



August 9, 2018

Dear Manufacturers of Drug/Device or Biologic/Device Combination Products assigned to Center for Drug Evaluation and Research (CDER) for premarket review:

On September 6, 2016, we published a [letter](#) in which we clarified that the compliance date for UDI label and GUDID submission requirements is September 24, 2018, for device constituents of 21 CFR 3.2(e)(2) (commonly referred to as “co-packaged”) and 21 CFR 3.2(e)(3) (commonly referred to as “cross-labeled”) combination products assigned to Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) for premarket review.

We are deploying enhancements to GUDID to better accommodate data submissions of combination products that are reviewed by CDER and contain device constituents. Similar enhancements are not required for combination products reviewed by CBER. For this reason, we are modifying our September 6, 2016, letter to extend the compliance date for GUDID submission requirements of device constituents of co-packaged combination products assigned to CDER for premarket review to September 24, 2019. Please note that we are not extending the compliance date for UDI label requirements; the UDI label compliance date for device constituents of all co-packaged and cross-labeled combination products remains September 24, 2018.

If you have any questions, please contact the FDA Office of Combination Products at combination@fda.gov or submit your question to the [UDI Help Desk](#).

Sincerely,

/s/

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