TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
NDA 021481	Fuzeon (enfuviritide) Injectable, 90 mg/vial.	Hoffmann-La Roche Inc. c/o Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.
NDA 021548	Lexivia (fosamprenavir calcium) Tablet, EQ 700 mg base.	Viiv Healthcare Co., 410 Blackwell St., Durham, NC 27701.
NDA 021606	Zemplar (paricalcitol) Capsules, 1 microgram (mcg), 2 mcg, and 4 mcg.	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 021656	TriCor (fenofibrate) Tablets, 48 mg and 145 mg	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 021779	Ventavis (iloprost) Solution, 10 mcg/mL (10 mcg/mL), 20 mcg/2 mL (10 mcg/mL) and 20 mcg/mL (20 mcg/mL).	Actelion Pharmaceuticals US, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 021947	Fentora (fentanyl citrate) Tablets, EQ 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, EQ 0.4 mg base, EQ 0.6 mg base, and EQ 0.8 mg base.	Cephalon LLC, a wholly owned subsidiary of Teva Pharmaceuticals USA Inc., 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 022116	Lexivia (fosamprenavir calcium) Suspension, EQ 50 mg base/mL.	Viiv Healthcare Co., 410 Blackwell St., Durham, NC 27701.
NDA 022206	Rapaflo (silodosin) Capsules, 4 mg and 8 mg	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 022224	Trilipix (choline fenofibrate) Delayed-Release Capsules, EQ 45 mg fenofibric acid and EQ 135 mg fenofibric acid.	AbbVie Inc., 1 N Waukegan Rd., North Chicago, IL 60064.
NDA 022511	Vimovo (esomeprazole magnesium; naproxen) Delayed-Release Tablets, EQ 20 mg base; 375 mg, and EQ 20 mg base; 500 mg.	Horizon Therapeutics USA, Inc., 1 Horizon Way, Deerfield, IL 60015.
NDA 050467	Doxorubicin Hydrochloride (doxorubicin HCl) Injectable, 10 mg/vial, 20 mg/vial, 50 mg/vial, and 150 mg/vial.	Pfizer Inc., 66 Hudson Blvd. East, New York, NY 10001.
NDA 201194	Oxycodone Hydrocholoride (oxycodone HCl) Solution, 5 mg/5 mL.	VistaPharm, LLC, 20 Waterview Blvd., Suite 303, Parsippany, NJ 07054.
NDA 202020	Rayos (prednisone) Delayed-Release Tablets, 1 mg, 2 mg, and 5 mg.	Horizon Therapeutics USA, Inc., 1 Horizon Way, Deerfield, IL 60015.
NDA 204623	Pennsaid (diclofenac sodium) Solution, 2%	Horizon Therapeutics Ireland DAC c/o Horizon Therapeutics USA, Inc., 1 Horizon Way, Deerfield, IL 60015.
NDA 204803	Posimir (bupivacaine) Solution, 660 mg/5 mL (132 mg/mL) ..	Innocoll Pharmaceuticals Limited c/o Allucent, 2000 Centregreen Way, Suite 300, Cary, NC 27513.
NDA 206030	Carnexiv (carbamazepine) Solution, 200 mg/20 mL (10 mg/mL).	Lundbeck Pharmaceuticals LLC, 6 Pkwy. North, Suite 400, Deerfield, IL 60015.
NDA 209128	Dsuvia (sufentanil citrate) Tablet, EQ 0.03 mg base	Vertical Pharmaceuticals, LLC, 1880 McFarland Pkwy., Suite 110B, Alpharetta, GA 30005.
NDA 209511	Xaracoll (bupivacaine HCl) Implant, 100 mg	Innocoll Pharmaceuticals Limited c/o Allucent, 2000 Centregreen Way, Suite 300, Cary, NC 27513.
NDA 211280	Reyvow (lasmiditan succinate) Tablets, EQ 50 mg base, EQ 100 mg base, and EQ 200 mg base.	Eli Lilly and Company, Lilly Corporate Center, Drop Code 2543, Indianapolis, IN 46285.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of August 5, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved NDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in table 1 that are in inventory on August 5, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13616 Filed 7–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6667]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biologics License Applications, Procedures and Requirements

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 activities associated with Biologics License Applications, Procedures and Requirements.

DATES: Either electronic or written comments on the collection of information must be submitted by September 4, 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 September 4, 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–2026–N–6667 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Biologics License Applications, Procedures and Requirements.'' 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@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.

