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

Biomed/Biotech Special Interest Group (SIG) Meeting

"Evaluation of Benefit and Risk"

To be presented by

Ellis F. Unger, MD

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Director, Office of Drug Evaluation – I

Office of New Drugs

Center for Drug Evaluation and Research, US FDA

Thursday, April 11, 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, CAPA-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, April 11****, 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:

The conclusion of risk and benefit evaluation for candidate drug, biologics, device, and food products forms the basis of regulatory market approval made by the US FDA. The qualitative and quantitative assessment itself and factors that need to be considered will be introduced in this presentation. The approval of a few marketed drugs will also be used as examples to further describe the decision-making process based on the totality of risk and benefit profiles of each drug.

Presenter's Bio:

Dr. Ellis F. Unger is the **Director**, Office of Drug Evaluation-I, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA). Dr. Unger is a **cardiologist** who obtained his medical degree from the University of Cincinnati, and received post-doctoral training at the Medical College of Virginia (***internal medicine***) and The Johns Hopkins Hospital (***clinical cardiology***).

Dr. Unger was a **Senior Investigator** in the Cardiology Branch, National Heart, Lung, and Blood Institute, National Institutes of Health, from 1983 to 1997, where he directed a ***translational research program*** in angiogenesis, developing new approaches for the treatment of coronary artery disease and peripheral vascular disease. From 1997 to 2003, Dr. Unger served as a **Medical Officer**, **Team Leader**, and subsequently **Branch Chief** in the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER), FDA. When regulatory authority for ***therapeutic biologics*** was transferred from CBER to CDER in 2003, Dr. Unger assumed the responsibilities of **Deputy Director**, Division of Therapeutic Biological Internal Medicine Products, Office of Drug Evaluation-VI, OND, CDER. With the dissolution of the therapeutic biologics division in 2005, Dr. Unger became **Deputy Director** of the Division of Cardiovascular and Renal Products. From November, 2006 until October 2007, Dr. Unger served as the **Acting Deputy Director** of the Office of ***Surveillance and Epidemiology*** in CDER. Dr. Unger became **Deputy Director**, Office of Drug Evaluation-I, in July 2009, and its **Director** in July 2012.

Dr. Unger has served on numerous agency-wide and international working groups, including the Risk Assessment Working Group - PDUFA III Implementation, Council for International Sciences (CIOMS) Working Group VII, the International Conference on Harmonization (ICH) Expert Working Groups on E2F (development safety update report) and E2C(R2) (periodic benefit-risk evaluation report). Dr. Unger has authored, co-authored, and edited numerous scientific articles, and is a co-holder of two patents.

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