Item descriptor *Note:* The description must match by model number or a broader descriptor that does not necessarily need to be company specific	Date of initial or subsequent BIS classification (ID = initial date; SD = subsequent date)	Date when the item will be designated EAR99, unless reclassified in another ECCN or the 0Y521 classification is reissued	Item-specific license exception eligibility
* * * * * * *			
0E521. Technology.			
No. 1 "Technology" required for the "development" or "production" of 0A521 No. 1 items.	August 8, 2016 (ID) ...	August 8, 2017	License Exception GOV under §740.11(b)(2)(ii) only.

Dated: July 25, 2016.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2016–18070 Filed 8–5–16; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA–2016–N–1170]

Standard Preparations, Limits of Potency, and Dating Period Limitations for Biological Products; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of September 16, 2016, for the final rule that appeared in the **Federal Register** of May 4, 2016. The direct final rule amends the general biological products standards relating to dating periods and removes certain standards relating to standard preparations and limits of potency. FDA is taking this action to update outdated requirements, and accommodate new and evolving technology and testing capabilities without diminishing public health concerns. This action is part of FDA's retrospective review of its regulations in response to an Executive order. This document confirms the effective date of the direct final rule.

DATES: Effective date of final rule published in the **Federal Register** of May 4, 2016 (81 FR 26687), confirmed: September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 4, 2016 (81 FR 26687), FDA solicited comments concerning the direct final rule for a 75-day period ending July 18, 2016. FDA stated that the effective date of the direct final rule would be on September 16, 2016, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: Therefore, under the biological products provisions of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, and 264) and the drugs and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, and 381), and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended. Accordingly, the amendments issued thereby are effective.

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–18584 Filed 8–5–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1105

[Docket No. FDA–2016–N–1555]

Refuse To Accept Procedures for Premarket Tobacco Product Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a rule describing when FDA will refuse to accept a tobacco product submission (or application) because the application has not met a minimum threshold for acceptability for FDA review. Under the rule, FDA will refuse to accept a tobacco product submission, for example, that is not in English, does not pertain to a tobacco product, or does not identify the type of submission. By refusing to accept submissions that have the deficiencies identified in the rule, FDA will be able to focus our review resources on submissions that meet a threshold of acceptability and encourage quality submissions. FDA is issuing this action directly as a final rule because we believe there is little likelihood that we will receive any significant adverse comments opposing the rule given the specific deficiencies identified that will result in FDA's refusal to accept the submission.

DATES: This rule is effective December 21, 2016. Submit either electronic or written comments on this direct final rule by October 24, 2016. If we receive no significant adverse comments during the specified comment period, we intend to publish a confirmation document on or before the effective date by publication of a document in the **Federal Register**.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that