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

**Biomed/Biotech Special Interest Group (SIG) Meeting**

# "FDA Regulatory Policy – How It Is Made and Who Makes It"

**To be presented by**


## Gary L. Yingling, MS, JD

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**Partner**

**Morgan, Lewis & Bockius LLP**


## Thursday, March 28, 2013

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:30 PM – Program (intermission at 7:40 pm)
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: non-ASQ members to cover pizza/drink cost;**
**Free: ASQ Members, MJ-DC Members, veterans, senior citizens, students, interns, residents, postdocs, FDA Commissioner's Fellows, and current job-seekers**

**Location: Kelly's Deli Conference Center, 7519 Standish Place, Rockville (Derwood, for GPS user), MD 20855**
**Registration Deadline:** Please register by ***Thursday noon, March 28****, 2013.*
**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 Cars:** 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 trains**: 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.

## Summary:

This presentation will provide an overview of the background and triggers of FDA regulatory policies as outlined below:

I. Background
II. Policy triggers
    A. Statutes
    B. Regulations (Writing and Interpreting)
    C. Guidances
    D. Enforcement (Bringing the Case and Court Decisions)
    E. Letters (Untitled Letters and Warning Letters)
    F. Actions by individuals in the agency

## Presenter's Bio:

**Mr. Gary L. Yingling** is a **Partner** in Morgan, Lewis and Brockius' FDA and Healthcare Practice. Mr. Yingling focuses his practice on issues involving the U.S. Food and Drug Administration (FDA) and has also represented clients in matters involving the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS), the Environmental Protection Agency (EPA), the Consumer Product Safety Commission (CPSC), the Federal Trade Commission (FTC), and various states. His clients have included individuals, partnerships, and corporations in cases involving labeling, importation, regulatory marketing strategy, recalls, seizures, and criminal matters.

Mr. Yingling's work in the **food industry** involves a variety of matters, including ingredient safety questions and product labeling, and his work in the **drug industry** ranges from the preparation of Investigational New Drug (IND) applications to product labeling. He also has a particular interest in **clinical research**, **contract research organization**, and **sponsor matters**. Prior to joining Morgan Lewis, Mr. Yingling was a partner in multiple food and drug practices of international law firms, resident in Washington, D.C. Before entering private practice, he served as **president** of the Food and Drug Law Institute for nine years. Earlier in his career, Mr. Yingling served in the FDA's office of the general counsel (OGC) for 10 years, first as a **trial attorney** and later as **associate chief counsel** for its Bureau of Veterinary Medicine and as the **deputy chief counsel for administration**. He was also **director** of the Over-the-Counter (OTC) Drug Review in the Bureau of Drugs for two years. Mr. Yingling received the **FDA's Award of Merit**, the agency's highest award, in 1974 for his legal and administrative work on the OTC Review.

Mr. Yingling earned his JD from Emory University School of Law in 1968. Prior to attending law school, he practiced community pharmacy and is a **registered pharmacist** in Maryland and the District of Columbia. He earned his MS from Purdue University in 1966 and his BS from the University of North Carolina in 1962. Mr. Yingling is admitted to practice in the District of Columbia (DC) and before in the U.S. Supreme Court and the U.S. District Court for DC.

Mr. Yingling is the past **Chair** of UNC Pharmacy Foundation, the past **President** of University of North Carolina School of Pharmacy Alumni Association, former **Chair**, Scholarship Committee of the Food and Drug Law Institute, and an **Adjunct Professor** of The University of Florida College of Pharmacy. He was the **Recipient** of the 2012 ACRP Global Conference Top Speaker Award and the 1998 FDLI's Distinguished Service and Leadership Award. He is also a **member** of American Society for Pharmacy Law, Association of Food and Drug Officials, District of Columbia Bar Association, Drug Information Association, Federal Bar Association, Regulatory Affairs Professionals Society, and International Society for Regulatory Toxicology and Pharmacology.

Mr. Yingling is also on the **Editorial Board** of *Clinical Research Practices and Drug Regulatory Affairs Journal*, the *Regulatory Toxicology and Pharmacology Journal*, the *Biomedical and Environmental Sciences Journal*, and the *FDA Enforcement Manual. He is also a* ***R*****eview Board Member**, U.S. Adopted Names Council.

**This event is cosponsored by the Monte Jade Science and Technology Association of Greater Washington (www.MonteJadeDC.org).**