

Michael Garvin, Pharm.D.

Director
Scientific and Regulatory Affairs



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April 25, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Request for Comments on the Draft Guidance for Industry on Nonclinical Safety Evaluation of Drug Combinations [Docket No. 2005D-0004, Federal Register, Vol. 70, No. 16/3714, January 26, 2005]

Dear Abigail Jacobs:

The attached comments on the above draft guidance are submitted on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA is a voluntary, non-profit trade association representing the firms that discover, develop and produce prescription drugs and biologic products. The large majority of new prescription medicines approved for marketing in the United States are produced by PhRMA member firms.

The PhRMA Pre-Clinical Leadership Committee has carefully reviewed the draft guidance and would like to take this opportunity to provide comments, which are attached.

Your consideration of these comments is appreciated. Please contact me if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads 'Michael Garvin'.

Michael Garvin, Pharm.D.

2005D-0004

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Pharmaceutical Research and Manufacturers of America

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