DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

April 18, 2014

TO: Center Director, Center for Tobacco Products (CTP)

FROM: Deputy Director, CTP

SUBJECT: Establishing Four CTP Performance Measures

Since 2009, CTP has worked to create a regulatory framework to oversee the manufacture, sale, and distribution of tobacco products.

To accomplish consistency, transparency, and predictability in its review of tobacco products, CTP has developed a rigorous, science-based process for the work related to the review of new tobacco products and substantial equivalence (SE) reports and is continuing to improve the process to make it more efficient. CTP is now prepared to establish performance goals in four areas to establish another transparent accountability mechanism.

The creation of regulatory performance goals has been built on the premise that a start-up period (FY 2009 through FY 2014) was needed to hire and train new staff, and to build infrastructure. We are now in a position to establish an initial set of such goals, which will get more ambitious as we go forward.

As described in Attachment A, RADM David Ashley, Director of CTP's Office of Science, has established performance measures that include timeframes for the review phases for: 1) the regular SE review process; 2) the exemption from SE review process; and 3) the Modified Risk Tobacco Product review process.

Since it is also important for CTP to continue to ensure that we can learn from those who wish to meet with us, we are also establishing meeting management performance measures that apply to CTP as a whole, as follows:

Category	**Performance Goal**	**Submission Cohort** [1]
Meeting Management	Respond to meeting requests within 21 calendar days. [2,3]	FY15: 80% FY16: 80% FY17: 90% FY18: 90%

[1] Submission Cohort defined as original report received in that FY.

[2] Guidance for Industry and Investigators: Meetings with Industry and Investigators on the Research and Development of Tobacco Products, May 2012.
(http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm305279.htm)

[3] Responding means that CTP accepts or denies the meeting request. This performance goal refers only to requests from entities external to government (e.g. stakeholders and regulated industry). CTP Offices determine when a request is a formal meeting request. The request is not complete until the Office has enough information to make a decision.

All four of these performance measures apply for FY2015 through FY2018, and will be implemented beginning on October 1, 2014.

Conducting scientific reviews of product applications and meeting with external stakeholders are important aspects of the Center's work. Going forward, we will continue to strengthen and expand these processes, which will enable us to be well positioned to meet more ambitious performance standards in the future.

Richard J. Turman

Attachment A