

**AFDO Conference Schedule at a Glance****“Regulatory Cooperation in 2011 and Beyond – The Road to a Fully Integrated System”**

“Joint Session” refers to those presentations pertinent to all attendees, both Food and Drugs/Devices

**SATURDAY, JUNE 18, 2011****SPECIAL ACTIVITIES**

- 7:15 – 8:00 AM Workshop Registration  
 8:00 AM – 6:00 PM Conference Registration  
 8:00 AM – 5:00 PM Pre-Conference Workshop  
 5:30 – 6:30 PM Committee Chairs’ Reception  
 6:30 – 8:00 PM First-Time Attendees’ Reception  
 (First-Time Attendees & Mentors are invited to participate to learn about AFDO and its conference events)

**DISSECTING FOODBORNE ILLNESS OUTBREAKS: IMPROVING INTEGRATION AND COMMUNICATIONS;  
 LIMITING THE SCOPE AND DURATION**

AFDO PRE-CONFERENCE WORKSHOP

SPONSORED BY THE INTERNATIONAL FOOD PROTECTION TRAINING INSTITUTE (IFPTI)

Moderating: *Dan Sowards, AFDO Training Coordinator; Training Specialist, IFPTI*

This workshop is intended for all federal, state, and local regulatory officials and epidemiologists; all industry officials who deal with recalls and foodborne illness related issues and complaints; academia, and consumers interested in this topic.

Participants should plan to receive updated information on how governments (federal, state, local) plan to improve/are improving communications and the leveraging of resources through integration of program capabilities, to significantly improve response time and identification of the source of outbreaks, including communication with regulated industry. Also to be discussed are the working relationships between regulators and industry, regulators and consumers; and between industry and consumers. Up-to-date information on these issues is the most important reason to participate in the workshop. This information should assist all concerned in improving food safety and response in the U.S. during the coming years.

- 8:00 – 8:15 AM Welcome, Opening Remarks & Overview  
*Dan Sowards, AFDO Training Coordinator; Training Specialist, IFPTI*
- 8:15 – 8:45 AM A Look at CIFOR: What Improvements Should We Expect?  
*Dr. Ernest Julian, Chief, Office of Food Protection, Rhode Island Department of Health*
- 8:45 – 9:15 AM Improved Communications and Useful Tools – CDC to State and Local/Vice Versa  
*Andrew T. Maccabe, DVM, MPH, JD, CDC Liaison to FDA for Food Safety, CDC*
- 9:15 – 9:45 AM A View from State Epidemiology: Where/What Can We Improve?  
*David Sweat, MPH, Foodborne Disease Epidemiologist, North Carolina Division of Public Health*
- 9:45 – 10:15 AM Break
- 10:15 – 10:45 AM The Role of Local Health Jurisdictions: Investigation and Communication  
*Janet Lane, R.S., M.P.H., EPH Manager, Food & Neighborhood Nuisance, Environmental Public Health Division, Harris County Public Health & Environment Services*
- 10:45 – 11:15 AM The Role of the State Food Inspection Program: Improved Communications, Use of ICS, Leveraging Issues, and Investigative Tools  
*Susan Tenmyson, Director, Environmental and Consumer Safety Section, Texas Department of State Health Services  
 Julie Loera, Manager, PSQA, Texas Department of State Health Services*
- 11:15 – 11:45 AM The Role of the FDA: Integrating with the States and CDC – What Improvements are Needed, Ensuring Continuity of Press Releases, Communicating with CDC, the States, Industry and Consumers  
*Jack Guzewich, Senior Advisor: Environmental Health, OFDCER, FDA/CFR/SAN*
- 11:45 AM – 12:15 PM USDA/FSIS: Improved Communications with Stakeholders; Working with States and Locals  
*Scott Seys, Chief, Foodborne Disease Investigations Branch, USDA*
- 12:15 – 1:30 PM Lunch
- 1:30 – 2:00 PM The Role of the Food Manufacturer: Improved Communication with Regulatory and Consumers; What to do to Limit the Impact  
*Sarah Geisert, Senior Director, Global Product Safety and Regulatory Affairs, General Mills*
- 2:00 – 2:30 PM The Role of Retailers: Working with States and Locals, Communications with Consumers, Identifying the Source and Other Issues  
*Terry J. Levee, Director of Quality Assurance and Food Safety, Giant of Maryland, representing Food Marketing Institute (FMI)*
- 2:30 – 3:00 PM The Consumer’s Viewpoint: Concerns and Suggested Improvements to the System  
*Reginald “Reggie” James, Director, Policy Outreach & Southwest Office, Consumers’ Union of U.S., Inc.*
- 3:00 – 3:30 PM Break
- 3:30 – 4:45 PM Bringing It All Together: Comments from the Speakers on the System and Needed Improvements, followed by Q&A from the Audience
- 4:45 PM Adjourn

