

Comments on Form 4057:

1. General comment: Form 4057 does not use terms for collecting information that are consistent with other forms, e.g., Form 3965, SE Report Submission.

Section I - Applicant Identification

2. The form recognizes that the Manufacturer may be different than the Applicant, but does not provide space for providing any address and contact information for the Manufacturer.
3. The form often collects address and contact information only for the responsible party, e.g., Authorized Representative, but does not collect corresponding organization information for the party.
4. The form does not indicate how to communicate the corresponding party or organization for an Alternate Point of Contact.

Section II - Submission Information:

5. The form allows for a bundled submission for multiple tobacco products, but does not accommodate a way for the submitter to indicate Cross-referenced submission content, Related Submissions, and prior meetings for a particular tobacco product.
6. The form does not specify what identifying information for submission content is necessary to ensure that FDA will be able to identify the Cross-referenced content.
7. The form does not provide a way to describe the intended use of the Cross-referenced content.

Section III - New Tobacco Product Information:

8. The form allows for a bundled submission for multiple tobacco products, including Co-packaged products, but does not accommodate a way to group the items (i.e., tobacco products) that are marketed in a single co-package product.
9. Questions 21 and 24 do not specify what information should be provided for co-packaged products or how to structure the information so that the properties for the items in a co-packaged product are clear.

Section IV - Application Contents:

10. The form does not specify what identifying information for submission content is necessary to ensure that FDA will be able to identify the application contents category (e.g., Administrative, Cover Letter) for particular items of submitted contents.