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M E M O R A N D U M

TO: Iowa Board of Pharmacy

FROM: Sue Mears, R.Ph., Compliance Officer

SUBJECT: 2015 Inter-governmental Working Meeting on Drug Compounding and Drug Supply Chain Security

DATE: December 9, 2015

Director Andrew Funk and I attended the above meeting at FDA headquarters in Silver Spring, MD November 16-17, 2015. Each section of the meeting included a panel of speakers/presenters as well as time for attendee comments and questions ("listening sessions"). Topics of discussion for compounding included:

* Memorandum of Understanding

Still a lot of discussion and varied opinions about the contents, including the appropriate percentage to identify, the authority the states have for entering into the MOU, how other practitioners' compounding falls under the MOU, the likely fiscal burden to the states, what responsibilities FDA has under the MOU, etc.

* Information Sharing and Disclosure

FDA offers a "Compounding 20.88" agreement as well as FDA Commission status as means for a state to obtain more detailed information than what is otherwise available as public record.

* Comparison of cGMP and USP 797

Presentation that compared the guidelines of the two standards of production. An example of the higher standard of cGMP is that environmental sampling is required continuously when USP 797 requires only at certain time frames (every 6 months generally).

* Inspections of sterile compounding facilities and enforcement

FDA will continue to inspect compounding facilities, regardless of status as 503A or 503B. FDA indicated it is working on a guidance document regarding insanitary conditions, which is the basis for which it believes it needs to continue to inspect 503A facilities.

The afternoon session of the second day was set aside for discussion about the Drug Supply Chain Security Act ("DSCSA"). As it was the first session FDA has held with the states regarding this new law, the participation among attendees was extensive with a lot of comments provided. The discussion primarily focused on the states' licensure of wholesalers and 3rd party logistics providers ("3PLs").