.C.3.a	1	1	1	40	40
Total			3		840

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

We base our estimates of the number of respondents and the average burden per response on our experience with Advisory Committee meetings and written appeals to the Commissioner. We estimate that, on average over the next three years, two sponsors will request Advisory Committees per year, across the entire Agency. As discussed, the sponsors will submit data and evidence and any objections to withdrawal that the sponsor considers relevant. Part of the information submitted will have been developed for the NDA or BLA file. Based on our experience, we estimate that it will take approximately 400 hours for the sponsor to prepare the submission for the Advisory Committee.

We estimate that, on average over the next three years, one or fewer sponsors will submit a written appeal of the proposed withdrawal of approval, across the entire Agency. As discussed, we expect that each sponsor will present its objections to the proposal to withdraw approval and will submit any supporting data, information, or evidence on which the sponsor relies for its appeal. Part of the information submitted will have been developed for the NDA or BLA file or presented in briefing materials to an advisory committee. Based on our experience, we estimate that it will take approximately 40 hours for the sponsor to prepare the submission for the written appeal.

The draft guidance ''Expedited Program for Serious Conditions—Accelerated Approval of Drugs and Biologics'' also refers to previously approved FDA collections of information. The collections of information in 21 CFR parts 10, 12–16, and 19 relating to administrative practice and procedures have been approved under OMB control number 0910–0191. The collections of information in 21 CFR part 312 relating to clinical trials associated with accelerated approval pathways have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications, including accelerated approval of new drugs for serious or life-threatening conditions, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 relating to the submission of biologics license applications have been approved under OMB control number 0910–0338.

In addition, section 3210 of the CAA provides statutory authority to help ensure timely completion of confirmatory trials of accelerated approval products, including that FDA may require as appropriate, a confirmatory study or studies to be underway prior to approval or within a specified time period after the date of approval of the product. The CAA also requires sponsors to submit postmarketing reports to FDA on the progress of required confirmatory trials approximately every 180 days. The draft guidance, ''Accelerated Approval and Considerations for Determining Whether a Confirmatory Trial is Underway'' (January 2025) describes FDA's policies for implementing this statutory authority. As described in the Notice of Availability for that guidance, published January 7, 2025 (90 FR 1171), FDA will use the reports to monitor the progress of confirmatory trials and take action, if necessary.

With regard to information collection relating to postmarketing study commitments, we reviewed the statutory authority granted by section 3210 of the CAA as well as our existing statutory authority and regulations. Section 506B of the FD&C Act (21 U.S.C. 356b), and implementing regulations in §§ 312.20, 314.81 and 601.70 (21 CFR 312.20, 314.81 and 601.70), provide for the submission of postmarket study reports, requiring sponsors of approved drugs and biological products to report to FDA on the progress of their postmarketing study commitments, including reports on required studies, clinical trials, and agreed upon commitments. We tentatively concluded that the change in our statutory authority with regard to postmarketing study commitments adds no further information collection requirements and imposes no further burden beyond what is already required in our statutes and regulations and included in the approved ICRs for reporting the status of postmarketing study commitments (90 FR 1171, at 1173).

Our estimated burden for the revised information collection reflects an overall increase of 840 hours and a corresponding increase of three responses, which we attribute to the proposed reporting provisions in the draft guidance ''Expedited Program for

Serious Conditions—Accelerated Approval of Drugs and Biologics.''

Brian Fahey,

Associate Commissioner for Legislation.

[FR Doc. 2026–02386 Filed 2–5–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–E–0152; FDA–2025–E–0153; and FDA–2025–E–0154]

Determination of Regulatory Review Period for Purposes of Patent Extension; COBENFY

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for COBENFY and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 7, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 5, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 April 7, 2026. 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 Nos. FDA–2025–E–0152; FDA–2025–E–0153; and FDA–2025–E–0154 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; COBENFY.'' 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 § 10.20 (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: Jack Dan, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical