

Opening Statement of Ann M. Adams Ph.D., Director, Kansas City District Laboratory

Good Morning. I'm Dr. Ann Adams, Director of the Kansas City District Laboratory located in Lenexa, Kansas. The lab and district office is centrally located in our country. The Kansas City area is home to an international railroad center and 2 more Smart Ports under development – both within an hour's drive from the lab. These centers are intended to unload and distribute imports which will be directly shipped to the KC area from San Diego and the west coast of Mexico. The largest FedEx trucking center is about 10 miles from the lab. We're also about 35 miles from the Kansas City international airport which is also developing a large distribution center.

My lab relocated to its present location in 1992 and was remodeled in 2001. We are well equipped with numerous scientific instruments including approximately \$2 million worth of new equipment in 2002. A large portion of that equipment expanded and enhanced our ability to respond to emergencies or terrorist events.

We are the 6th largest lab in ORA with about 56 employees in the lab branch and 3 chemists in the Total Diet Research Center. We are a full service chemistry lab, analyzing both human and animal foods and drugs. We are ISO 17025 accredited for numerous programs including drugs, dioxins, mycotoxins, elemental analysis, pesticide residues, industrial chemicals (such as acrylamide, perchlorates and melamine), and the Total Diet Study. My lab also provides chemists for participation in both foreign and domestic drug inspections, and for the deployment of FDA's mobile chemistry lab.

We are the national center for the Total Diet Study – coordinating, processing, and analyzing 4 collections a year, each containing about 280 separate food items from around the country for volatile organic compounds; over 350 pesticide, herbicide, and fungicide residues; toxic elements such as lead, cadmium, arsenic, and mercury; and nutritional elements including iodine, calcium, sodium, and magnesium. We have also analyzed samples for acrylamide and perchlorates. We provide Total Diet samples to 3 other ORA labs for analysis of folic acid, dioxins, and radiological elements.

The Total Diet Study began in 1961 and has become a complex and unique program by which the actual consumption of residues and elements from common foods in the American diet can be monitored. Foods are purchased from grocery stores and prepared as if they are to be consumed by the public. Each year we analyze over 1100 samples and report over 45,000 data points in this program. These data are used by toxicologists and nutritionists in FDA, USDA, in academia, and other organizations in their exposure studies.

Our program is recognized by the WHO as the standard for other countries to model their programs. We have regularly participated in the international Total Diet meetings sponsored by WHO, providing guidance and instruction to numerous countries in various stages of developing their own programs. Many countries have sent their analysts to our lab for training, including Australia, Canada, Kuwait, New Zealand, Pakistan, Sweden, the Philippines, and Saudi Arabia.

We also have a research center with a primary mission to develop or improve methods for the Total Diet Study. Many of these methods have been published, validated and incorporated into other FDA, state and national programs in addition to the Total Diet.

Our lab is one of 2 in ORA which analyzes for dioxins. We have 4 chemists working in our dioxin program analyzing for dioxins, furans, and PCBs in fish and shellfish. They also analyze dietary supplements and vitamins that contain fish oil for these contaminants. With these data, FDA can perform risk assessments comparing the benefits versus the exposure levels. This program is important to FDA and the American public because even at low levels, these chemicals can increase rates for cancer and birth defects.

In addition to Total Diet samples, our elemental analysis group tests regulatory samples of human and animal foods and ceramic ware for toxic elements. We are one of the primary servicing labs for metals for FDA's import district. We analyze many samples of imported products including seafood, candies, snacks, seasonings, and juices for toxic elements, particularly lead and mercury.

Our mycotoxin group analyzes 800 to 1000 samples a year of various grains, nuts, apples and finished products for toxins produced by molds. Mycotoxins can cause cancer, liver damage, reproductive failure, and even death. Our lab is currently the only lab in ORA analyzing for fumonisins in cereal products. These mycotoxins can cause neurotoxic effects in animals, particularly in horses.

Lastly, our drug lab analyzes a wide variety of human and veterinary pharmaceutical products and participates in FDA's drug survey program. We participate in both foreign and domestic drug inspections, providing expertise for the evaluation of labs within drug firms.