FDA Responses to Action Items from October 10-11, 2019, Inter-governmental Working Meeting on Drug Compounding

FDA will strive to provide timely responses and encourage states to participate in the commissioning process

FDA is committed to continuing to work with states to improve information exchange and has continued to encourage states to participate in the commissioning process. In addition, the agency's <u>intergovernmental affairs (IGA) mailbox</u> is an appropriate entry point for states to request information and/or assistance from the agency, particularly as related to policy concerns.

FDA will identify ways to enhance incident information sharing through a centralized compounding mailbox

FDA is currently sharing incident information with the states and sends notification letters from the centralized <u>compounding incidents mailbox</u>. In cases where FDA believes there may be an imminent threat to public health, FDA may also call the state in addition to sending a letter to ensure rapid awareness. FDA also continues to invite states to participate in inspections and will continue to find ways to enhance incident information sharing with the states.

FDA will identify opportunities to improve information accessibility on our website

In the spring of 2020, FDA launched a new <u>searchable database</u> for outsourcing facility product reports. The database contains information reported to FDA within the last two years (last four reporting periods) and may be used to identify outsourcing facilities that have produced certain drugs. The database is searchable by reporting period, active ingredient and compounder name.

FDA will provide training opportunities for states and other opportunities related to the Compounding Quality Center of Excellence

FDA launched the <u>Compounding Quality Center of Excellence</u>, which has featured a series of multi-day instructor-led and trainings, as well as self-guided web courses, on topics related to compounding laws and policies, including those related to current good manufacturing practice. FDA has made these trainings free to participants and has provided a number of seats at these trainings to state-regulators. Additionally, FDA hosted the first annual conference of the Compounding Quality Center of Excellence in September 2020 and invited all states to participate along with members of the outsourcing facility sector, other compounders and stakeholders. FDA looks forward to continuing to include states in opportunities related to the Compounding Quality Center of Excellence in the coming year.