

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–E–3595; FDA–2025–E–3596; FDA–2025–E–3939; FDA–2024–E–4125; FDA–2024–E–4128; FDA–2024–E–4129; FDA–2024–E–4130; FDA–2024–E–4131; FDA–2025–E–0485; FDA–2025–E–0486; FDA–2025–E–0488; FDA–2025–E–0489; FDA–2025–E–0490; FDA–2025–E–5206; and FDA–2025–E–0707]

Determination of Regulatory Review Period for Purposes of Patent Extension; Correction of Notices—ANDEMBRY; ANZUPGO; ANKTIVA; BIZENGRI; BRINSUPRI; DAYVIGO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is announcing corrections to the notices of Determination of Regulatory Review Period for Purposes of Patent Extension for ANDEMBRY; ANZUPGO; ANKTIVA; BIZENGRI; BRINSUPRI; and DAYVIGO. The original determinations were announced in the **Federal Registers** of August 10, 2026 (BRINSUPRI, DAYVIGO), August 17, 2026 (BIZENGRI), and September 9, 2026 (ANDEMBRY, ANZUPGO, ANKTIVA). Those notices correctly identified the dates on which the testing and approval phases began and ended but incorrectly stated the length of the regulatory review period due to calculation errors. No other changes are made.

DATES: All due dates for submission of comments, redetermination requests, and submission of petitions for due diligence as well as the dates used to determine the regulatory review periods for the products noted above remain the same as originally published.

FOR FURTHER INFORMATION CONTACT:

Patrick Clouser, Office of the Commissioner, Food and Drug Administration, 240–402–5276.

SUPPLEMENTARY INFORMATION: FDA announced the regulatory review period determination for BRINSUPRI in the **Federal Register** of August 10, 2026 (91 FR 51493). In Document No. 2026–16247, on page 51494, second column, in the first paragraph of section II., the Determination of Regulatory Review Period portion of the document, the following correction is made:

FDA has determined that the applicable regulatory review period for BRINSUPRI is 2,925 days. Of this time, 2,681 days occurred during the testing phase of the regulatory review period,

while 244 days occurred during the approval phase.

FDA announced the regulatory review period determination for DAYVIGO in the **Federal Register** of August 10, 2026 (91 FR 51494). In Document No. 2026–16246, on page 51495, third column, in the first paragraph of section II., the Determination of Regulatory Review Period portion of the document, the following correction is made:

FDA has determined that the applicable regulatory review period for DAYVIGO is 3,116 days. Of this time, 2,648 days occurred during the testing phase of the regulatory review period, while 468 days occurred during the approval phase.

FDA announced the regulatory review period determination for BIZENGRI in the **Federal Register** of August 17, 2026 (91 FR 53261). In Document No. 2026–16713, on page 53262, second column, in the first paragraph of section II., the Determination of Regulatory Review Period portion of the document, the following correction is made:

FDA has determined that the applicable regulatory review period for BIZENGRI is 2,912 days. Of this time, 2,636 days occurred during the testing phase of the regulatory review period, while 276 days occurred during the approval phase.

FDA announced the regulatory review period determination for ANKTIVA in the **Federal Register** of September 9, 2026 (91 FR 57350). In Document No. 2026–18297, on page 57351, third column, in the first paragraph of section II., the Determination of Regulatory Review Period portion of the document, the following correction is made:

FDA has determined that the applicable regulatory review period for ANKTIVA is 3,925 days. Of this time, 3,224 days occurred during the testing phase of the regulatory review period, while 701 days occurred during the approval phase.

FDA announced the regulatory review period determination for ANZUPGO in the **Federal Register** of September 9, 2026 (91 FR 57355). In Document No. 2026–18298, on page 57356, first column, in the first paragraph of section II., the Determination of Regulatory Review Period portion of the document, the following correction is made:

FDA has determined that the applicable regulatory review period for ANZUPGO is 3,535 days. Of this time, 3,169 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase.

FDA announced the regulatory review period determination for ANDEMBRY in the **Federal Register** of September 9,

2026 (91 FR 57356). In Document No. 2026–18300, on page 57357, third column, in the first paragraph of section II., the Determination of Regulatory Review Period portion of the document, the following correction is made:

FDA has determined that the applicable regulatory review period for ANDEMBRY is 2,531 days. Of this time, 1,918 days occurred during the testing phase of the regulatory review period, while 613 days occurred during the approval phase.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–21711 Filed 10–22–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–2246]

Questions and Answers Regarding Mandatory Cosmetics Recalls; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Questions and Answers Regarding Mandatory Cosmetics Recalls: Guidance for Industry.” The guidance document provides answers to common questions that might arise about FDA’s mandatory recall authority for cosmetics. It is intended to inform regulated industry about the Agency’s current thinking on implementation of certain aspects, including the criteria, process, and expectations, for mandatory recalls of cosmetic products. The guidance announced in this notice finalizes the draft guidance of the same title published on December 18, 2025.

DATES: The announcement of the guidance is published in the **Federal Register** on October 23, 2026.

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 below (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-2025-D-2246 for "Questions and Answers Regarding Mandatory Cosmetics Recalls: Guidance for Industry." 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 guidance to the Division of Inspectorate Policy, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Peter Ajuonuma, Office of Inspections and Investigations, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 71, Rm. 1241, Silver Spring, MD 20993-0002, 301-796-2277, OIipolicystaffs@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Questions and Answers Regarding Mandatory Cosmetics Recalls: Guidance for Industry." The purpose of this guidance document is to provide guidance to industry on the implementation of the mandatory cosmetics recall provisions of section 611 of the Federal Food, Drug, and Cosmetic Act, which was added by section 3502 of the Modernization of Cosmetics Regulation Act of 2022. The

guidance is in the form of Questions and Answers and provides answers to common questions that might arise about these mandatory recall provisions and FDA's current thinking regarding their implementation.

In the **Federal Register** of December 18, 2025 (90 FR 59129), FDA announced the availability of the draft guidance entitled "Questions and Answers Regarding Mandatory Cosmetics Recalls: Draft Guidance for Industry."

FDA received seven comments on the draft guidance, which were broadly supportive of the guidance, and some of which asked for certain clarifications of issues discussed in the guidance. After considering the comments we received, we are publishing the guidance as drafted with no substantive changes. The guidance announced in this notice finalizes the draft guidance dated December 18, 2025.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on mandatory cosmetics recalls. 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.

II. Paperwork Reduction Act of 1995

This guidance contains no new collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-11261]

Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction and Combination Products

AGENCY: Food and Drug Administration, HHS.