FDA U.S. FOOD & DRUG ADMINISTRATION

April 6, 2020

Compounding Policy Clarifications

We have received many emails from stakeholders about a few of our policies and we wanted to clarify a few things:

- Our guidance for hospital and health systems, which includes the "one mile radius" provision, is still in draft and we are planning to issue a revision. This draft guidance document was issued for public comment and has not been implemented.
- Although federal law specifies a 5 percent limit on interstate distribution of compounded drug products for pharmacy compounders, we do not intend to enforce the 5 percent limit until after we have finalized a Memorandum of Understanding (MOU) and given states an opportunity to sign it. The MOU is currently in draft form.
- We do not consider drugs that are on FDA's shortage list or that have been discontinued and are no longer marketed as "commercially available" under the "essentially a copy" provision for pharmacy compounders.
- We also do not consider a compounded drug produced by an outsourcing facility as "essentially a copy" if it is identical or nearly identical to an FDA-approved drug that is on FDA's drug shortage list. The agency also does not intend to take action under this provision if the facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

See human drug compounding and drug shortages for more information. Please email compounding@fda.hhs.gov with questions.

For more information, please visit FDA's Human Drug Compounding web site.