"This is a take-off on the real-estate adage, location, location, location… FSMA, FSMA, FSMA," stated Landa in his opening remarks, while describing the key activities in CFSAN for 2011. Not surprisingly, CFSAN devoted significant resources to the implementation of The Food Safety Modernization Act (FSMA) in 2011 and will continue to do so for many years to come. Landa characterized 2011 FSMA progress and activities as "intake", described as listening to various audiences to understand how best to carry out the Act. "He was always alive to the possibility of learning something new from someone," said Landa, quoting a Brazilian philosopher and "we should do intake with that spirit in mind."

Landa gave an update on FSMA progress highlighting key rules in the pipeline, including: preventive controls for human food and animal feed; produce safety standards; the proposed rule to specify foreign supplier verification activities; and a proposed rule that will allow FDA to accredit expert organizations to certify third party auditors. The preceding rules are the furthest along and in the final stages of Administration review noted Landa, while third party accreditation is still at FDA.

Turning to the N in CFSAN, Landa discussed the Center's progress on nutrition-related priorities, including: last year's proposed rules on vending machine and menu labeling as required by the health reform law; the final rule on infant formula; gluten-free labeling; and continuing efforts to reduce sodium in the food supply. Finally, Landa described CFSAN's third priority for 2012 as "keeping it healthy for the future," which encompasses the development of new leaders and a continuing effort to fill key positions within the Center.

Boeckman's response focused on FSIS' new generic food labeling program. Engeljohn explained the benefits of the new generic labeling program that allows labels to be generally approved. Under the previous program all individual labels had to be cleared through a pre-approval process with an average delay of 25-26 days. Under the generic program, only those with a claim will be required to undergo the pre-approval process prior to sale and will therefore provide considerable relief to industry.

Corbo voiced his frustrations regarding progress under FSMA, highlighting OMB's handling of key rules and agency funding as key impediments. "We can't continue to saddle this agency with mandates that it cannot implement without the proper resources," stated Corbo.

"Is there authority that you would have liked to have seen that FSMA didn't grant?" asked Degnan in a final question. "Until such times as new obligations come with new money.. I am not interested…I don't like seeing on the books, with maybe rare exceptions, laws that the government… doesn't have a ghost of a chance of enforcing," responded Landa.

Center for Biologics Evaluation and Research

By Davina Rosen, Conference Manager, Medical Products and Tobacco Team Member

"It is pretty easy to think of CBER [FDA's Center for Biologics Evaluation and Research) as a relatively small actor in the whole FDA healthcare area," said Stephen Paul Mahinka, Partner, Morgan, Lewis & Bockius, during a break-out session of CBER. In reality, "CBER is going to have a tremendous impact on the range of products, far more than it has had in the past."

Diana A. Maloney, Associate Director for Policy at CBER, outlined a four-year plan of strategic goals for the center. They include emergency preparedness for bioterrorism and pandemic influenza; global public health in collaboration with the World Health Organization; safety of biologic products; and facilitation of product development.

CBER has created innovative systems to meet its goals. Mary A. Malarkey, Director, Office of Compliance and Biologics Quality, CBER, explained that the Center uses a Directory Call Classification System to combine data from biological product deviation reports to classify product recalls.

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[Featured above] Diane M. Maloney, Associate Director for Policy, CBER, FDA, delivers a presentation on CBER's goals for the coming year.

In 2011, CBER received 120-140 investigational new drug applications (IND), primarily for cell therapies.

CBER relied on draft guidance doucments to communicate its IND findings to the public. Dr. Celia M. Witten, Director, Office of Cellular, Tissue and Gene Therapies, CBER, elaborated that guidance documents are necessary to communicate "to the research and industrial community what [CBER's] expectations are." Mr. Mahinka called for CBER to release guidance documents this year to clarify issues in personalized medicine and biosimilars.

Kay Holcombe, Senior Policy Advisor at Genzyme and Director of FDLI, closed the session by expressing concern to CBER about shortages in the vaccine drug supply. Malarkey responded that CBER "remain[s] vigilant," being actively engaged with the Center for Drug Evaluation and Research to identify and address shortage issues.

Deyton Reviews CTP Progress

By Jennifer Kane, Editor, Medical Products and Tobacco Team Member

"We need to build a similar kind of familiarity with the regulatory process and how to work with FDA," Lawrence Deyton, MSPH, MD, Director, Center for Tobacco Products (CTP), FDA, explained, comparing the relationship with the newly FDA-regulated tobacco community with the industries long regulated by FDA's other product centers.

During the April 24, 2012 Center Director roundtable, Deyton presented an update from CTP on a panel that also included respondents James E. Dillard III., Senior Vice President, Altria Client Services, Inc., Nancyellen Keane, Of Counsel, Troutman Sanders LLP, and Matthew L. Myers, President, Campaign for Tobacco-Free Kids. Mark S. Frankel, PhD, Director, Program on Scientific Responsibility, Human Rights and Law, AAAS, moderated the discussion.

Deyton reviewed CTP's progress since the establishment of the Center in 2009, including a significant increase in the number of staff at the Center added throughout the implementation period since the Family Smoking Prevention and Tobacco Control Act ("the Act") was passed. Deyton discussed the challenges of developing the regulatory and compliance framework that the Act requires, both as implemented directly from the statute and as issued in selected regulation and guidances from the Center.

Deyton highlighted recent FDA tobacco product regulations, including: the established list of 93 harmful and potentially harmful constituents in the March 2012 issued draft guidance; draft guidance on submitting applications for modified risk tobacco products (MRTPs), also issued in March 2012; and the aggressive compliance program currently underway to enforce all regulatory requirements. Finally, Deyton also spoke about ongoing public education campaigns, emphasizing the importance of individuals from all sectors learning how to work with FDA and how the regulatory process works, a key part of public education campaigns. Deyton emphasized the importance of frequent communication with the agency.