*Cover photos compliments of the Plano Convention & Visitors Bureau.  
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**SUNDAY, JUNE 19, 2011**  
**OPENING SESSIONS**

**SUNDAY ACTIVITIES**

<b>7:30 AM – 6:00 PM</b>	<b>Registration</b>
<b>8:00 AM – 12:30 PM</b>	<b>AFDO Committee Meetings:</b>
8:00 – 9:30 AM	Education & Training Committee
8:00 – 9:30 AM	Food Protection & Defense Committee
8:00 – 9:00 AM	Endowment Foundation
8:30 - 10:30 AM	Meat and Poultry Committee
9:00 - 10:30 AM	Associate Membership Committee
9:30 - 10:30 AM	Field Committee
10:00 - 11:30 AM	Drugs and Devices Committee
10:30 - 12:30 PM	Food Committee
<b>Noon – 4:00 PM</b>	<b>Silent Auction Opens</b>
<b>1:00 PM – 3:30 PM</b>	<b>AFDO Committee Meetings:</b>
1:00 - 2:00 PM	Alumni Committee
1:00 - 2:30 PM	International & Government Relations Committee
1:00 - 2:30 PM	Seafood Committee
2:30 - 4:00 PM	Laboratory, Science & Technology Committee
2:00 - 3:30 PM	Membership & Media & Public Affairs Committees
2:30 - 3:30 PM	Laws & Regulations Committee
2:30 - 3:30 PM	Retail Food Committee
2:30 - 3:30 PM	Administration Committee
<b>4:30 PM</b>	<b>Opening Session</b>
	<i>Ron Klein, AFDO President</i>
	<b>Invocation</b>
	<i>Robert Matthews, Plano Police &amp; Fire Chaplain</i>
	<b>Welcome from Plano, TX</b>
	<i>Phil Dyer, Mayor, City of Plano</i>
	<b>Welcome from MCAFD0</b>
	<i>Steve Moris, MCAFD0 President &amp; Program Manager, Kansas Department of Agriculture</i>
	<b>Endowment Foundation Address and Award</b>
	<i>John Young, Chair, AFDO Endowment Foundation and Partner, Young &amp; Associates</i>
	<b>IFPTI's Applied Science, Law, and Policy: Fellowship in Food Protection</b>
	<i>Jerry Wojtala, Executive Director, International Food Protection Training Institute</i>
	<b>President's Address</b>
	<i>Ron Klein, AFDO President and Program Manager, Alaska Department of Environmental Conservation</i>
	<b>Glenn W. Kilpatrick Memorial Address</b>
	<i>Dr. David William Kennedy Acheson, Managing Director, Food &amp; Import Safety Practice, Leavitt Partners</i>
	<b>A Vision for AFDO – 2011 &amp; Beyond</b>
	<i>Oscar Garrison, AFDO President-Elect</i>
<b>6:30 PM</b>	<b>Welcome Reception</b>
	<i>Sponsored by the AFDO Associate Members and the Mid-Central Association of Food and Drug Officials (MCAFD0) – All are welcome to attend!</i>
<b>8:30 PM</b>	<b>AFDO BINGO</b>

**HOTEL INFORMATION**

**Dallas/Plano Marriott at Legacy Town Center**

(972) 473-6444 • Fax: (972) 473-6440

7120 Dallas Parkway, Plano, TX 75024

Surrounded by scenic parks and ponds, the Dallas/Plano Marriott at Legacy Town Center is a luxurious Plano hotel conveniently located within walking distance to upscale shopping, fine dining and entertainment. On-site amenities include a beautiful outdoor heated pool, hot tub, fitness center, Copper Bottom Grille restaurant and Chaddick's lounge. Relax and refresh in the spacious guest rooms that offer luxurious Revive bedding, flexible workspace and freshly appointed bathrooms.

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|------------------------------------|---------------------------|
| ☛ Chaddick's (Restaurant & Lounge) | ☛ ATM Machine             |
| ☛ Copper Bottom Grille (Breakfast) | ☛ Outdoor Pool/Whirlpool  |
| ☛ Gift/Newsstand                   | ☛ Health & Fitness Center |
| ☛ Complimentary Self-Parking       | ☛ Sauna                   |
| ☛ Wired/Wireless Internet in rooms | ☛ Safe Deposit Boxes      |

**ROOM RATES & RESERVATIONS**

\$100 + tax – Single/Double

Phone: (972) 473-6444

You must mention that you are with the "Association of Food and Drug Officials (AFDO) 2011" to receive the discounted room rate.

