

2013-2014 AFDO FINAL COMMITTEE REPORT

Drugs, Devices and Cosmetics Committee

***Chair:** Thomas Brinck, Texas Department of State Health Services, Austin, TX

Chair: Dennis Baker, U.S. Food & Drug Administration, Southwest Region, Dallas, TX

Charge 1: Plan and identify important topics, and secure presenters for the DDC program at the annual conference.

Discussion: The Drugs, Devices and Cosmetics (DDC) Committee conducted a number of annual educational conference (AEC) planning calls beginning in August 2013 in order to solicit topics and themes for the upcoming AEC. Based upon these initial conference calls, the DDC Committee established its intent to develop the 2014 DDC Program using a format similar to the one used previously at the 2013 AEC. The 2013 DDC Program consisted of a two-day drug and medical device session running concurrently with the AFDO food-related session. The Committee decided that the 2014 DDC Program should be developed under a co-sponsorship agreement with the FDA Denver District Office and the Rocky Mountain Regulatory Affairs Society. Advertising for the program would be accomplished through the use of several methods that have previously been found to be effective, including direct mail notifications (e.g., postcards), email distribution lists and a notice in the Federal Register (FR). The Committee worked closely with the AFDO Project Specialist in developing relevant topics and presenters for the 2014 DDC Program and continued its efforts to finalize the program agenda using a number of additional conference calls during the fall of 2013 and spring of 2014. The Committee reached out to its associate and international members and to the FDA Denver District Director for assistance with program development, including tasks associated with approval of the co-sponsorship agreement, posting of the FR notice and identification of potential speakers and attendees for the 2014 DDC Program. The Committee has benefited greatly from the involvement of the FDA Denver District Office this year and considers this co-sponsorship relationship to be a major factor in the success of its programs during the past few years. As a result of its planning conference calls, the Committee identified the theme of its 2014 program to be "FDA and Global Engagement – Progress on the Pathway to Global Product Safety" and ultimately this theme was incorporated into AFDO's co-sponsorship agreement with FDA. During subsequent conference calls, appropriate topics were chosen and presenters were confirmed. The Committee attempted to secure presenters representing both FDA and regulated industries. Email and direct mail notifications were sent out with the assistance of the AFDO Office and the FDA Denver District Office.

Recommendation: Charge completed. Create a new charge to direct the DDC Committee to identify and develop similar objectives for next year's annual educational conference.

Executive Committee Action:

Approval



Disapproval



Date

6/2/14

Charge 2: Beginning in March, solicit mentors for First-Time Attendees for the Drug & Device Forum of the Conference, and provide volunteers to Membership Committee Chairs and the AFDO Office.

Discussion: Throughout the year, the Committee solicited assistance from its members to actively participate in AEC planning activities, including the engagement and mentoring of first-time attendees. A number of members volunteered to assist with onsite preparations and logistical support and would be willing to reach out and mentor first time attendees at the Drug & Device Forum. In addition, these individuals stand ready to offer their support to Membership Committee Chairs and the AFDO Office. The names of these mentors and volunteers are available to the AFDO Office upon request.

**Responsible for submission of reports*

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Recommendation: Charge completed. Create a new charge to direct the DDC Committee to identify and develop similar objectives for next year's annual educational conference.

Executive Committee Action:

Approval

Disapproval

Date

6/2/14

Charge 3: Advise AFDO Board of recommendations for increasing AFDO participation with drugs, devices, and cosmetics.

Discussion: The DDC Committee discussed this charge during several conference calls in the fall of 2013. A number of recommendations have been communicated to the AFDO Office this year via its Project Specialist and to the Board. Recommendations to improve the quality and access to DDC-relevant information on AFDO's website resulted in a dedicated DDC web page during the fall of 2013. In addition, our efforts to improve the visibility of AFDO's DDC membership resulted in the creation of an AFDO DDC conference banner and its subsequent display by one of our members at an exhibitor's booth at the University of Georgia Medical Device Regulations Conference in November 2013. This event, held in Athens, Georgia, was co-sponsored with the FDA and involved a comprehensive one-day conference convening leaders and specialists in the fields of bio-design, in-vitro diagnostics, medical devices, combination products, and biotechnologies. Finally, at the request of the AFDO Executive Director, members of the DDC Committee organized a Subcommittee on Body Art (Tattoo and Body Piercing) this year in order to identify some of the significant regulatory issues affecting the growth in that industry, including suggestions for how AFDO may become more involved with developing guidance documents related to Body Art.

Recommendation: Charge completed. Create a new charge to direct the DDC Committee to provide similar recommendations for next year.

Executive Committee Action:

Approval

Disapproval

Date

6/2/14

**Responsible for submission of reports*