

# FDA Announces Updated Instructions for Serious Adverse Event Reporting for Cosmetic Products

Article By:

Shoshana Golden

Emily M. Leongini

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On December 14, the US Food and Drug Administration (FDA) issued new instructions for cosmetic companies to use when submitting mandatory serious adverse event reports to the agency.

As we [reported last year](#), the Modernization of Cosmetics Regulation Act of 2022 (MoCRA) imposed extensive new requirements related to cosmetic products marketed in the United States, one of which was a requirement to submit reports of serious adverse events to the FDA. Specifically, MoCRA requires cosmetic companies to report to FDA any serious adverse event associated with the use (in the United States), of a cosmetic product manufactured, packed, or distributed by the company within 15 business days of receiving the information.

MoCRA defines a serious adverse event as an adverse event that:

- Results in:
  - death;
  - a life-threatening experience;
  - inpatient hospitalization;
  - a persistent or significant disability or incapacity;
  - a congenital anomaly or birth defect;
  - an infection; or
  - significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or
- Requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described above.

The new mandatory reporting requirement takes effect on December 29, 2023. Last month, FDA updated the MoCRA page on the agency's website, recommending that cosmetic companies use MedWatch Form 35000A to submit serious adverse event reports for cosmetics. On December 14, FDA announced that it had issued updated instructions to make it easier for cosmetic companies to complete the MedWatch Form and also indicated that it will provide more information on the launch date for the electronic submission of serious adverse event reports for cosmetic products in the coming months.

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