PROPOSAL for REVISIONS to CANADIAN GMPs

Line	Health Canada Proposed Change	PDA Recommendation and Rationale
1836 – 1837,	Add new Section 4.2: Five consecutive lots from the establishment located in a non-MRA country are tested and found to comply with the specifications.	We recommend that this requirement not be implemented as proposed. It is unclear how the proposed change provides any additional protection for public health, and it's implementation will add additional burden for the manufacturer.
1851 - 1856	Modify Section 4.5 as follows: Periodic complete confirmatory testing is performed *on every fifth lot received or two lots a year, whichever is greater*. Re-testing by the original laboratory is acceptable; however, it is recommended that re-testing be performed by an alternate laboratory. No confirmatory testing for sterility, pyrogen *(endotoxin)*, bacterial endotoxin, particulate matter, or general safety is required.	We recommend that this change not be implemented as proposed, and that the existing testing requirements remain in force. It is unclear how the proposed change provides any additional protection for public health. The retesting that is already excluded under the existing regulation is that which has the highest probable impact on safety. It is unclear what value the re-testing of the other quality attributes provides in protection of the public health.
2141 - 2184	Delete existing Section 5 which provides for use of alternate, non-Canadian retain sites. Annex B also deleted.	We recommend that the this Section not be deleted and that the GMPs continue to permit alternate sites for retained samples, as currently implemented and approved by the authorities. It is unclear how the proposed change provides any additional protection for public health or what safety related event(s) might have prompted the proposal for the change.