

## Amendment Tips

### Completing Form FDA 4057a



Form FDA 4057a—Premarket Tobacco Product Application Amendment and General Correspondence Submission is a required form for applicants to use when submitting amendments and other general correspondence to FDA. In most circumstances, the agency can only consider premarket tobacco product application (PMTA) amendments for review that include Form FDA 4057a, which can be downloaded at <http://bit.ly/3lxJWcb> (PDF 926 KB).

In general, when submitting amendments for a PMTA, FDA will review the required Form FDA 4057a first. If required content is missing from the form, FDA may not continue reviewing the amendment.

This fact sheet offers tips for correctly completing Form FDA 4057a.

#### Section I—Applicant Identification

- Fill out Subsection A so that the information matches the application you are amending.
- If you are adding, updating, replacing, or removing an applicant, authorized representative, point of contact, U.S. agent, or manufacturer, carefully read and follow the instructions under Subsection C. These instructions explain what demographic information is needed based on the change(s) being made.

#### Section III—Submission Information

- Select “Amendment” under the “Type of Submission.”
- Include the FDA submission tracking number (STN) assigned to the application you are amending.
- Select the appropriate amendment response type (i.e., “Deficiency Letter,” “Unsolicited,” or “Other”). If selecting “Unsolicited” or “Other,” include a description under the “Submission Summary.”

#### Section VI—Certification Statement

- Complete the “Certification Statement,” as required by 21 CFR 1114.9(a) and described in 21 CFR 1114.7(m).
- The “Certification Statement” is required and separate from any signature used on the electronic forms for eSubmitter and the CTP Portal. You can learn more about submitting documents via the CTP Portal at <http://bit.ly/3JzeHHA>.

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If you have questions or need additional support, please call the CTP Call Center at **1-877-287-1373** between 9 a.m. and 4 p.m. ET.

Learn more about preparing PMTAs and amendments at <http://bit.ly/3YalmMu>.

### Finding Your STN

You can find your STN in the CTP Portal at [ctportal.fda.gov](http://ctportal.fda.gov). Watch this video to help you use the CTP Portal and locate your STN: <http://bit.ly/43nG4w4>.

If you do not have a CTP Portal account and you submitted a physical copy of your amendment, you can get your STN by contacting your assigned Regulatory Health Project Manager (RHPM) or FDA.

If you are unsure of your assigned RHPM, FDA can help. Contact FDA by calling 1-877-287-1373 or emailing [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).



### CONTACT US

1.877.CTP.1373 | [AskCTP@FDA.hhs.gov](mailto:AskCTP@FDA.hhs.gov) | [www.fda.gov/tobacco](http://www.fda.gov/tobacco)

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