PDA
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Connecting People, Science and Regulation®

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**January 27, 2010**

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

Reference: Postmarketing Safety Reporting for Combination Products;
Federal Dockets Management System Docket FDA-2008-N-0424

Dear Sir/Madam,

PDA is pleased to offer comments on the proposed rule under 21 CFR Part 4 titled "Postmarketing Safety Reporting for Combination Products". 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 quality, and regulatory affairs. Our comments were prepared by a committee of experts with experience in combination product issues, including members representing our Combination Products Interest Group and our Science Advisory Board. PDA appreciates the opportunity to offer comments on this proposed rule and wishes to thank FDA for the opportunity to do so.

PDA embraces this proposed rule as a significant step forward in establishment of FDA requirements regarding postmarketing reporting requirements for combination products and assuring appropriate information is provided to the designated FDA Center to allow the Agency to access data necessary to fulfill the Agency's mission of consumer protection. PDA is willing to offer any possible assistance to FDA in furthering implementation of this FDA final rule, including public workshops or other educational events.

With regard to the proposed rule 21 CFR 4, the following comments represent overall points noted throughout the proposed rule that PDA believes are important to address in order to strengthen this rule and improve the ability of manufacturers to comply with its requirements:

- We believe the requirement regarding submission of reports to both centers for sponsors holding multiple submissions in instances where they have not identified which constituent part led to the event, may be overly burdensome (reference section II.G. Separate Applications and/or Reporters - second paragraph - page 50749). Because of the complexity of combination devices, in many cases it may not be possible to identify the source constituent part within the shortest reporting period. We believe it would be less burdensome but still meet the Agency's needs if, in these situations, the primary mode of action should determine which Center's reporting requirements should be used. We suggest the following alternate language: "If it is unclear which constituent part led to the adverse event, you would satisfy reporting requirements for the part of the combination product with the primary mode of action of the combination product."

FDA also indicates Form 3486 (BPDR) may be used to meet the reporting requirements of the Rule. Although comments directly applicable to Form 3486 are not within the scope of FDA's comment period for proposed 21 CFR 4, we recommend the agency open a comment period for Forms referenced in proposed rules such as 21 CFR 4 to allow the industry to provide feedback on these forms due to their critical relationship to meeting the requirements of this proposed rule.

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

Richard Johnson
President, PDA

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