**\*\*Reservation rate cutoff is 5/20/2011\*\***

**CANCELLATION POLICY**

Cancellations may be made without penalty if made by 6:00 PM on the registered date of arrival.

**SPECIAL EVENTS & ACTIVITIES**

**Saturday, June 18<sup>th</sup>**

5:30 PM – Committee Chair Reception

6:30 PM – First-Time Attendees Reception

**Sunday, June 19<sup>th</sup>**

12:00 PM – Silent Auction Opens

6:30 PM – Welcome Reception

8:30 PM – AFDO BINGO

**Monday, June 20<sup>th</sup>**

12:00 PM – Burditt Luncheon

7:00 PM – Monday Night Event

**DALLAS...a Southfork Ranch Experience**

(5:45 PM Boarding Time)

**Tuesday, June 21<sup>st</sup>**

5:30 PM – Silent Auction Closes

6:30 PM – President's Reception

7:30 PM – Wiley Award Banquet

**Wednesday, June 22<sup>nd</sup>**

10:35 AM – AFDO Business Meeting

**Accolades for AFDO 2011 Conference Hotel**



AFDO is pleased to announce that the host hotel of AFDO's 2011 Annual Educational Conference, the [Dallas/Plano Marriott at Legacy Town Center](#), was recently voted the **Best Hotel** with Meeting Space in North Texas by readers of *Texas Meetings and Events Magazine*. In addition, the Dallas/Plano Marriott at Legacy Town Center is ranked #1 of all Texas Marriott's and in the Top 10% of Marriott-branded hotels in North America in customer satisfaction scores.

For more information about AFDO's upcoming 115th Annual Educational Conference, please visit the [Conference Web page](#).

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**MONDAY, JUNE 20, 2011**

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**7:30 AM – 5:00 PM – Registration****8:00 AM – 5:00 PM – IFPTI Poster Sessions****8:00 AM – 5:00 PM – Silent Auction**

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**MORNING JOINT SESSION**

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*Moderating: Tressa Madden, Division of Federal-State Relations, FDA***8:00 – 8:10 AM – Welcome***Ron Klein, AFDO President and Program Manager, Alaska Department of Environmental Conservation***8:10 – 8:40 AM – FDA Keynote***Michael Taylor, Deputy Commissioner for Foods, FDA***8:40 – 9:40 AM – Global Supply Chain Impacts**

This presentation will highlight FDA global engagement in support of our public health mission, including our increased ability to coordinate inspectional and other regulatory efforts with foreign entities, and share information in ways that increase capacity of foreign regulatory counterparts to better understand and achieve compliance with FDA regulations, standards, and requirements.

*Mary Lou Valdez, MSM, Associate Commissioner for International Programs, Office of the Commissioner, FDA*

FDA has completed strategic planning on globalization and the approach to imports (food, drugs & devices). This insightful presentation will cover elements of the plan and explain how the impacts on supply chains from foreign countries are addressed.

*Domenic Veneziano, Director of Import Operations & Policy, Office of Regulatory Affairs, FDA*

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**9:40 – 10:05 AM – Break & Move to Desired Conference Tracks**

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**MONDAY MORNING FOOD SESSION**

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*Moderating: Tressa Madden, Division of Federal-State Relations, FDA***10:05 – 10:20 AM – Presentation of AFDO Exhibitors**

A brief overview of the interesting and informative things you'll learn when you visit the conference exhibitors. Hear about some of the valuable "gems" of information or tools you can take back with you. Make your conference-going experience complete – visit the AFDO exhibits!

*Oscar Garrison, Deputy Director, Georgia Department of Agriculture***10:20 – 11:05 AM – Consumer Concerns in the Current State of Food Protection**

This panel will present important perspectives about food safety, allergen safety, regulatory concerns and issues important to consumers.

*David W. Plunkett, J.D., J.M., Senior Staff Attorney, Center for Science in the Public Interest  
Chris Waldrop, Director of Food Policy Institute, Consumer Federation of America***11:05 – 11:45 AM – The New Seafood HACCP Hazard Guide**

AFDO and the Seafood HACCP Alliance (SHA) has been anticipating the FDA release of the 4th edition of the Fish and Fishery Products Hazards and Controls Guidance with plans for a series of educational events and all new revised SHA training materials. The events include Update and Trainer sessions for commercial and regulatory audiences across the country, and in some nations, through presentations, webinars, web-site postings and special topic workshops scheduled from June 2011 into 2012.

