

From NABP <news@nabp.pharmacy>

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To Barron, Karin (DOH) <karin.barron@dc.gov>

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FDA Releases Draft Guidance for FDA Form 483 Inspectional Observations

Food and Drug Administration (FDA) has developed a draft guidance to help clarify the expectations of human and animal drug manufacturers when responding to FDA's Form 483 Inspectional Observations. The *Responding to FDA Form 483 Observations at the Conclusion of a Drug CGMP Inspection* guidance outlines the type of information manufacturers should submit to verify that they have corrected their actions since inspection. Individuals may submit comments related to the draft guidance to FDA by May 8, 2026.

[Read the FDA Form 483 Guidance](#)

FDA Issues New Draft Guidance for Proposed Biosimilar Product Development

A new draft guidance intended to help streamline the development of proposed biosimilar and interchangeable biosimilar products has been issued by [FDA](#). Presented in a question-and-answer format, the *New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 4)* outlines circumstances in which facilities may use comparative clinical data from a product not licensed in the United States to support the development of a US-licensed biosimilar.

FDA has also withdrawn the *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* final guidance.

[Read FDA's Draft Biosimilar Guidance](#)

FDA Requests Health Care Providers Thoughts on In-Home Opioid Disposal Kits

FDA is requesting health care providers to share their thoughts on possible new standards for [in-home opioid disposal kits](#). Currently, the agency recommends that patients dispose of unused opioids at drug take-back sites or use prepaid mail-back envelopes to return them to pharmacies or other authorized dispensers. FDA's request for information is intended to help determine criteria for establishing safe in-home disposal systems that could reduce the risk of misuse and overdose. Individuals may submit comments to this notice by April 6, 2026.

CDC Releases New 2024 US Dispensing Data Maps

Centers for Disease Control and Prevention (CDC) has released its US Dispensing Rate Maps and a table showing dispensing rates for [buprenorphine](#), [opioid](#), and [naloxone](#) prescriptions at community pharmacies from 2019-2024. According to the data, opioid dispensing rates have declined over time. In 2019, community pharmacies dispensed 46.8 opioid prescriptions per 100 people, compared with 35.4 per 100 people in 2024.

In 2024, community pharmacies dispensed more than 1.5 million naloxone prescriptions and 15.4 million buprenorphine prescriptions.

[View CDC's Data](#)

Innovations: 'From Discipline to Development: Does Remedial Education Improve Outcomes?'

Pharmacists and physicians pledge an oath to apply their attained knowledge and skills to obtain the best outcomes for patients. When health care professionals fail to meet the standards of care, their respective professional licensing boards are responsible for investigating the professional conduct and determining the appropriate course of action to discipline the individuals, whether it is issuing a monetary penalty, revoking or suspending a license, or assigning remedial continuing education (CE) courses. The notion of assigning remedial CE centers on the idea that individuals who analyze and correct their wrongdoing will reduce their likelihood of reoffending. Yet, there are few studies that can prove remedial courses actually reduce recidivism.

Discover the challenges with measuring recidivism and researchers' advice for exploring this topic in the January/February 2026 issue of *Innovations*[®].

[Access the Full Story](#)

FDA Releases New Adverse Event Monitoring System Platform

FDA has released its new unified platform, FDA Adverse Event Monitoring System (AEMS). The platform presents adverse event reports for drugs, biologics, vaccines, cosmetics, and animal food (that were sent to FDA) in a single dashboard. FDA will begin transferring historical adverse event data to AEMS, remove certain legacy systems, and introduce improved application program interfaces, along with data analytics tools.

[Learn More About FDA's New Tool](#)

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1600 Feehanville Dr
Mount Prospect, IL 60056