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

Reference: Draft Guidance for Industry on Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009, Docket No. FDA-2011-D-0611

Dear Sir/Madam,

PDA is pleased to offer comments on the proposed Draft Guidance for Industry on Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009. 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. Our comments were prepared by a committee of experts with experience in biopharmaceutical product issues, including members representing our Biotechnology Advisory Board and our Regulatory Affairs and Quality Advisory Board. PDA appreciates the opportunity to offer comments on this proposed guidance and wishes to thank FDA for the opportunity to do so.

PDA reviewed the Draft Q&A guidance along with the Draft Guidance on Quality Considerations and the Draft Guidance on Scientific Considerations as they complement one another but our comment below is related just to the Draft Q&A Guidance.

With regard to the proposed Draft Guidance for Industry on Biosimliars: Questions and Answers Regarding Implementation of the Biologic Price Competition and Innovation Action of 2009, PDA would like to encourage and looks forward to FDA's further guidance on the specific issue of "interchangeability".

Again, PDA appreciates the opportunity to comment on this proposed guidance document and provides this comment for your consideration. PDA believes that this comment will clarify and strengthen the final guidance to better serve the needs of both regulators and industry.

Division of Docket Management Food and Drug Administration April 16, 2012

We would be pleased to offer our expertise in a public discussion and/or meeting with FDA to provide clarification of our comment. Should you wish to pursue that opportunity, or if there are any other questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson President, PDA

CC: Robert Dana, PDA Rich Levy, PhD, PDA