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

Codex Alimentarius and Veterinary Drugs - Ractopamine HCl as A Case Study

To be presented by

Kevin Greenlees, MS, PhD, DABT

Senior Advisor for Science and Policy
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Center for Veterinary Medicine (CVM), US FDA

Thursday, June 9, 2011

6:00 – 6:20 PM – Networking; Pizza/drink
6:20 – 8:30 PM – Program
8:30 – 8:50 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, postdocs, and FDA Commissioner's Fellows**

Location: Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855
Registration Deadline: Please register by ***Thursday noon, June 9****, 2011.*
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: "Codex Alimentarius and Veterinary Drugs - Ractopamine HCl as A Case Study"

Codex Alimentarius ("*food book*") Commission (the Commission) is a body of the Food and Agriculture Organization (FAO) of the United Nations (UN) and World Health Organization (WHO). The Commission establishes internationally agreed upon voluntary food standards. With a collection of important mission including to protect consumers' health, promote fair food trade practices, facilitate coordination of food standards, and determine priorities for and establish/publish/amend (when appropriate) food standards, the Commission has 1 executive committee and 24 specialty committees within its operation. One of those specialty committees is the **Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF)** which is responsible to establish food standards for veterinary drug residues. The **Joint Expert Committee of Food Additives (JECFA)**, though not officially part of the Commission, is an *ad-hoc*, independent international scientific expert body to performing risk assessment and to provide technical advices to the Commission and its special committees, including CCRVDF. **Ractopamine HCl** (Ractopamine) is a beta-adrenergic agonist drug and has anabolic effects tending to the conservation of lean muscle and reduction of fat in animals. Ractopamine has been approved in US to use in swine, non-dairy cattle, and turkey and does not require a withdrawal time in those food animals before slaughtering for human consumption. The **maximal residue level (MRL)** of Ractopamine in animal tissue products and the **acceptable daily intake (ADI)** of Ractopamine for human has been a significant subject for review/discussion/decision-making within the Commission's operation within the past two decades.

This presentation will describe the quality operation and challenges of the Commission, with focus on CCRVDF and JECFA responsibility and achievements while using Ractopamine as a case example. Technical details on setting MRLs or ADIs, specific discussion of Ractopamine as a veterinary drug, and the international issues in setting Codex standards in general could also be touched upon.

Presenters' Bios: Kevin Greenlees, MS, PhD, DABT (kevin.greenlees@fda.hhs.gov)

Dr. Greenlees received a Bachelors of Science in Biology from SUNY Cortland in 1975. While serving in the Air Force at the USAF Aerospace Medical Research Laboratory in Dayton, Ohio, he received a Master of Science in Pulmonary Physiology from Wright State University. He also received a Doctoral degree in Cardiopulmonary Physiology at Colorado State University in 1983. Following post-doctoral positions at the University of Guelph, Canada, and the Virginia-Maryland Regional College of Veterinary Medicine at Blacksburg, Virginia, he joined the FDA Center for Veterinary Medicine in 1989. Dr. Greenlees is currently a **Senior Advisor** for Science and Policy within the Office of New Animal Drugs at the Center for Veterinary Medicine, US FDA.

Dr. Greenlees has spent most of his career evaluating the safety of residues of veterinary drugs in food. He worked as a **review scientist** for residue and toxicological evaluations of veterinary drugs used in food producing animals. He has been a Diplomate of the American Board of Toxicology since 1995. In addition to his work at FDA, he has served as an **expert** and **member** of the FAO/WHO Joint Expert Committee on Food Additives (JECFA) since 2000 and is the US delegate to the Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF). Dr. Greenlees also **chairs** the Safety Working

Group of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH).