Paul G. King Consulting

SUPPORT IN CHEMICALS & PHARMACEUTICS

Friday, 18 June 1999

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Documents Management Branch [**HFA-305**]
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 99N-0386

FORMAL COMMENTS TO:

Docket Number : 99N-0386

Comments: **Speaker's Response To The Summary Miss-characterization Of My Comments As Made In the FDAMA Stakeholders Meeting Held On 28 April 1999 On The Campus Of Temple University In Philadelphia, Pennsylvania.**

On "5/21/99," CDER published a "Summary for CDER" in the FDAMA Docket 99N-0386.

In spite of the fact that both of the "stakeholder" speakers spoke for about the same time, the summary document "summarized" my comments in one-fourth the space given to the comments made by the other presenter, Dr. Lorna Trotman.

Moreover, while the summary of Dr. Trotman's presentation accurately reflected her comments, the summary of my comments was, to say the least, not accurate.

The following page contains my summary of my comments. In order to be fair, I have restricted them to the same "space" as given to Dr. Trotman's comments.

Please post the following document to the docket with the title "Dr. King's CDER FDAMA Remarks Summary."

Thank you.

Respectfully,

Paul G. King, Ph.D. 21 June '99

C50

99N-0386

33 Hoffman Ave., Lake Hiawatha, NJ 07034-1922

Tel: 1-973-263-4843 • FAX: 1-973-331-0131
e-mail: drking@gti.net

Dr. King's Summary Of His FDAMA Remarks At PA Meeting

Paul G. King, Ph.D., a consultant, expressed his views on the FDA and the drug industry that it regulates. He began by stating that it is both wrong and illegal for CDER not to comply with the FDC Act's "must" that all drug establishments be inspected by CDER at least biannually. He then noted that an Agency that disregards the law should not be surprised that the drug industry does the same and worse. Next, he observed that CDER lacks any metric-based proof of the competency of its inspection, review and management personnel. He then outlined a training- and assessment- based approach to correcting that deficiency so that their requisite competencies could be established in both the requirements of the statutes and regulations they administer and the basics of inspection science and statistics appertaining thereto. He then suggested that all approved and pending drug applications should be audited and shown to provide scientifically sound proof that they meet the strictures of CGMP regulations because his experience is that this is often not the case.

33 Hoffman Ave., Lake Hiawatha, NJ 07034-1922 Tel: 1-973-263-4843 • FAX: 1-973-331-0131
e-mail: drking@gti.net

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PAUL G. KING
PAUL G. KING CONSULTING
[illegible] HOFFMAN AVE
LAKE HIAWATHA, NJ 07034-1922

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