

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
ANDA 081250	ACETAMINOPHEN AND CODEINE PHOSPHATE (acetaminophen; codeine phosphate) tablet, 300 mg; 30 mg.	Do.
ANDA 086398	BUTALBITAL, ASPIRIN AND CAFFEINE (aspirin; butalbital; caffeine) tablet, 325 mg; 50 mg; 40 mg.	Do.
ANDA 090293	GILDESS 24 FE (ethinyl estradiol; norethindrone acetate) tablet, 0.02 mg; 1 mg.	Par Health USA LLC, U.S. Agent for PH Health Ltd.
ANDA 091520	Bupropion HCl extended-release tablet, 150 mg	Do.
ANDA 203413	CYCLAFEM 0.5/35 (ethinyl estradiol; norethindrone) tablet, 0.035 mg; 0.5 mg.	Do.
ANDA 203911	FLUDEOXYGLUCOSE F18 (Fludeoxyglucose F-18) injectable, 4–500 millicurie/milliliter (mCi/mL).	Nukemed, Inc. dba SpectronRx, 17490 Dugdale Dr., South Bend, IN 46635.
ANDA 203912	Sodium fluoride F-18 injectable, 10–200 mCi/mL.	Do.
ANDA 204455	AMMONIA N 13 (ammonia N-13) injectable, 30 mCi-300 mCi/8 mL (3.75–37.5 mCi/mL).	Do.
ANDA 205699	Bosentan tablet, 62.5 mg and 125 mg	Par Health USA LLC, U.S. Agent for PH Health Limited, 9 Great Valley Parkway, Malvern, PA 19355.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of November 9, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved abbreviated new drug application 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 November 9, 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. 2026–20762 Filed 10–8–26; 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; Submission for Office of Management and Budget Review; Comment Request; Biologics License Applications, Procedures and Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 9, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0338. Also include the FDA docket number found in brackets in the heading of this document.

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, 240–402–5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 general 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>.

In the **Federal Register** of July 6, 2026 (91 FR 41046), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14 Reporting of product deviations by licensed manufacturers	3486	70	7.186	503	2.0	1,006

ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments and transfusion services	3486	2,455	6.630	16,277	2.0	32,554
1271.350(b) Reporting requirements (human cells tissues and cellular and tissue-based products)	3486	86	2.465	212	2.0	424
1271.350(b) CBER addendum report	² 3486A	127	6.50	826	0.25	207
Total				17,818		34,191

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

² Five percent of the number of respondents $((2,455 + 86) \times 0.05 = 127)$.

Following publication of the 60-day notice, the Agency identified a multiplication and rounding error in the burden calculations. The corrected estimates are reflected in this 30-day notice. This revision does not reflect a substantive or programmatic change to the information collection. Our estimated burden for the information collection reflects an overall increase of approximately 4,612 hours and a corresponding increase of 2,642 responses. We attribute this adjustment to an increase in the number of product deviations we received in FY 2024 from licensed manufacturers, unlicensed registered blood establishments and transfusion services under § 606.171. This is likely due to the issuance of the revised guidance document titled, “Biological Product Deviation Reporting for Blood and Plasma Establishments” (85 FR 14682; March 13, 2020), which provided blood and plasma establishments with revised recommendations related to BPD reporting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20768 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0053]

Challenges and Solutions in Lot-Level Food Traceability; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting titled “Challenges and Solutions in Lot-Level Food Traceability.” The purpose of the meeting is to provide a forum for

the public to share information on continued implementation of the “Requirements for Additional Traceability Records for Certain Foods” final rule and areas of concern, especially as they relate to lot-level tracking, and identify potential flexibilities to support compliance.

DATES: The public meeting will be held on November 6, 2026, from 12:00 p.m. to 3:30 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by December 6, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually, and login instructions will be provided at registration.

You may submit comments as follows. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 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–2014–N–0053 for “Challenges and Solutions in Lot-Level Food Traceability: Public Meeting.” 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