5/18/15

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

Re: SSPS Comments on the Draft Guidance For Industry "Adverse Event Reporting for Outsourcing FacilitiesUnder Section 503B of the Federal Food, Drug and Cosmetic Act"

Docket No.: FDA-2014-D-2138

Dear Madame or Sir,

The Specialty Sterile Pharmaceutical Society appreciates the opportunity to reply and provide comments on the recently proposed Draft Guidance For Industry "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug and Cosmetic Act". Our Society supports the Agency's work to provide a document that has the goal of ensuring that serious adverse events are reported in a timely fashion to the FDA and in such a way that allows the appropriate investigation into the event.

The Specialty Sterile Pharmaceutical Society is available to assist the FDA in any way to improve the safety of the industry. We are listing specific comments to the document below.

Sincerely,
Donnie Calhoun

Line 128
The requirement that the outsourcing facility report ***all*** serious adverse drug experiences associated with their compounded prescription drug products constitutes and unnecessary reporting burden on outsourcing facilities that is not required of all others required to report such events. While we acknowledge that FDA may *suspect* that serious adverse events associated with compounding may occur that do not fit the definition of an *unexpected* adverse event, there is insufficient evidence to support this suspicion. Until it can be shown that reports of unexpected adverse events are being reported by sources other than the appropriate outsourcing facility, it appears that FDA is placing the burden of proof on the outsourcing facility rather than themselves.

Lines 251-254
FDA *encourages*, as appropriate, that the outsourcing facility to attach to the report (1) hospital discharge summaries, (2) autopsy reports/death certificates, (3) relevant laboratory data, and (4) other critical clinical data. In case of a death, an outsourcing facility *should* also provide any available information on the event(s) that led to the death. While the language only *encourages* submission of the four data elements, it is unlikely that an outsourcing facility will be given access to the data elements voluntarily by the health care facility where the serious adverse event occurred without being legally compelled to do so.