Ongoing information collections	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Total annual burden hours
National Center on Substance Abuse and Child Welfare Convening Registration Information Collection	105	1	0.057	6
National Center on Substance Abuse and Child Welfare Grantee Meeting Registration Information Collection	300	1	0.033	10
National Center on Substance Abuse and Child Welfare Learning Exchange Registration Information Collection	350	1	0.083	29
National Center on Substance Abuse and Child Welfare Policy Academy Meeting and Training Registration Information Collection	1,000	1	0.033	33
National Center on Substance Abuse and Child Welfare Site Visit Registration Information Collection	650	1	0.083	54
National Center on Substance Abuse and Child Welfare Training Registration Information Collection	785	1	0.066	52
Tribal Maternal, Infant, and Early Childhood Home Visiting (TMIECHV) Kickoff Meeting Registration	20	1	0.100	2
Fiscal Responsibility Act Outcomes Working Group Interest Form	50	1	0.080	4
Child Care Quality and Business Support Center, Events Registration Questions	7,360	1	0.032	242
Office of Child Care Events Registration and Post-Event Survey	4,500	1.75	0.064	506
Office of Child Care National Tribal Conference Registration Questions	400	1	0.083	33
Office of Child Care Regional Meeting Registration Questions	330	1	0.082	27
Office of Child Care State and Territory Administrator's Meeting Registration Questions	400	1	0.082	33
Office of Child Care Tribal Child Care and Development Fund (CCDF) Plan Training	630	1	0.084	53
Office of Child Care Tribal Cluster Meeting Registration Questions	190	1	0.084	16
Registration for National Center on Subsidy Innovation and Accountability Events	1,000	1	0.033	33
Community Economic Development Grant Recipient Conference	200	1	0.229	96
Head Start Registration Form Questions	34,000	1	0.017	567
Evaluation Surveys for the National Center on Early Childhood Development, Teaching, and Learning's Practice-Based Coaching Training and Technical Assistance Learning Community	40	8	.10	31
Sum Totals	59,405			2,224

Authority: Social Security Act, Section 1110. [42 U.S.C. 1310]

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–16583 Filed 8–13–26; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–D–7957]

Container Closure Systems for Human Drugs and Biological Products; Draft Guidance for Industry; Availability

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 ''Container Closure Systems for Human Drugs and Biological Products.'' This document provides guiding principles for evaluating the quality of container closure systems (CCSs) used to package drugs and biological products, for human use. This includes CCSs that are also device constituent parts of combination products and CCSs used to package the drug or biological product constituent parts of combination products.

DATES: Submit either electronic or written comments on the draft guidance by October 13, 2026 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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–2026–D–7957 for ''Container Closure Systems for Human Drugs and Biological Products.'' 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; or Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., WO32, Hub/Mail Room #5129, 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: Ashley Boam, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4192, Silver Spring, MD 20993–0002, 301–796–6341, *cder-quality-policy@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Container Closure Systems for Human Drugs and Biological Products.'' This document provides guiding principles for evaluating the quality of CCSs used to package drugs and biological products for human use. This includes CCSs that are also device constituent parts of combination products and CCSs used to package the drug or biological product constituent parts of combination products. Specifically, this guidance discusses FDA's current thinking on how to evaluate CCSs according to a risk-based framework that includes quality assessments and quality control of packaging materials and components. It applies to applications, including amendments and supplements to approved applications for human drug and biological products, as well as for combination products. It also applies to drug products legally marketed according to section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(h)) without an approved application under section 505 of the FD&C Act (21 U.S.C. 355). FDA intends to supplement this guidance with additional guidances to provide topic-specific recommendations related to the general information described in this guidance. These topic-specific guidances will address methods related to evaluating and characterizing novel CCSs and provide information about specific quality attributes and testing requirements, including considerations for extractables and leachables evaluations and associated toxicological risk assessments.

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 ''Container Closure Systems for Human Drugs and Biological Products.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 211 have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 201 subpart C relating to over-the-counter monographs have been approved under OMB control number 0910–0340. The collections of information in 21 CFR part 314 relating to generic drug product development and controlled correspondence have been approved under OMB control number 0910–0727. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 820 relating to device quality system regulations have been approved under OMB control number 0910–0073.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, 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. 2026–16638 Filed 8–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–4698]

Determination That LASIX (Furosemide) Tablets, 20 Milligrams, 40 Milligrams, and 80 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that LASIX (furosemide) tablets, 20 milligrams (mg), 40 mg, and 80 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035, *jennifer.forde@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, are the subject of NDA 016273, held by Validus Pharmaceuticals LLC, and initially approved on July 1, 1966. LASIX is indicated for adults and pediatric patients for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including nephrotic syndrome. Oral LASIX may be used in adults for the treatment of hypertension alone or in combination with other antihypertensive agents.

LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lachman Consultant Services, Inc. submitted a citizen petition dated April 29, 2026 (Docket No. FDA–2026–P–4698), under 21 CFR 10.30, requesting that the Agency determine whether LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list LASIX (furosemide) tablets, 20 mg, 40 mg, and 80 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16648 Filed 8–13–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–8163]

Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is hosting a public meeting to discuss proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA) for fiscal years (FYs) 2028 through 2032. PDUFA authorizes FDA to collect user fees to support the process for the review of human drug applications. The current legislative authority for PDUFA expires in September 2027. At that time, new legislation will be required for FDA to continue collecting prescription drug user fees in future fiscal years. Following discussions with the