Information Sharing and Disclosure

2015 Inter-Governmental Working Meeting on Drug Compounding
November 17, 2015

Lauren DiPaola, Testimony Specialist, ORA/OPRM
Sarah Kotler, Director, DFOI

Update on Long-Term, Single-Signature Drug Compounding 20.88 Agreements

- Known as a "Drug Compounding 20.88"
- Launched in Summer 2015
- 4 Agreements currently in place
- Managed through ORA's Office of Policy and Risk Management (OPRM)

Action Items Concerning Information Sharing and Disclosure

Action Item #5: Can FDA develop a modified Information Sharing Agreement for use in a state with Sunshine Laws?

FDA will work with states that choose not to sign the 20.88 to identify whether state laws are the impediment and if so, whether the agreement can be modified to allow for some types of information to be disclosed consistent with both Federal and state law.

Action Item #6: Can the Drug Compounding 20.88 be signed by multiple state agencies (for example, both a state Board of Pharmacy and the state Attorney General's office)?

FDA has determined that the Drug Compounding 20.88 can be signed by multiple state agencies. FDA will work with individual state agencies that wish to sign such an agreement to make the necessary modifications.

Action Item #7: When can a state use information a commissioned state inspector obtained during a joint FDA/state inspection for a state regulatory action?

- The information obtained by a FDA commissioned state employee on their own during the joint inspection belongs to the state.
- Information obtained during the inspection by the FDA investigators, independent from the state inspectors, could be provided to the state inspector but generally could not be further used to support a state action.
- ***It is generally best for state inspectors to obtain information under their own authority information needed to bring a state regulatory action.***

Action Item #8: When can FDA share information with the states from FDA's evaluations of corrective actions that compounders implemented after an inspection or regulatory action, and what can be shared?

- If a Form FDA-483 is issued, FDA will send a copy of the Form FDA-483 to all 50 states with nonpublic information redacted.
- If a Warning Letter is issued, FDA will send a redacted copy of the Warning Letter to all 50 states.
- State officials commissioned by FDA may request a completely unredacted version of the Form FDA-483 or the Warning Letter.
- States operating under a 20.88 agreement can contact FDA to request a version of the Form FDA 483 or Warning Letter that has been redacted in accordance with the terms of the 20.88 agreement (e.g., including confidential commercial info but not Trade Secrets).

Action Item #9: What types of information can FDA share with states that do not enter into a 20.88 Information Sharing Agreement when there is a report of a serious adverse event or product quality issue?

With respect to adverse event reports for human drugs, what can be provided depends on the content of the specific report and who reports the event, among other things. FDA intends to further clarify what can be provided as soon as possible.

Action Item #10: How quickly after an inspection can FDA share information about an outsourcing facility with the states so that the state can consider the information when licensing the facility?

- Firm asked to respond to the observations within 15 days indicating whether it has an objection regarding an observation, or has implemented, or plans to implement corrective actions to address the observations.
  - Firms usually, but not always, submit a response.
  - FDA reviews the observations made by the investigator, and the firm's response, and considers whether regulatory action against the facility is warranted. That process may take several months to complete.
- In the interim, commissioned officials can contact FDA to discuss the findings of the inspection, corrective actions proposed by the firm, status of the case, and any regulatory actions being contemplated.
- State officials operating under a signed 20.88 agreement could also contact FDA at Infoshare-ORA@fda.hhs.gov for information about the inspection; FDA will share information as provided in the agreement.

Continued on Next Slide...

Action Item #10: How quickly after an inspection can FDA share information about an outsourcing facility with the states so that the state can consider the information when licensing the facility?

Continued…

- When no information sharing agreement and no commissioned official, FDA can only share information that is otherwise available to the public under FOIA.

- States can contact the firm directly to request a copy of correspondence with the Agency, including response to the FDA Form-483 and other related correspondence, such as corrective action updates or responses to Warning Letters, if any

Inter-governmental Working Meeting on Drug Compounding and DSCSA

U.S. Food and Drug Administration
Silver Spring, Maryland

November 16-17, 2015