FDA Annual NTTAA Report Questions – FY 2010

Question 1: *Please describe the importance of standards in the achievement of your agency's mission, how your agency uses standards to deliver its primary services in support of its mission, and provide any examples or case studies of standards success. Please include relevant Internet links and links to your agency's standards website.*

The development and use of standards have been integral to the execution of the mission of FDA since its establishment. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA staff has historically participated in a range of standard setting activities outside the Agency. As noted in 21 CFR 10.95 (a), "FDA encourages employee participation in outside standard-setting activities that are in the public interest."

Standards developed through interactions with various standard development bodies, including voluntary consensus standard organizations and or industry consortia, can provide benefit to both the Agency and our stakeholders in multiple ways such as:

- Standards can assist reviewers with assessment of product applications;
- Standards often result in better utilization of limited internal resources;
- International standards can be used by multiple regulatory regions, following our legal mandate to facilitate harmonization on an international level; and
- Direct participation by various stakeholders in development of standards results in a consensus among users, manufacturers and government regulators on safety and effective use of regulated products.

For more information about standards in the achievement of FDA's mission, please see: http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm193332.htm

Question 2: *Please list the government-unique standards your agency used in lieu of voluntary consensus standards during FY 2010:*

FDA has introduced no new government unique standards (GUS) in FY 2010. The standard reported in 2009 is repeated here. The International Organization for Standardization (ISO) has a standard that defines some general requirements for aseptic processing of health care products (ISO 13408-1) which FDA is not using. Instead, FDA is using the FDA guidance on Aseptic Processing (revised and reissued in 2004). FDA is not using the ISO standard because the applicability of these requirements is limited to only portions of aseptically manufactured biologics and does not include filtration, freeze-drying, sterilization in place, cleaning in place, or barrier-isolator technology. There are also significant issues related to aseptically produced bulk drug substance that are not included in the document.

Question 3: *Please list the voluntary consensus standards your agency substituted for Government Unique Standards (GUS) in FY 2010 as a result of review under section 15(b)(7) of OMB Circular A-119:*

There were no new standards substituted for regulation in 2010.

Question 4: *Please provide the total number of Voluntary Consensus Standards your agency began to use during FY 2010. Optional: If possible, also please provide the total number of Non-consensus Standards that are developed in the private sector your agency began to use during FY 2010. In addition, please provide your agency's rationale for using the Non-consensus Standards that are developed in the private sector counted in this question.*

Standards are cited by our regulated industry as part of their submissions to meet regulatory requirements for product entry into trade and/or to meet their requirements under the Good Manufacturing Practice regulations. FDA has no means to ascertain the number of standards that should be included here. Please also note our response to Question 5. The majority of these organizations and, therefore, the standards they develop, are not "consensus" using the ANSI and WTO definitions.

Question 5: *Please enter the Voluntary Consensus Standards Bodies (VCSB) in which your agency participated in during FY 2010:*

Voluntary Consensus Standards Bodies: 163. A list of SDOs is also provided in the complementary attachment.

Question 6: *Please provide the total number of your agency's representatives who participated in voluntary consensus standards activities during FY 2010 and the total number of activities these agency representatives participated in:*

Number of individuals who represent FDA: 584.
Number of Activities: 886

Question 7 :*Please provide any conformity assessment activities (as described in "Guidance on Federal Conformity Assessment Activities" found in the Federal Register, Volume 65, Number 155, dated August 10, 2000) in which your agency was involved in FY 2010.*

Conformance activities are conducted under applicable regulations and guidance. Standards may become part of conformance activities as they may provide an acceptable approach to be in compliance with applicable laws and regulations.

Question 8: *Please provide an evaluation of the effectiveness of Circular A-119 policy and recommendations for any changes:*

FDA policy is to develop and use voluntary consensus standards wherever possible in the management of risks for the products we regulate. FDA supports the letter and spirit of the NTTAA and the OMB Directive.

Question 9: *Please provide any other comments you would like to share on behalf of your agency.*

None

Question 10: *Please use this box to provide any additional comments on how your agency currently reports its use of voluntary consensus standards.*

> ***Question 10.1****: No Question listed*
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> ***Question 10.2:*** *No Question listed*
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> ***Question 10.3:*** *No Question listed*
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> ***Question 10.4:*** *Does your agency report standards that it uses for guidance purposes (as opposed compliance purposes)? (a) Yes; (b) No; (c) Not applicable?*
>
> (a) Yes
>
> ***Question 10.5*** *Does your agency report use of standards from non-ANSI accredited standards developers, industry consortia groups, or both? (a) non-ANSI Accredited; (b) Consortia; (c) Both; (d) Neither; or (e) Not applicable?*
>
> (c) Both
>
> ***Question 10.6*** *Does your agency have a schedule for periodically reviewing its use of standards for purposes of updating such use? (a) Yes; (b) No*
>
> Three times a year the agency reviews standards activities, including any standards as needed, within its FDA Standards Committee.
>
> ***Question 10 .7*** *How often does your agency review its standards for purposes of updating such use? [enter the number of years]*
>
> Three times a year the agency reviews standards activities, including any standards as needed, within its FDA Standards Committee.