*Steve Otwell, Ph.D., Professor, University of Florida & Chairman, Seafood HACCP Alliance***11:45 AM – Noon – 2011 Fellowship in Food Protection**

The Fellowship in Food Protection provides select future leaders from the state and local food protection community an intense professional development experience during a series of three week-long sessions held over one year. The Fellows complete research projects and present their findings at the AFDO Conference during the poster session. A select project will be briefly presented.

*Presenter to be Announced*

**MONDAY MORNING DRUGS & MEDICAL DEVICES FORUM**

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*Moderating: Cynthia Culmo, Abbott Laboratories***10:05 – 10:15 AM – Welcome & Introductions***Ron Klein, AFDO President and Program Manager, Alaska Department of Environmental Conservation**Reynaldo "Ricky" Rodriguez, Jr., Director, Dallas District, FDA***10:15 – 11:10 AM – Supplier Quality – Industry Update & Update on RX 360**


During this session you will hear how one company is managing their supplier Quality Assurance program across multiple regions. The presentation will review components of a risk criteria process to help set priorities as well as practical approaches to manage the supplier QA relationship. Also, during this time, the presenter will provide an overview of Rx360, a pharmaceutical international, not-for-profit consortium developed to leverage resources across the industry to secure the supply chain and develop an industry aligned approach.

*Ballard H. Graham, Divisional Vice President, Compliance Oversight, Abbott Laboratories***11:10 AM – Noon – Medical Product Complaint Investigations**

FDA will share information about common, major deficiencies related to complaint investigations cited on FDA-483's, including statistics about MDR reporting observations and what to expect during a review of these records.

*Phillip M. Pontikos, Consumer Safety Officer, National Expert, Medical Device Program, FDA*

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**Noon – 1:30 PM – Burditt Luncheon **  
**Back to the Future XXII**

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**MONDAY AFTERNOON FOOD SESSION**

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*Moderating: Ellen Laymon, Division of Federal-State Relations, FDA***1:30 – 3:00 PM – FDA Top 10 Violations – Trends in Compliance**

Data on the most frequent violations on 483's & state inspections including food labeling trends in different establishment categories will be presented. Panel discussion on data analysis: what's working, how best to respond to a 483, what are best practices to model, risk factors, visible violations vs. process control – training issues, compliance strategies and questions & answers.

*Robertia Wagner, Acting Deputy Director for Regulatory Affairs, FDA/CFSAN  
FDA Panel:**Mark Rob, Director, Pacific Region, FDA**Kathleen Sinninger, Supervisor CSO, Florida District, FDA**Joann Givens, Director, Detroit District, FDA**Scott MacIntire, Director, Chicago District, FDA***3:00 – 3:20 PM – Break****MONDAY AFTERNOON DRUGS & MEDICAL DEVICES FORUM**

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*Moderating: Ballard Graham, Abbott Laboratories***1:30 – 2:15 PM – Good Importer Practices – A Proactive Way to Help Ensure Compliance***Todd Cato, Director, Southwest Import District, FDA***2:15 – 3:00 PM – Medical Product Theft: Cargo/Warehouse Thefts**

Cargo thefts of medical products are increasing. FDA, state and industry representatives have developed plans to help prevent, and investigate cargo thefts. FDA offers its perspective on how thefts can be prevented and how to respond to a report of cargo thefts.

*Special Agent Gregg Goneconto, Senior Operations Manager, Office of Criminal Investigations, FDA***3:00 – 3:20 PM – Break**

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## MONDAY, JUNE 20, 2011, CONT.

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### MONDAY AFTERNOON FOOD SESSION

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#### 3:20 – 3:40 PM – President's Awards

*Ron Klein, AFDO President and Program Manager, Alaska Department of Environmental Conservation*

#### 3:40 – 4:10 PM – Retail Food Safety Trends

FDA's 10-year study of food safety risk factors in foodservice and retail food establishments suggest some significant progress has been made and calls attention to areas where further improvement is needed. Hear about the latest trends and how this information can be used to enhance industry and regulatory food safety programs.

*Kevin Smith, Director, Retail Food and Cooperative Programs Coordination, FDA/CFSAN*

#### 4:10 – 5:00 PM – Case Study: SE in Eggs Recall 2010

A rare opportunity to dissect the Salmonella outbreak of 2010 due to shell eggs. Hear about the cause, components, investigation, lessons learned, tangential impacts, feed, lab results, and agency policies established as a result of this major outbreak.

