

## 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.*

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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