**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
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April 18, 2014

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

FROM: Director, Office of Science

SUBJECT: Establishment of Performance Measures

CTP, Office of Science has established performance measures that include timeframes for the review phases within the substantial equivalence (SE), exemption from SE review, and modified risk tobacco product (MRTP) applications processes. The Office of Science will implement these performance measures for regular SE reports, exemption from SE requests and MRTP applications by October 1, 2014. Implementation in this context means that the Office of Science will start monitoring the time it takes to review and act on regular SE reports, exemption from SE requests, and MRTP applications received on or after October 1, 2014. The interim time between now and October 1, 2014, will be used to develop tracking systems for monitoring progress in meeting the performance goals.

Regulatory Performance Measures

**Substantial Equivalence Reports for products currently regulated by FDA (cigarettes, cigarette tobacco, smokeless tobacco, roll-your-own tobacco)**

| **Category** | **Performance Goal** | **Submission Cohort[1]** |
|---|---|---|
| Regular SE Reports | Finalize jurisdiction and completeness review (and issue letter as appropriate) within 21 days of FDA receipt [2] of SE Report | FY15: 50%<br>FY16: 60%<br>FY17: 70%<br>FY18: 80% |
| | Review and act on an original SE Report within 90 days of FDA receipt | FY15: 50%<br>FY16: 60%<br>FY17: 70%<br>FY18: 80% |
| Regular SE Report Resubmissions[3] | Review and act on a SE Report resubmission within 90 days of FDA receipt | FY15: 50%<br>FY16: 60%<br>FY17: 70%<br>FY18: 80% |

[1] Submission Cohort defined as original report received in that FY.
[2] Official receipt by CTP Document Control Center
[3] A "Resubmission," is a complete response to FDA's Scientific Advice and Information Letter or Preliminary Finding letter.

**Exemption from SE Requests for products currently regulated by FDA (cigarettes, cigarette tobacco, smokeless tobacco, roll-your-own tobacco)**

| Category | Performance Goal | Submission Cohort |
|---|---|---|
| Exemption from SE[4] | Review and act on a Request for Exemption from SE within 60 days of FDA receipt | FY15: 50%<br>FY16: 60%<br>FY17: 70%<br>FY18: 80% |

**Modified Risk Tobacco Product Applications for products currently regulated by FDA (cigarettes, cigarette tobacco, smokeless tobacco, roll-your-own tobacco)**

| Category | Performance Goal | Submission Cohort |
|---|---|---|
| MRTPA[5] | Review and act on a complete MRTP application within 360 days of FDA receipt | FY15: 50%<br>FY16: 60%<br>FY17: 70%<br>FY18: 80% |

Several terms were used in the regulatory performance measures listed above. A brief explanation follows:

- "Review and act on" means issuance of a letter (e.g., Scientific Advice and Information Letter, Preliminary Finding Letter, NSE or SE Order) after the review of an accepted regular SE report or resubmission; issuance of an order or letter after the review of an exemption from SE request; or the issuance of an order or letter after the complete review of a filed MRTPA application. This timetable for MRTPAs is FDA's best estimate, but it is based on limited information.
- "Issue letter as appropriate" means the issuance of an Acknowledgement Letter or Refuse to Accept Letter. If acknowledged, and the administrative review notes missing information, the information will be addressed during scientific review.
- Scientific Advice and Information Letter or Preliminary Finding Letter means a written communication which lists deficiencies in a SE Report that preclude either further scientific review or issuance of an SE Order.

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[4] As of December 31, 2013, FDA had received 59 Exemption from SE Requests. FDA had issued Refusal to Accept (RTA) letters for 22 of the 59 Exemption from SE Requests received because the manufacturers did not meet the requirements for such an exemption.

[5] As of December 31, 2013, CTP had received seven MRTP applications. CTP refused to file/accept for a substantive review six of the seven applications because they failed to include information required under the Act and/or were about products that CTP does not currently regulate. One application was withdrawn by the manufacturer.