*David Elder, Director, Office of Regional Operations, FDA*

### MONDAY AFTERNOON DRUGS & MEDICAL DEVICES FORUM

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#### 3:20 – 4:00 PM – Proposed Changes to the 510(k) Review Process – An ORA Perspective

Mr. Arvelo will be discussing the ORA's perspective of Center proposed changes to the 510(k) review process for Medical Device approval. Medical products companies, along with state and federal regulators, will have an opportunity to obtain the latest information concerning the changes and the potential impact these changes will have on Medical Device regulation.

*David Arvelo, Small Business Representative, US Food & Drug Administration, Southwest Regional Office*

#### 4:00 – 5:00 PM – FDA Health Fraud Enforcement & Outreach: Bogus Claims to Tainted Supplements

US Consumers are bombarded with promotions for fraudulent and unapproved health products on the internet, on TV, radio, and in print ads. These products can pose serious health risks and may cause consumers to delay getting proper diagnosis and treatment for serious diseases. FDA efforts to combat fraudulent health products include taking regulatory and enforcement actions and by helping to educate consumers how to recognize and avoid health scams.

*Gary Coody, National Health Fraud Coordinator, FDA/OE*

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#### 5:45 PM – Boarding for Monday Night Event (6:00 PM Departure)

#### 7:00 – 10:00 PM – Monday Night Event: DALLAS...a Southfork Ranch Experience

The buses leave at 6:00 PM to take participants to the famed Ewing residence at the Southfork Ranch where they'll get a good old-fashioned Texas beef barbecue dinner, libations, music and dancing, tours of the ranch, and free admission to the Ewing Mansion and Southfork Museum.

Ticket includes round-trip transportation, dinner, entertainment, 2 drink tickets, tours and access to Southfork Museum

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## Accolades for AFDO 2011 Conference Monday Night Event Site

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The site of AFDO's Monday Night Event, the Southfork Ranch, was voted the **Most Unique Venue** in North Texas by the readers of *Texas Meetings and Events Magazine*. Monday Night Event tickets are available on the [AFDO Conference Registration Form](#) and cost \$50 per person. Your ticket includes round-trip transportation, a beef barbecue dinner, entertainment, 2 drink tickets, tours and access to the Southfork Museum.

For more information about AFDO's upcoming 115th Annual Educational Conference, please visit the [Conference Web page](#).

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## TUESDAY, JUNE 21, 2011

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7:30 AM – 5:30 PM – Registration

8:00 AM – 5:00 PM – IFPTI Poster Sessions

8:00 AM – 5:30 PM – Silent Auction

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### MORNING JOINT SESSION

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*Moderating: Angela Montalbano, Food Safety & Inspection, New York State Department of Agriculture & Markets*

#### 8:00 – 8:30 AM – DHS Keynote

*Todd M. Keil, Assistant Secretary for Infrastructure Protection, Department of Homeland Security*

#### 8:30 – 9:00 AM – To Be Announced

#### 9:00 – 10:00 AM – Streamlining the FDA Enforcement Process

The FDA Commissioner approved a proposal to streamline the approval process for seizures and injunctions in the first step to streamlining FDA enforcement processes. Some of the actions entail moving from sequential review of cases to concurrent review, elimination of certain paperwork, accelerating time deadlines for internal approval of cases, and calling for collaboration between ORA, the Centers, and OCC at an early stage of case development. Implementing the reform will require fundamental business changes for FDA and will have direct impact on both the states and regulated industry. The presenters will discuss the effect of this streamlining endeavor and discuss outline plans for further improvement.

*Ralph Tyler, Chief Counsel, FDA*

*Howard Sklamberg, Director, Office of Enforcement, FDA*

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10:00 – 10:20 AM – Break & Separate to Desired Conference Tracks

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**TUESDAY MORNING FOOD SESSION**

*Moderating: Angela Montalbano, Food Safety & Inspection, New York State Department of Agriculture & Markets*

**10:20 – 10:50 AM – CFIA Keynote**

*Cameron Prince, Vice President of Operations, Canadian Food Inspection Agency*

**10:50 – 11:20 AM – Meat Import Issues and Trends**

What is the process used by FSIS to allow meat to be imported? Can China import meat into the US? How does FSIS verification of a country's equivalency take place? Do market forces impact exports? What are the trends? These and answers to many more questions are explored.

*Ron Jones, Assistant Administrator for International Programs, USDA*

**11:20 AM – Noon – The Integrated Food Safety System**

An update on the progress made to date in establishing a fully integrated food safety system.

