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April 13, 2012

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

Reference: Draft Guidance for Industry on Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, Docket No. FDA-2011-D-0605

Dear Sir/Madam,

PDA is pleased to offer comments on the proposed Draft Guidance for Industry on Scientific Considerations in Demonstrating Biosimilarity to a Reference Protein Product. 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PDA reviewed the Draft Guidance on Scientific Considerations along with the Draft Guidance on Quality Considerations and the Q&A Guidance as they complement one another but our attached comment relates just to the Scientific Considerations Guidance.

With regard to the proposed Draft Guidance for Industry on Scientific Considerations in Demonstrating Biosimilarity to a Reference Protein Product, we have provided a specific comment identified by line number of the proposed guidance and have included a supporting rationale in the accompanying table. In addition to the comment provided in the attached document, PDA would like to highlight two additional issues that we believe are broader than the specific comment enclosed. First, we propose FDA provide additional clarification regarding its thinking on the use of the term "finger print-like analysis" on lines 252 - 253. Second, we propose FDA consider developing future guidance on what it considers to be

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Food and Drug Administration
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clinically meaningful differences in terms of “differences in expected range of safety, purity, and potency” and differences that would not rise to the level of clinical significance in terms of “slight differences in rates of occurrence of adverse events between the two products” for establishing biosimilarity as described on lines 294 - 298.

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

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Richard Johnson', written in a cursive style.

**Richard Johnson
President, PDA**

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

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Line No.	Current Text	Proposed Change	Rationale
169-171	For example, differences in biological systems used to manufacture a protein product may cause different post-translational modifications, which in turn may affect the safety or effectiveness of the product.	“...For example, differences in biological systems used to manufacture a protein product may cause different post-translational modifications, which in turn may affect safety and/or effectiveness of the product.”	Post-translational modifications may affect both safety and efficacy of any given biotherapeutic/biosimilar.