American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting

"How Are Candidate Food and Feed Ingredients and Animal Drugs Reviewed at FDA for Safety of Human Food?"

To be presented by

Karen Ekelman, PhD, MPM

Director, Division of Human Food Safety
Office of New Animal Drug and Evaluation
Center for Veterinary Medicine, US FDA
(karen.ekelman@fda.hhs.gov)

Thursday, January 26, 2012

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:30 PM – Program
8:30 – 8:45 PM – Door-prizes drawing; Networking

Online Registration site: http://www.asq509.org/ht/d/DoSurvey/i/35817

Open to Public - $5 for non-ASQ members to cover pizza/drink cost;
Free to ASQ Members, students, local interns, residents, postdocs, FDA Commissioner's Fellows, and current job-seekers

Location:
Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Registration Deadline: Please register by ***Thursday noon, January 26****, 2012.*

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: By Car: From **I-270** (N or S bound): Take Exit 9A and exit from the FIRST right exit; turn left (east) onto Shady Grove Dr.; turn right (south) onto Rockville Pike (**Route 355**); turn left (east) onto East Gude Dr.; turn left (north) immediately onto Crabb's Branch Dr.; turn left (west) immediately onto Standish Place. The first building on your right side is 7519 Standish Place; open parking). The venue is on the first floor with its entrance opposite to the left side of building main entrance. **By Metro train**: Off from Red Line **Shady Grove Station**, and take RideOn **Route**

59 TOWARD ROCKVILLE and get off from "**Calhoun Place**" stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

Presentation Summary:

"How Are Candidate Ingredients Reviewed at FDA for Use in Human Food, Animal Feed, or New Animal Drugs?"

Dr. Ekelman will discuss the various ways in which chemicals that are, or may be, human carcinogens are reviewed - and sometimes approved - as food additives, animal feed ingredients, and new animal drugs at the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) of US FDA. She will provide examples and describe some of the current unresolved policy issues associated with such substances.

Presenter' Bio: Karen Ekelman, PhD, MPM

Dr. Karen Ekelman has a PhD in developmental biology from the Ohio State University, where she studied mechanisms of human chemical carcinogenesis with Dr. George Milo. After graduation, Karen conducted research in this area for several more years at the Argonne National Research Laboratory and at the University of Chicago School of Medicine. After moving to Maryland, Karen earned a MPM (Masters of Public Management) degree at the University of Maryland – College Park and spent several years as an **IEEE Science Fellow** at the USEPA and as a **Fellow** at the National Academy of Engineering, National Academy of Sciences, working and writing in the areas of environmental and human health risk assessment policy and practice.

In 1987, Karen joined FDA's Center for Food Safety and Applied Nutrition (CFSAN) as a **toxicologist** in the Office of Food Additive Review (OFAR). During her 14 years with CFSAN, she was recognized as an **expert** in the review of carcinogenic food additives, break-down products, and constituents, and served as **Executive Secretary** of CFSAN's Cancer Assessment Committee. In 2001 Karen joined Center for Veterinary Medicine (CVM) as **Leader** of the Feed Safety Team in the Division of Animal Feeds/Office of Surveillance and Compliance (OSC), and in 2008 she became **Director** of the Division of Human Food Safety in CVM's Office of New Animal Drug Evaluation (ONADE).