*Steven M. Solomon, DVM, MPH, Assistant Commissioner for Compliance Policy, Office of Regulatory Affairs, FDA*

**Noon – 1:00 PM – Lunch (on your own)**

**TUESDAY AFTERNOON FOOD SESSION**

*Moderating: Susan Parachini, Colorado Department of Public Health & Environment*

**1:00 – 1:40 PM – Ingredient Supplier Control & Verification – How Do We Know It's Safe?**

Strategies used by food companies to assure their suppliers/vendors provide safe food ingredients; the differences between imported and domestic supplies and ways to comply with the new supplier verification requirements for importers.

*Mark A. Moorman, Ph.D., Senior Director, Food Safety & Sanitation, Kellogg Company*

**1:40 – 2:15 PM – FDA's Food Safety International Technical Assistance/Capacity Building Strategies & Activities**

A review of FDA's strategy and approach to assist the international food safety community in efforts to improve the safety of the global supply chain and to fulfill its obligations under the WTO-SPS Agreement

*Elizabeth M. Calvey, Ph.D., Team Leader, Liaison & Partnership Team, FDA/CFSAN*

**2:15 – 2:35 PM – Break**

**2:35 – 3:35 PM – Federal/State Relations**

Much is happening in Federal-State Relations. Hear about opportunities to engage in the activities that impact and strengthen food safety programs.

*Joseph Reardon, Director, Division of Federal-State Relations, FDA*

**3:35 – 4:25 PM – New Efforts in Training & Development**

This panel will present important perspectives about the latest training efforts being taken at FDA and FSIS to support capacity-building and the integration of the food safety system.

*Allan Bateson, Ph.D., Statistician/Psychometrician, Division of Human Resource Development, FDA*

*Jim Fear, Manager, State Training, FDA*

*Ronald K. Jones, DVM, Office of International Affairs, USDA/FSIS*

**4:25 – 5:00 PM – Environmental Health Specialists Network (EHS-Net) Research Update**

EHS-Net is a collaborative forum identifying and preventing environmental factors contributing to foodborne/waterborne illness and disease outbreaks.

This update will provide the latest findings from research regarding retail food-handling practices.

*Carol Selman, MPH, Senior Public Health Advisor & Team Leader, National Center for Environmental Health, Centers for Disease Control & Prevention*

**TUESDAY MORNING DRUGS & MEDICAL DEVICES FORUM**

*Moderating: Dennis Baker, FDA Southwest Region*

**10:20 – 10:25 AM – Welcome & Announcements**

**10:25 – 11:30 AM – Future of Medical Products Regulation**

Panel Discussion – FDA District and Regional Directors

*Renaldo "Ricky" Rodriguez, Jr. Director, Dallas District, FDA (Devices)*

*Mark Rob, Director, Pacific Region, FDA (Vet Medicine)*

*Diana Amador-Toro, Director, New Jersey District, FDA (Drugs)*

*Evelyn Bonnin, Director, Baltimore District (Biologics)*

*Kim Young, Deputy Director, Division of Compliance, FDA/CVM (Veterinary Products)*

*Steven Silverman, Director, Office of Compliance, FDA/CDRH (Devices)*

**11:30 AM – 12:10 PM – Medical Devices in Canada**

An overview of the requirements for the sale, importation and post-market reporting of medical devices in Canada

*Chris Rose, Manager, Medical Device Compliance Unit, Health Products & Food Branch Inspectorate*

**12:10 – 1:30 PM – Haunted by Your Words: How to Avoid Mistakes that Destroy Your Credibility**

Working lunch presentation sponsored by Sparta Systems, Inc.

\*Ticket included for Drug & Medical Device Forum Registrants only\*

*Nancy Singer, Compliance-Alliance, former prosecutor US Department of Justice*

*Virginia Connelly, Director of Investigations, Cincinnati District, FDA*

*Marla Phillips, Xavier University*

**TUESDAY AFTERNOON DRUGS & MEDICAL DEVICES FORUM**

*Moderating: David Arvelo, FDA Southwest Region*

**1:30 – 2:15 PM – The Freedom of Information Act: Behind-the-Scenes Views from FDA & Industry**

Procedures and techniques for successful submissions

*Marlene Bobka, Vice President, FOI Services*

*Frederic J. Sadler, Director, FDA Freedom of Information Staff, FDA (Mr. Sadler's remarks will be presented by Ms. Bobka)*

**2:15 – 3:00 PM – Global Supply Chain Security/Protection**

Well-organized criminal groups pose an ongoing challenge to the security of the global supply chain. Cooperation, communication, and coordination between the private sector and the public sector is required to effectively address this challenge. Precisely how this objective is achieved will be discussed in this segment.

