Potential for Confusion with Proposed Compounding cGMPs

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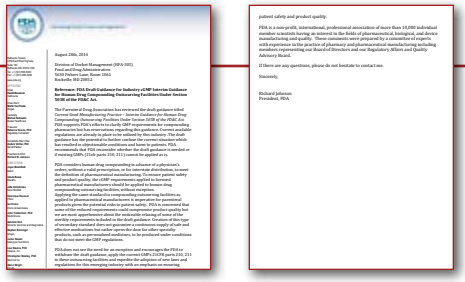

August 28th, 2014

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

Reference: FDA Draft Guidance for Industry cGMP Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.

The Parenteral Drug Association has reviewed the draft guidance titled Current Good Manufacturing Practice – Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act. PDA supports FDA's efforts to clarify GMP requirements for compounding pharmacies but has reservations regarding this guidance. Current available regulations are already in place to be utilized by this industry .The draft guidance has the potential to further confuse the current situation which has resulted in objectionable conditions and harm to patients. PDA recommends that FDA reconsider whether the draft guidance is needed or if existing GMPs (21 CFR parts 210, 211) cannot be applied as is.

PDA considers human drug compounding in advance of a physician's orders, without a valid prescription, or for interstate distribution, to meet the definition of pharmaceutical manufacturing. To ensure patient safety and product quality, the cGMP requirements applied to licensed pharmaceutical manufacturers should be applied to human drug compounding outsourcing facilities, without exception.

Applying the same standard to compounding outsourcing facilities as applied to pharmaceutical manufacturers is imperative for parenteral products given the potential risks to patient safety. PDA is concerned that some of the reduced requirements could compromise product quality but we are most apprehensive about the noticeable relaxing of some of the sterility requirements included in the draft guidance. Creation of this type of secondary standard does not guarantee a continuous supply of safe and effective medications but rather opens the door for other specialty products, such as personalized medicines, to be produced under conditions that do not meet the GMP regulations.

PDA does not see the need for an exception and encourages the FDA to withdraw the draft guidance, apply the current GMPs 21CFR parts 210, 211 to these outsourcing facilities and expedite the adoption of new laws and regulations for this emerging industry with an emphasis on ensuring patient safety and product quality.

PDA is a non-profit, international, professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. These comments were prepared by a committee of experts with experience in the practice of pharmacy and pharmaceutical manufacturing including members representing our Board of Directors and our Regulatory Affairs and Quality Advisory Board.

If there are any questions, please do not hesitate to contact me.

Sincerely,
Richard Johnson
President, PDA

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