

Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers; Guidance for Industry; Availability

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The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Postapproval Manufacturing Changes to Biosimilar and Interchangeable Biosimilar Products: Questions and Answers." This guidance provides answers to commonly asked questions from applicants and other interested parties regarding postapproval manufacturing changes made to biosimilar and interchangeable biosimilar products licensed under the Public Health Service Act (PHS Act). This guidance finalizes the draft guidance of the same title issued on July 23, 2024.

Agency: Health and Human Services Department; Food and Drug Administration.

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<https://www.federalregister.gov/documents/2026/10/13/2026-20817/postapproval-manufacturing-changes-to-bio-similar-and-interchangeable-biosimilar-products-questions>

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