

Comments on Form 4057a:

General comments

- A. Form 4057a does not use terms for collecting information that are consistent with other amendment forms, e.g., Form 3964, Tobacco Amendment and General Correspondence Submission.
- B. The layout, e.g., section contents, does not align with the layout of the PMTA Submission, Form 4057.
 - a. Section III of the amendment contains updates to information that is contained in Section I of the PMTA Submission
 - b. Section IV, Change in Ownership could be considered an update to Applicant information contained in Section I of the PMTA Submission
 - c. Section II, Submission Information and Contents, contains information found in Sections II and IV of the PMTA Submission

Comments on existing form information	Comments on missing form information
Applicant Identification Information	
It seems that Section I Name of Applicant, and Applicant Address and Contact is duplicative of the information collected in Section IV, Current Owner Information. If Section IV were combined with Section 1, this duplication of effort could be eliminated. If it is not duplicative, then further instructions are necessary.	The form captures information about a Manufacturer that is different than the Applicant, but does not provide space for providing any address and contact information for the Manufacturer.
The form does not accommodate collecting the organization for an Alternate Point of Contact.	The form collects address and contact information for a responsible party, e.g., Authorized Representative, but does not collect organization information for the party. In cases when the responsible party is unexpectedly unavailable, the organization information would provide important contextual information.
Since there is only one Authorized Representative on the PMTA Submission, adding a choice of "Replace" would eliminate the need the two-step process of "Remove" and "Add".	
Section II - Submission Information and Contents	
The checklist comprising "Submission Content included in the amendment" would be more appropriate for a section corresponding to Section IV, Application Contents on the PMTA Submission.	The form does not mirror the PMTA Submission in allowing the submitter to indicate if the amendment is for a single product or a bundled submission for multiple tobacco products.
	The form does not accommodate changes to Cross-referenced submission content, Related Submissions , and prior meetings, which is collected on the PMTA Submission.
	The information collected on the amendment should allow the submitter to indicate the

	addition, update, or removal of Cross-referenced submission content, Related Submissions , and prior meetings.
	The information collected on the amendment should allow the submitter to uniquely identify the Cross-referenced submission content, Related Submissions , and prior meetings that are being amended.
	For Cross-referenced submission content being added, the form should allow the collection of information describing the intended use of the Cross-referenced content.
	Section II does not contain a Submission Summary where the submitter could describe the overall contents of the amendment.
	The form does not allow for a bundled submission for multiple tobacco products
New Tobacco Product Information	
	Other than brand(s) to be transferred, the form does not accommodate updating any tobacco product information. The form should contain a section that mirrors Section III, New Tobacco Product Information, on the PMTA Submission.
	The form should allow changes to Co-packaged products, i.e., tobacco products that are marketed as a single co-package product.
- Application Contents	
	The form should allow the submitter to indicate the addition, updates, and removal of application contents that were submitted with the PMTA Submission, including information about submission contents necessary to ensure that FDA will be able to identify the intended use (e.g., Administrative, Cover Letter) for particular items of submitted contents.