



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
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Dear Colleagues:

In 2009, we operate in a period of intense and rapid change. There have been significant consolidation changes in the pharmaceutical industry, the Food and Drug Administration (FDA) received a significant influx of resources through the FY08 budget supplemental, and there have substantive changes in FDA programs and guidance. Operations are becoming more global in nature, and FDA has opened its first-ever foreign offices. The Agency's Pre-Approval Inspection Program and Foreign Inspection Program drive much of our inspectional efforts in the pharmaceutical area. There are many new and continued initiatives underway, and others are being considered which will impact how FDA will carry out its obligations.

For example, the modernization of pharmaceutical manufacturing and product quality regulation, which began with the Agency's Pharmaceutical cGMPs for the 21st Century initiative, continues with the issuance of guidance emphasizing risk-based approaches and quality by design, such as the new draft guidance for process validation and an analysis of the root causes of drug recalls. The Agency is also focusing inspectional and analytical resources on imported active pharmaceutical ingredients. Developmental issues and technology transfer continue to play an important role in evaluating pre- and post-approval compliance. As you know, pharmaceutical manufacturers are increasing their use of risk management tools to identify and minimize potential cGMP issues that may impact their products.

The FDA and the Central Atlantic States Association of Food and Drug Officials (CASA) are jointly sponsoring a one-day seminar on May 11, 2009 for the pharmaceutical industry to give you an update on all of these issues.

The program is designed to provide you with the most up-to-date information about our pharmaceutical inspection programs and other issues impacting those programs. This seminar will feature speakers from FDA's Center for Drug Evaluation and Research, as well as the local and headquarters field offices, and will cover FDA's current initiatives in inspecting foreign establishments and expectations and requirements for importing and exporting drugs. The seminar will also include sessions regarding the pre- and post-approval inspection programs, preventing cross-contamination during processing, the Drug Quality and Field Alert Reporting systems, and the draft process validation guide.

We hope you will find this program to be valuable in the development of your employees and to your company. The space at this seminar is limited; therefore, we recommend that you make your reservations as soon as possible. A registration form is attached or a complete package for the seminar may be obtained by visiting the CASA website at: www.casafdo.org

The seminar will be held at the Philadelphia Airport Hilton Hotel, 4509 Island Avenue, Philadelphia, PA 19153, telephone 215-365-4150, from 8:30am – 5:00pm (registration 7:30am – 8:30am). Hotel availability may be limited, so you are encouraged to make your hotel reservation as soon as possible. The hotel registration deadline is April 16, 2009 and you can access the hotel web site at: <http://www.hilton.com/en/hi/groups/personalized/PHLAHHF-ANN-20090510/index.jhtml>

Thanks for considering this seminar. We look forward to seeing you in May.

Yours truly,

Melinda K. Plaisier
Regional Food and Drug Director
Central Region