UNIVERSITY OF CALIFORNIA, IRVINE

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The UCI Center for Statistical Consulting

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Dear Colleague:

Medical device manufacturers such as yours have raised concerns about the FDA inspection process leading the FDA to institute revisions. These revisions are now under review. A combined FDA and industry task force is studying the effects of the revised inspection procedure and is seeking the industry's opinions about how well the current FDA inspection process is working.

Your company, having just been through a Quality System/Good Manufacturing Practices (QS/GMP) or pre-market inspection, is being asked to give its opinion on these matters. In order that the results will truly represent the thinking of the medical device industry, it is important that each questionnaire be completed and returned.

You may be assured of complete confidentiality in spite of the fact that your name appears on the first page. The identification is so that we may check your name off the mailing list when your questionnaire is returned, and that we may contact you if we have questions about your responses. Your questionnaire should be returned to me at the University of California, Irvine. I will be overseeing the data entry, performing the analyses and writing a report of the results. I will **not** release individual companies' responses to the FDA, to industry associations, nor to anyone else. The final report will present data in such a way that individual responses are not discernable, thus protecting the anonymity of the respondents.

The results of this research will be used exclusively by the FDA and industry taskforce to improve the inspection process as well as to further cooperation between FDA and the medical device industry. A summary of the results will be posted on the FDA (www.fda.gov), HIMA (www.himanet.com), AMDM (www.amdm.org) and MDMA (www.medicaldevices.org) web sites.

We would be most happy to answer any questions you might have. Please contact: Nancy Singer, Special Counsel to Health Industry Manufacturers Association (HIMA), at (202) 434-7222 or e-mail nsinger@himanet.com; Leif Olsen, President, Association of Medical Diagnostics Manufacturers (AMDM), at (301) 898-7025 or e-mail leif@biowhittaker.com; or Denise Dion, Investigator, Division of Emergency and Investigational Operations, FDA, at (301) 827-5645 or e-mail ddion@ora.fda.gov; or Anita Iannucci at the University of California, Irvine, at (949) 824-1682 or e-mail iannucci@uci.edu.

Thank you for your assistance.

Sincerely,

Anita L. Iannucci

Anita L. Iannucci, Ph.D.
UCI Center for Statistical Consulting

FDA Officials:

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