4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-D-4388]

New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry entitled "New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers." This draft guidance is intended to assist applicants requesting New Clinical Investigation exclusivity (also referred to as 3-year exclusivity) for a new drug application (NDA) or NDA supplement. The guidance discusses the statutory and regulatory criteria for eligibility for 3-year exclusivity and provides recommendations on the content and format of requests for 3-year exclusivity in the form of questions and answers (Q&As). FDA intends to update this draft guidance document to include additional Q&As as appropriate.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF THE PUBLICATION OF THE FEDERAL REGISTER].

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-2024-D-4388 for "New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers." 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-7936.

With regard to the proposed collection of information: 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, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers." This guidance is intended to assist applicants requesting New Clinical Investigation exclusivity, also referred to as 3-year exclusivity, for an NDA or NDA supplement under section 505(c)(3)(E)(iii)-(iv) and 505(j)(5)(F)(iii)-(iv) of the FD&C Act (21 U.S.C. 355(c)(3)(E)(iii)-(iv) and 355(j)(5)(iii)-(iv)).

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (Hatch-Waxman Amendments), which added section 505(b)(2) and (j) to the FD&C Act, reflect Congress's efforts to balance the need to "make available more low cost generic drugs by establishing a generic drug approval procedure" with new incentives for drug development in the form of exclusivities and patent term extensions. These incentives include a 3-year period of exclusivity for drugs approved in certain NDAs or supplements to NDAs during which applications submitted pursuant to section 505(b)(2) of the FD&C Act (505(b)(2) applications)

and abbreviated new drug applications submitted under section 505(j) of the FD&C Act (ANDAs or 505(j) applications) may not be approved for exclusivity-protected conditions of approval of such drugs.

Pursuant to section 505(c)(3)(E)(iii)-(iv) and 505(j)(5)(F)(iii)-(iv) of the FD&C Act, an application may qualify for 3-year exclusivity if it is a 505(b) application or supplement to a 505(b) application: (1) for a drug, which includes an active moiety (or active moieties) that has been approved in another 505(b) application, and (2) that contains reports of new clinical investigations that are: (i) not bioavailability studies, (ii) essential to the approval of the application (or supplement), and (iii) conducted or sponsored by the applicant. FDA defined many of the terms in the exclusivity provisions of the FD&C Act at 21 CFR 314.108(a), and FDA established the framework for the timing of approval for a 505(b)(2) application or ANDA impacted by New Clinical Investigation exclusivity at 21 CFR 314.108(b). Using a Q&A format, this guidance discusses each of the statutory and regulatory criteria for eligibility for 3-year exclusivity and clarifies the processes for applicants to request 3-year exclusivity, for FDA to make 3-year exclusivity eligibility determinations, and for providing notice of those determinations in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"). FDA intends to update this draft guidance document to include additional Q&As as appropriate.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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, we invite 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.

Template for Requesting New Clinical Trial Exclusivity

OMB Control Number 0910-0001--Revision

This information collection helps support implementation of regulatory requirements that govern an NDA or NDA supplement. We have issued regulations in 21 CFR part 314, Applications for FDA Approval to Market a New Drug, setting forth applicable standards and procedures that include associated reporting and recordkeeping requirements.

We are revising the information collection to support the use of a template for requesting New Clinical Investigation exclusivity, also referred to as 3-year exclusivity. We recommend that the applicant use the model language we provide to request 3-year exclusivity. The draft guidance for industry entitled "New Clinical Investigation Exclusivity (3-Year Exclusivity) for Drug Products: Questions and Answers" includes the model language in its Appendix.

All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents that utilizes topic-specific search terms. We intend to finalize the guidance document upon OMB approval of the attendant information collection.

The use of a template can assist applicants in more efficiently communicating requests for 3-year exclusivity and providing the information required in our regulations. Under 21 CFR 314.50(j)(4), an applicant claiming eligibility for 3-year exclusivity must provide certain information to show that the NDA contains "new clinical investigations" that are "essential to approval of the NDA or supplement" and were "conducted or sponsored by the applicant," including a certification required by 21 CFR 314.50(j)(4)(i) that "to the best of the applicant's knowledge each of the clinical investigations included in the NDA meets the definition of 'new clinical investigation' set forth in § 314.108(a)." The elements listed in that section are included in the template. The draft guidance describes FDA's policies for implementing this regulation. The submission of a claim for 3-year exclusivity is explained in section QV.1. of the draft guidance. We will use the information provided in the templated request as we process requests for exclusivity. The information is needed to support FDA's efforts to protect the health of users of drugs approved under 21 CFR part 314 and to efficiently determine eligibility of an NDA or supplement for 3-year exclusivity.

Description of Respondents: Respondents to this information collection are pharmaceutical industry entities who contribute to the preparation and marketing of pharmaceutical products regulated by the FDA.

Burden Estimate: We reviewed our statutory authority at section 505(c)(3)(E)(iii)-(iv) and 505(j)(5)(F)(iii)-(iv) of the FD&C Act, and implementing regulations in 21 CFR part 314, which provide for the submission of requests for 3-year exclusivity.

We tentatively conclude that providing the template proposed in the draft guidance 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 ICR under OMB control number 0910-0001.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 314, which relate to the submission of new drug applications and include requirements for the content and format of new drug applications in 21 CFR 314.50(j) and 21 CFR 314.108, have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 312, which relate to the submission of investigational new drug applications, and Form FDA 1571 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 11 relating to electronic records and signatures have been approved under OMB control number 0910-0303.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-04291 Filed: 3/3/2026 8:45 am; Publication Date: 3/4/2026]