California State Board of Pharmacy
1625 N. Market Blvd., Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

May 15, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: COMMENTS OF THE CALIFORNIA STATE BOARD OF PHARMACY
Docket No. FDA-2014-D-2138
Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry

To Whom It May Concern:

I write on behalf of the California State Board of Pharmacy (Board). We are pleased to have this opportunity to submit comments on Docket No. FDA-2014-D-1399-0001: "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability." We will be brief. We support the concept of requiring and specifying adverse event reporting by outsourcing facilities, but we are concerned that the requirements and timelines specified do not sufficiently protect the public.

As we have learned again from tragic events over the last few years, contaminants and other problems with compounded drugs, particularly sterile preparations, have the potential to be significant threats to the health of individuals and the public. It is imperative that we get notice of these potential problems and initiate recalls as quickly as possible. This is especially urgent with regard to outsourcing facilities, which could be shipping large quantities of drugs that are not being tracked by patient, and where a single contaminated lot or contaminants in the facility could be spread nationwide in a matter of hours or days. The urgency of a quick response is at least as great as it would be for finished drugs, and given the direct injection or administration of many of the drugs produced by outsourcing facilities, the consequences could be far worse.

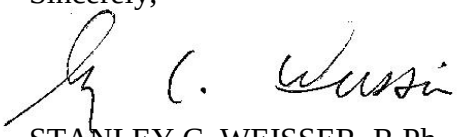
Under these circumstances, the *15 calendar days* that can elapse before an outsourcing facility is required to report a serious and unexpected adverse drug experience is far too long, as is the allowance for an additional 15 days to do investigation and follow-up reporting. During this 30-day period, an untold number of illnesses, injuries, or deaths might result. Moreover, allowing this kind of delay in reporting will likely also delay initiation of recall procedures.

This time period for reporting should be significantly cut down, to no more than 48 or 72 hours, with an equally prompt follow-up and investigation period, and an immediate decision on a recall. The first concern should be adequate protection of patients or potential patients.

Moreover, we believe that if the FDA "strongly recommends" that outsourcing facilities report all serious adverse drug events and experiences if associated with an outsourcing facility's compounded prescription drug products (i.e., regardless of expectation), the FDA should require such reporting. We agree with the FDA's concluding remarks that such reporting of all serious adverse events would provide important information required for public health. We also suggest that the FDA immediately share all adverse events reported with the home state regulator, so this state agency is also aware of potential problems at one of its licensee's facilities.

Thank you for your attention to these matters, and for your willingness to hear our input. We look forward to continuing to work together to secure the nation's drug supply. Please feel free to contact the Board at any time if we can be of assistance. The best route for contact is via Executive Officer Virginia Herold, at (916) 574-7911, or Virginia.Herold@dca.ca.gov.

Sincerely,



STANLEY C. WEISSER, R.Ph.
President, California State Board of Pharmacy