*Tom Kubic, Executive Director, Pharmaceutical Security Institute*

**3:00 – 3:20 PM – Break**

**3:20 – 4:20 PM – Interactive Session: Writing CAPA Procedures & Documents to Reflect Compliance Initiatives**

During this session, attendees will benchmark best practices and determine who in a firm should open a CAPA, how to determine the threshold of when to open a CAPA and how to apply the definitions for correction, corrective action and preventive action.

*Tim Mobn, Industry Principal, Sparta Systems, Inc.*

*Javad Seydedzad, Senior Vice President, Global Quality Assurance & Regulatory Affairs, Gambro*

*Paul A. Arrendell, Vice President, Global Quality, Kinetic Concepts, Inc.*

*Virginia Connelly, Director of Investigations, FDA/Cincinnati District*

**4:20 – 5:00 PM – FDA Top 10 483 Observations**


The Speakers will present a review of the Top 10 observations cited by FDA Investigators in Turbo EIR (the FDA inspectional software) during the years 2006 through 2010 for both Medical Device firms and Pharmaceutical firms. The review will identify areas of concern that have continued across several years that, hopefully, can be addressed through education and outreach efforts.

*Ricki Chase, Director of Investigations, FDA Chicago District*

*Regina Barrell, Senior Case Review Expert, Division of Compliance Management & Operations, Office of Enforcement, FDA*

**5:30 PM – Silent Auction Closes**

**6:30 – 7:30 PM – President's Reception – all are invited to attend!**

**7:30 PM – Wiley Award Banquet** 

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## WEDNESDAY, JUNE 22, 2011

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*Moderating: Stephen D. Stich, Director, New York State Department of Agriculture & Markets*

### 8:00 – 8:30 AM – Department of Homeland Security Initiatives

Hear about the latest Food and Agriculture Sector-specific initiatives at the Department of Homeland Security and how they impact all who work in this sector.

*John D. Martin, DVM, Food & Agriculture Lead Sector Infrastructure Analyst, DHS*

### 8:30 – 9:00 AM – Emerging FSIS Policies

Dr. Jones will look at emerging regulatory strategies and discuss how they reflect evolving public health imperatives, new technologies, improving agency capabilities, and industry trends.

*Ronald K. Jones, DVM, Office of International Affairs, USDA/FSIS*

### 9:00 – 9:45 AM – Maple Leaf's Food Safety Journey: Step Changing Environmental Pathogen Control Program Post-2008 Listeriosis Outbreak

In August 2008 *Listeria monocytogenes* was found in products manufactured by Maple Leaf which resulted in a Listeriosis outbreak that claimed the lives of 23 Canadians. The presentation will focus on the journey Maple Leaf took to develop a more effective pathogen control program, including sharing the key success drivers and other learning that enabled the company to step change its food safety performance.

*Steve Tsuyuki, Senior Director for Food Safety, Maple Leaf Consumer Foods*

### 9:45 – 10:05 AM – Break

### 10:05 – 10:20 AM – Directory of State & Local Officials (DSLO) – A Newly Improved Tool Supporting Communication & Integration

Interactive presentation on the new AFDO portal designed to give the user quick access to information and listings of state and local officials.

*Leigh Ann Stambaugh, Senior Administrative Specialist & Grants/IT Coordinator, AFDO*

### 10:20 – 10:35 AM – CoreSHIELD

A Common Organizational Registry Environment for enhanced information sharing within Food and Agriculture.

*William R. Krueger, Food & Agriculture Sector Specialist, Department of Homeland Security*

### 10:35 – 11:05 AM – AFDO Business Meeting

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Visit [www.afdo.org](http://www.afdo.org) for the latest program & event information.

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## EXHIBIT & SPONSORSHIP OPPORTUNITIES

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**Exhibit:** Exhibit space is \$950 for a 6' x 8' space for up to four (4) days presence at the conference. Exhibit space will be in the Trinity Foyer immediately adjacent to the conference meeting space.

**Sponsor:** Sponsorship opportunities exist for several high-visibility events such as the President's Reception and continental breakfasts, full sponsorships ranging from \$525 to \$5,000. Partial sponsorships are also available.

#### Benefits of Hosting an Exhibit or Sponsoring an Event:

- Networking opportunities and exposure for your organization
- Unique opportunity for you to reach out to both the Regulatory and Industry communities
- Extending your marketing return
- Increase your visibility by setting you apart from your competitors
- Your company's name and logo will appear in the conference program with the event your company will be sponsoring as well as on-site placards at the event

Information will be posted on AFDO's website listing sponsors and a link can be provided directly to your company's website

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## AFDO SILENT AUCTION

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Opens Sunday, June 19<sup>th</sup>, at Noon

Closes Tuesday, June 21<sup>st</sup>, at 5:30 PM

You will find almost every imaginable item. You will have the opportunity to silently bid on as many items as you desire, and to bid as often as you like in this fun and competitive event.

