Science Writers Symposium – November 10, 2008

FDA: Novel Approaches to Critical Medical Problems

8:15-8:45 **Registration and Networking**

8:45-9:15 **Welcome**: Moderator, Larry G. Kessler, Sc.D., Director, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA

Science at FDA
Frank M. Torti, M.D., M.P.H., Principal Deputy Commissioner and Chief Scientist, FDA

9:15-9:45 **New Influenza Vaccines that Protect against the Unexpected**: FDA's research into a broadly protective vaccine
Suzanne Epstein, Ph.D., Associate Director for Research, Office of Cellular, Tissue and Gene Therapies, Center for Biologics Evaluation and Research, FDA

Every year up to 15% of the population is sidelined by the influenza virus and more vulnerable people may develop flu-related complications or even die. An influenza pandemic would be even more deadly. The influenza virus evolves quickly, resulting in changes in the structure of surface proteins that are key targets for antibodies. For this reason, flu vaccines must be replaced frequently. Predictions of what virus strains will circulate are imperfect and an unexpected outbreak may not match the available vaccine supply. FDA is investigating a vaccination strategy aimed at far less changeable viral components. Animal studies have already shown that these vaccines induce powerful, long-lasting, immunity against differing virus strains including divergent subtypes of the lethal "bird flu" strains.

9:45-10:15 **CSI: Heparin**: How FDA scientists defied conventional wisdom and reached out to the best and brightest scientific thinkers in the country to solve a scientific mystery
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, FDA

Severe allergic reactions and deaths associated with the blood-thinning drug heparin had industry scientists stumped when raw and finished lots of the product passed standard drug quality tests. FDA scientists collaborated with some of the most advanced analytical labs in the country to consider more specific bioassay methods, advanced separation methodologies and detailed structural analyses. Within a matter of weeks the consortium had identified an unexpected heparin-like contaminant – oversulfated chondroitin sulfate.

10:15-10:30 **Break**

10:30-11:00 **Fishing for an Answer:** How did melamine, "a non-toxic compound," cause so much toxicity in pets and kids?
Renate Reimschuessel, V.M.D., Ph.D., Division of Animal Research, Office of Research, Center for Veterinary Medicine, FDA.

Pet food was not the only animal food that was adulterated during the 2007 pet food recall. Fish, pig and chicken feeds were also contaminated with melamine, posing a potential food safety problem. FDA had to develop chemical methods for detecting melamine in edible animal tissues and to understand why melamine in animal feed was causing kidney disease. Tests showed melamine in combination with cyanuric acid induced renal crystals in fish and pigs, ultimately solving the mystery.

Group 1:

11:00-12:15 **Guided Tour of the Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, White Oak**

The OSEL lab conducts research in 22 specialty areas, including electrophysiology, nanobiophotonics, atomic force microscopy, electronic microscopy, fluid dynamics, three-dimensional x-ray imaging, electro-magnetic and wireless technologies, radiation biology, and experimental pathology.

12:15-1:00 **Lunch** (on your own – bring food back to meeting room)

1:00-1:30 **Nutrigenomics**: How diet and genetics come together
James Kaput, Ph.D., Director, Division of Personalized Nutrition and Medicine, National Center for Toxicological Research, FDA

The growing field of nutrigenomics holds the promise of helping to prevent disease and maximize health by using people's genetic profiles to tailor what they eat. FDA's Division of Personalized Nutrition and Medicine is working on experimental strategies to reach this future goal. It involves methods of sorting people into metabolic groups for future research that will eventually lead to risk factors for individuals.

Group 2:

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1:30- 2:00 **When a Device is More than a Device**: The science of evaluating combination products
John W. Karanian, Ph.D., Director, Laboratory of Cardiovascular and Interventional Therapeutics, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA

Combining a biologic or drug with a medical device can incorporate cutting edge technologies such as drug-eluting stents or beads that have shown great promise for advancing patient care. But combining products also raises new scientific and technical issues such as the potential for complex interactions with the patient's tissues and organs which may result in unanticipated hazards. Scientists from the Office of Science and Engineering Laboratories have developed new imaging and analytical technologies to better model and evaluate the safety, failure modes and study signals of these products.

2:00-2:30 **Anatomy of an Outbreak:** Salmonella
Steven M. Musser, Ph.D., Director, Office of Regulatory Science, Center for Food Safety and Applied Nutrition

David W. K. Acheson, M.D., F.R.C.P., Associate Commissioner for Foods, FDA

When hundreds of people around the country were sickened by an unusual form of Salmonella earlier this year, it was FDA's job to trace the actual source of the contamination. It meant sending teams of microbiologists to hundreds of restaurants, grocery stores, farms, and packing houses to identify and track the specific food pathogen. The investigation of food vehicles and food sources was complicated by the nature of the food consumed (mixtures of tomatoes, hot peppers, cilantro, avocados and other potential ingredients, and foods prone to cross-contamination with non-ingredients during handling and preparation) and the complex marketing patterns of tomatoes. Adding to the difficulty in the traceback was the length of time it took to identify *Salmonella* in food samples and subsequently assay positive samples for identification of the Saintpaul sub-species.

2:30-3:00 **Closing remarks and informal discussion**