Biologics License Applications (BLAs), Procedures and Requirements

OMB Control Number 0910–0338—Extension

This information collection helps support implementation of statutory and regulatory requirements under the Public Health Service Act (PHS) and the Federal Food, Drug, and Cosmetic Act (FD&C Act) that govern biologics product licensing. The Food and Drug Administration (FDA) has promulgated regulations in 21 CFR parts 600–680 setting forth applicable standards and procedures that include associated reporting, recordkeeping, and disclosure requirements. Respondents to the information collection are persons or entities who engage in manufacture of biologics. Respondents to this collection of information are licensed manufacturers of biological products. Based on existing data, we estimate there are 371 such respondents. We provide relevant information and resources on our website at *https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber* regarding biologics license applications (BLAs).

Regulations in 21 CFR part 600, subparts A through C (21 CFR 600–600.21), and regulations in 21 CFR 601, subpart A (21 CFR 601.2–21 CFR 601.9) cover genera provisions and prescribe requisite content and format elements for applications. Regulations in 21 CFR part 601, subpart C (21 CFR 601.12–21 CFR 601.29) pertain to BLA changes; the electronic submission of information; the suspension, revocation, and reissuance of BLAs; and also provide for the availability of guidance documents by FDA to assist respondents in complying with applicable requirements (21 CFR 601.29). Regulations in 21 CFR 601, subparts D and E, respectively, establish requirements applicable to diagnostic radiopharmaceuticals and for

the accelerated approval of biological products for serious or life-threatening illnesses. Confidentiality of information submitted to FDA is covered in 21 CFR 601, subpart F (601.50–601.51). The regulations also provide for the approval of biological products when human efficacy studies are not ethical or feasible, as established in 21 CFR 601, subpart H. Finally, regulations in 21 CFR parts 610–680 establish both general and specific standards applicable to all biological products, including FDA requests for and protocols as required under 21 CFR 610.2, 660.6, 660.36, and 660.46 (previously approved under OMB control no. 0910–0206), as well as labeling provisions pertaining to exceptions or alternatives to the labeling of products in the Strategic National Stockpile (SNS) established in 21 CFR 610.28 (previously approved under OMB control no. 0910–0616).

To assist respondents with individual information collection elements, we have developed the following instruments, noting that FDA forms may be approved for use in other information collections:

Forms

Form FDA 356h, *Application to Market a New or Abbreviated New Drug or Biologic for Human Use,* provides a uniform format for submitting BLAs. Form FDA 356h is a fillable PDF form that may be submitted through our Electronic Submission Gateway (ESG), for which respondents must create and maintain a user account. Utilizing Form FDA 356h helps to ensure that an application is complete and contains all the necessary information, so that delays due to lack of information may be avoided. In addition, the form provides key information to FDA for efficient handling and distribution to the appropriate staff for review.

Form FDA 2252, *Transmittal of Annual Report for Drugs and Biologics for Human Use,* is used by an applicant of a licensed biological product to submit annual reports required by § 601.70(b) (21 CFR 601.70(b)). Form FDA 2252 is also a fillable PDF form.

Form FDA 2253, *Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use,* was developed for use by respondents to transmit specimens of advertisements and promotional labeling (*e.g.,* circulars, package labels, container labels, etc.), as well as labeling changes. The submission of this information is required by § 601.12 (21 CFR 601.12) for biological products and by 21 CFR 314.81 for drug products. Form FDA 2253 is a fillable PDF form.

Form FDA 3674, *Certificate of Compliance Under 42 U.S.C. 282(j)(5)(B), with Requirements of ClinicalTrials.gov* Data Bank, was developed for use by respondents to certify submissions as required by section 402(j)(5)(B) of the Public Health Service (PHS) Act and is submitted through our ESG.

Cover Sheets

As provided for under 21 CFR part 601.2(a), FDA utilizes cover sheets, so denoted for purposes of identifying specific content information within a given application. For more information regarding BLA cover sheets, please refer to *https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/regulatory-submissions-electronic-format-cber-regulated-products.*

Guidance Documents

Agency regulations in 21 CFR 601.29 complement our Good Guidance Practice regulations in 21 CFR 10.115 by providing for the issuance of guidance documents to assist respondents with applicable requirements in 21 CFR part 601. We have issued the following guidance documents to assist respondents with activities covered by the information collection:

- The guidance document ''*Cooperative Manufacturing Arrangements for Licensed Biologics,*'' (November 2008), available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cooperative-manufacturing-arrangements-licensed-biologics,* discusses strategies for meeting an increased need for flexible manufacturing arrangements. Since cooperative manufacturing arrangements can take a considerable amount of time to develop, the guidance is intended to be useful for planning purposes in the early phases of product development. Many companies that perform only limited aspects of manufacturing processes are interested in sharing or contracting parts of manufacturing in order to facilitate product development and manufacturing flexibility. The guidance document discusses recommended communication between licensed manufacturers and contract manufacturers regarding changes to production and facilities, results of tests and investigations regarding the product, types of products manufactured in the contract facility, and standard operating procedures. We believe that the information collection provisions in the guidance do not create a new burden for respondents but incorporate reporting and recordkeeping provisions that are part of usual and customary business practices.
- The guidance document entitled, ''Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies'' (October 2023), describes a standards recognition program for regenerative medicine therapies (SRP–RMT) designed to identify and recognize Voluntary Consensus Standards (VCS) to facilitate the development and assessment of regenerative medicine therapy (RMT) products when such standards are appropriate. The guidance document also explains that any interested party may request recognition of a VCS. The guidance document is available for download from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-consensus-standards-recognition-program-regenerative-medicine-therapies.*

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR subchapter F: biologics or other authority; information collection activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Parts 601 (§§ 601.2–601.95); applications and changes, including applicable labeling standards in part 610 (610.15, 610.65).	356h	371	177.40	65,814	~12.35	812,607
601.12; Changes to an approved application	356h	170	27.888	4,741	10	47,410
Guidance documents issued in accordance with 601.29:	NA	9	1	9	3	27
• Cooperative Manufacturing Agreements						
• Voluntary Consensus Standard Programs						
610.15(d); Request for exceptions or alternatives to the regulation for constituent materials.	NA	1	1	1	1	1

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR subchapter F: biologics or other authority; information collection activity	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Part 680 (§§ 680.1–680.3); additional standards	NA	10	1	10	2	20
Section 402(j)(5)(B) of the PHS Act (42 U.S.C.); Certification to accompany biological product applications.	3,674	371	1	371	0.28 (17 minutes)	105
Total		371		70,946		860,170

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The numbers in this column have been rounded.

Noting that 5 CFR 1320.3(m) defines a recordkeeping requirement to include the reporting to the Federal government regarding such records, we have characterized the submission tasks reflected in Table 1 as reporting burden, assuming that respondents retain records in support of the respective submissions.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
601.6(a); Requirement to notify selling agents and distributors upon suspension of license.	1	20	20	0.33 (20 minutes) ..	7

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The number in this column has been rounded to the nearest whole number.

Based on our experience with the information collection, we account for disclosures under 21 CFR 601.6(a) distinctly, as reflected above in Table 2. Again, FDA assumes that respondents subject to regulatory requirements in 21 CFR 601.6 will retain corresponding records.

Cumulatively, these adjustments result in an average decrease of 2,168 responses and an average increase of 29,133 burden hours annually. We consider these nominal adjustments that reflect minimal change in the number of submissions and burden attributable to applicable requirements.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13533 Filed 7–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–4699]

Expedited Investigational New Drug Pilot Program; Request for Information; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 24, 2026. That notice opened a public docket to solicit input and comments on a proposal to establish a pilot program, the Expedited Investigational New Drug pilot program, to shorten the time it takes from drug identification to first-in-human study, while protecting clinical trial participants. FDA is correcting the email address of the document.

FOR FURTHER INFORMATION CONTACT: Benjamin Cook, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 2, Rm. 2114, Silver Spring, MD 20993–0002, 240–338–4685, *ExpeditedINDPilot@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 24, 2026 (91 FR 37996), in FR Doc. 2026–12621, the following correction is made:

On page 37997, in the third column, in the **FOR FURTHER INFORMATION CONTACT** section, the email is corrected to *ExpeditedINDPilot@fda.hhs.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–13592 Filed 7–2–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS–OASH–2026–0232]

Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I; Request for Information

AGENCY: Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice; request for information; establishment of a public docket.

SUMMARY: The Office of the Assistant Secretary for Health (OASH or we) is opening a public docket to solicit input and comments on a proposed threshold for 7-hydroxymitragynine (7–OH) scheduling under the Controlled Substances Act. Public comments submitted to this docket will be provided by the Secretary for Health and Human Services for consideration by the Attorney General.

DATES: Submit either electronic or written comments, data, or information by July 31, 2026.

ADDRESSES: *Request for Information (RFI) Docket:* You may examine the RFI docket at *regulations.gov* under HHS–OASH–2026–0232. The docket contains this RFI and all comments received to date. To submit a response, click the ''Comment'' button inside Docket: HHS–OASH–2026–0232 and follow all instructions.