**Please check with the staff at the AFDO registration desk if you wish to donate items. Help make this year's Silent Auction a huge success by donating a souvenir, keepsake gift or novelty item, or by bidding on items in the Auction. All proceeds of this Auction will benefit the AFDO Scholarship Fund.**

# 2011 AFDO ANNUAL EDUCATIONAL CONFERENCE REGISTRATION FORM

Please complete and return this form with credit card or check payable to: AFDO

2550 Kingston Road, Suite 311, York, PA 17402 • 717-757-2888 (PHONE) • 717-650-3650 (FAX) • afdo@afdo.org

## PERSONAL INFORMATION

Full Name \_\_\_\_\_

Title \_\_\_\_\_

Badge Name (as you desire it to appear on your name badge) \_\_\_\_\_

Organization \_\_\_\_\_

Address \_\_\_\_\_

City, State, Zip \_\_\_\_\_

Phone \_\_\_\_\_ Email \_\_\_\_\_

How did you learn of this Conference? \_\_\_\_\_

First-time attendee?  Yes /  No

I would like to serve as a Mentor to First-Time-Attendees:  Yes /  No

Will your spouse/children/guest be attending?  Yes /  No Spouse/Guest's Name \_\_\_\_\_

Children's Name(s) \_\_\_\_\_

 Please indicate any special needs (i.e., diet, adaptive meeting rooms, etc.) \_\_\_\_\_

I am a/an (please check ALL that apply):

AFDO Member

Conference Speaker

Exhibitor

MCAFDO Member

Workshop Speaker

Sponsor

## CONFERENCE REGISTRATION (DOES NOT INCLUDE WORKSHOP REGISTRATION/MATERIALS)

Please select session registering for (please select only one):  Food General Sessions  Drugs & Medical Devices Forum  
(Attendees are permitted to participate in presentations in either track, with exception of Tuesday working lunch which is limited to D/D registrants)

Please select one of the following:

AFDO and/or MCAFDO Member .....\$425.00

Speaker attending (1) day ONLY .....\$0.00

Non-Member .....\$525.00

Exhibitor COMPLIMENTARY (limit 1).....\$0.00

Alumni/Honorary Member .....\$175.00

Exhibitor HALF-PRICE (limit 2) .....\$ \_\_\_\_\_

Spouse/Guest/Child Registration ..... # \_\_\_\_ @ \$ 25.00

REGISTRATION SUB-TOTAL \$ \_\_\_\_\_

## DAILY CONFERENCE REGISTRATION

AFDO and/or MCAFDO Member .....\$225.00

List Day(s): \_\_\_\_\_

Non-Member .....\$275.00

DAILY SUB-TOTAL \$ \_\_\_\_\_


## PRE-CONFERENCE IFPTI SPONSORED WORKSHOP REGISTRATION (DOES NOT INCLUDE CONFERENCE REGISTRATION/MATERIALS)

Register for Workshop ..... \$75.00 WORKSHOP

SUB-TOTAL \$ \_\_\_\_\_

## SPECIAL EVENT TICKETS Please indicate # desired - events are NOT included in the registration fee and may not be available on-site

 Burditt Luncheon ..... # \_\_\_\_ @ \$30.00

 Wiley Award Banquet ..... # \_\_\_\_ @ \$50.00

 Monday Night Event: Dallas/Southfork ... # \_\_\_\_ @ \$50.00

SPECIAL EVENTS SUB-TOTAL \$ \_\_\_\_\_

LATE CHARGE Conference/Workshop Registration Postmarked After May 24, 2011 = \$100.00

LATE CHARGE \$ \_\_\_\_\_

## TOTAL

TOTAL DUE \$ \_\_\_\_\_

## METHOD OF PAYMENT

-Check enclosed  -Please charge my  MasterCard /  Visa

Amount \$ \_\_\_\_\_

Name on Card \_\_\_\_\_

Card Number \_\_\_\_\_ Expiration Date \_\_\_\_\_

Billing Address \_\_\_\_\_

City \_\_\_\_\_ State/Zip \_\_\_\_\_

CANCELLATION Cancellations with refund (less \$50 processing fee) will be accepted through close of business May 24, 2011. Effective May 25, 2011, substitutions will be permitted without penalty.

AFDO Tax ID #: 74-6051887