FDA Responses to Action Items from September 25-26, 2018 Intergovernmental Working Meeting on Drug Compounding

FDA will work to consider and develop systems states may use to obtain information to address the distribution of "inordinate amounts of compounded drug products interstate" under the standard Memorandum of Understanding, once final.

In June 2019, FDA announced a cooperative agreement grant opportunity to fund a three-year pilot project to enable increased information-sharing and information management related to state-licensed entities, primarily pharmacies, that engage in drug compounding, and to conduct research to enable better understanding of the distribution of compounded drugs interstate.

The goal of this information-sharing and research initiative is to improve the information available to state regulators and FDA regarding state-licensed compounders and the distribution of compounded drugs interstate to support better and more targeted regulation and oversight of compounding activities to reduce risk to patients. Importantly, this initiative will also facilitate state information reporting to FDA under future (separate) agreements between the states and FDA addressing interstate distribution of compounded drugs.

Overall, this information will be important to further public health protections associated with compounded drugs, including the ability of states to focus their limited resources on compounders for which they have primary oversight responsibility that present the greatest risk. It will also facilitate FDA's ability to determine when additional federal oversight is warranted, such as when a large-scale compounder distributes drug products to multiple states; such a pharmacy has a wide patient exposure and can cause significant and widespread harm if its products are substandard. This information will promote collaborative oversight by state and federal regulatory agencies.

FDA awarded this grant to the National Association of Boards of Pharmacy (NABP) on September 2, 2019. FDA and NABP will work together under this cooperative agreement to further implementation of this initiative.

FDA will continue to engage with state regulators to understand any insanitary conditions they are observing in non-pharmacy settings in their states.

FDA is committed to an open dialogue on this issue and appreciates any information that state regulators bring to the agency's attention in furtherance of these efforts.

FDA will continue to engage with state regulators to better understand state actions that are informed by Form FDA 483s and other FDA documents.

As permitted under information-sharing agreements, FDA has continued to engage in conversations with states regarding specific Form FDA 483 documents to better inform state

approaches following the issuance of a Form FDA 483. FDA also intends to continue to engage with states on this topic at the 2019 Intergovernmental Meeting on Drug Compounding.

In consultation with NABP, FDA will consider providing states additional resources and in-person training opportunities regarding insanitary conditions and key current good manufacturing practice requirements.

FDA continues to consider opportunities for training for states. In FY 2020, FDA intends to deploy a series of in-person and online trainings on current good manufacturing practice and other compounding-related topics targeted to the outsourcing facilities. FDA anticipates there will be some seats available to state regulator participants at in-person trainings, and online trainings may also be accessed by state regulators, as well as the general public.