

TIMING AND TIPS— NEWLY DEEMED TOBACCO PRODUCT APPLICATIONS

*Presented by
Cristi Stark, M.S.
Associate Director for Science Policy
Office of Science, CTP, FDA)*

June 2016



FDA

CENTER FOR
TOBACCO
PRODUCTS

- Premarket Review of Newly Deemed Tobacco Products
- Timing: Premarket Submissions and Marketing of Newly Deemed Tobacco Products
- Helpful Reminders

PREMARKET REVIEW OF NEWLY DEEMED TOBACCO PRODUCTS

- As explained in the final deeming rule, newly deemed tobacco products are subject to premarket review requirements
- “New tobacco product” means any tobacco product not commercially marketed in the U.S. as of 2/15/2007; or any modification of a tobacco product where the modified product was commercially marketed in the United States after 2/15/2007
- A tobacco product is “grandfathered” if it was commercially marketed in the US on 2/15/2007

PREMARKET REVIEW OF NEWLY DEEMED TOBACCO PRODUCTS

- 3 pathways to market for “new tobacco products”:
 - 1) Premarket tobacco product application (PMTA);
 - 2) Substantial equivalence (SE) report; and
 - 3) SE exemption
- A predicate tobacco product (comparison product) for the SE pathway may be either:
 - A tobacco product commercially marketed in the U.S. as of 2/15/2007 or,
 - A tobacco product that FDA has previously determined to be SE and in compliance with the FD&C Act

TIMING: PREMARKET SUBMISSIONS AND MARKETING FOR NEWLY DEEMED TOBACCO PRODUCTS

- For newly deemed tobacco products that are on the market as of the effective date, August 8, 2016, FDA is providing two compliance periods, one for submission and FDA receipt of applications and one for obtaining premarket authorization.
- FDA does not intend to initiate enforcement action against such products for failure to have premarket authorization during these respective compliance periods.

TIMING: PREMARKET SUBMISSIONS AND MARKETING FOR NEWLY DEEMED TOBACCO PRODUCTS

- Premarket applications for new, newly deemed tobacco products can be submitted and received by FDA starting on the effective date of the rule
- The staggered compliance period for submission and FDA receipt of applications under the 3 premarket pathways is as follows:
 - SE Exemption requests - 12 months from the effective date of this final rule
 - SE Reports - 18 months from the effective date of this final rule
 - PMTAs - 24 months from the effective date of this final rule

TIMING: PREMARKET SUBMISSIONS AND MARKETING FOR NEWLY DEEMED TOBACCO PRODUCTS

- Unless FDA has issued an order denying or refusing to accept the submission, newly deemed tobacco products for which timely premarket submissions have been submitted will be subject to a continued compliance period for up to 12 months after the initial compliance period
- Compliance period closes:
 - Exemption requests - 24 months from the effective date of this final rule
 - SE Reports - 30 months from the effective date of this final rule
 - PMTAs – 36 months from the effective date of this final rule

TIMING: PREMARKET SUBMISSIONS AND MARKETING FOR NEWLY DEEMED TOBACCO PRODUCTS

Unless the new, newly deemed tobacco product has received premarket authorization:	Applications received during the following timeframe qualify for a compliance period	Compliance period if a timely application was received	Date tobacco product will be subject to enforcement action if timely application not received	Date tobacco product will be subject to enforcement action if application was received
Grandfather tobacco product	Not required	N/A	N/A	N/A
SE EX Request pathway	08/8/16 – 08/8/17	08/8/16 – 08/8/18	08/9/17	Date RTA or a Found Not Exempt Order issues (if issued after 8/8/17), or If an order has not yet issued: 08/9/18
SE Report pathway	08/8/16 – 02/8/18	08/8/16 – 02/8/19	02/9/18	Date RTA or an NSE Order issues (if issued after 2/8/18), or If an order has not yet issued: 2/9/19
PMTA pathway	08/8/16 – 08/8/18	08/8/16 – 08/8/19	08/9/18	Date RTA, RTF, or NMO issues (if issued after 8/8/18), or If an order has not yet issued: 8/9/19

HELPFUL REMINDERS

- All premarket submissions are considered regulatory correspondence and must be received by the CTP DCC at the following address:
Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center
Building 71, Room G335
Silver Spring, MD 20993-002
- We are unable to accept regulatory submissions by electronic mail.
- FDA staff are unable to deliver regulatory documents to the CTP DCC on behalf of any applicant

HELPFUL REMINDERS

- If a submission has a due date that falls on a weekend or holiday, it is to be received by the CTP DCC on or prior to that date:
 - CTP encourages electronic submissions via the Electronic Secure Gateway (ESG) in which submissions can be received 24 hours a day, 365 days of the year.
 - If delivering physical mail, use the CTP mailing address. Delivery hours are 8am – 4pm. Deliveries received after 4pm will be date stamped as received the next business day.

HELPFUL REMINDERS

- It is recommended you submit your application well in advance of the compliance period timelines:
 - If you receive a RTA*, RTF**, or negative order, you can submit the application again. If the resubmitted application is received prior to the compliance period for submission and FDA receipt of applications, FDA does not intend to initiate enforcement for failure to have premarket authorization during the continued compliance period.
- You may submit an application for a new tobacco product under multiple pathways

*RTA = refuse to accept letter

**RTF = refuse to file letter

HELPFUL REMINDERS

- To facilitate the review process it is helpful to identify the name and manufacturer of the tobacco product, the package type and quantity of the tobacco product, a characterizing flavor, and the category/subcategory
- All premarket applications for newly deemed tobacco products require an environmental assessment for acceptance and filing. Currently, a claim of categorical exclusion does not apply. Examples of environmental assessments can be found posted on our website.

IF YOU HAVE ADDITIONAL QUESTIONS,
PLEASE SEND THEM TO
ASKCTP@FDA.HHS.GOV.

THE END



FDA

CENTER FOR
TOBACCO
PRODUCTS