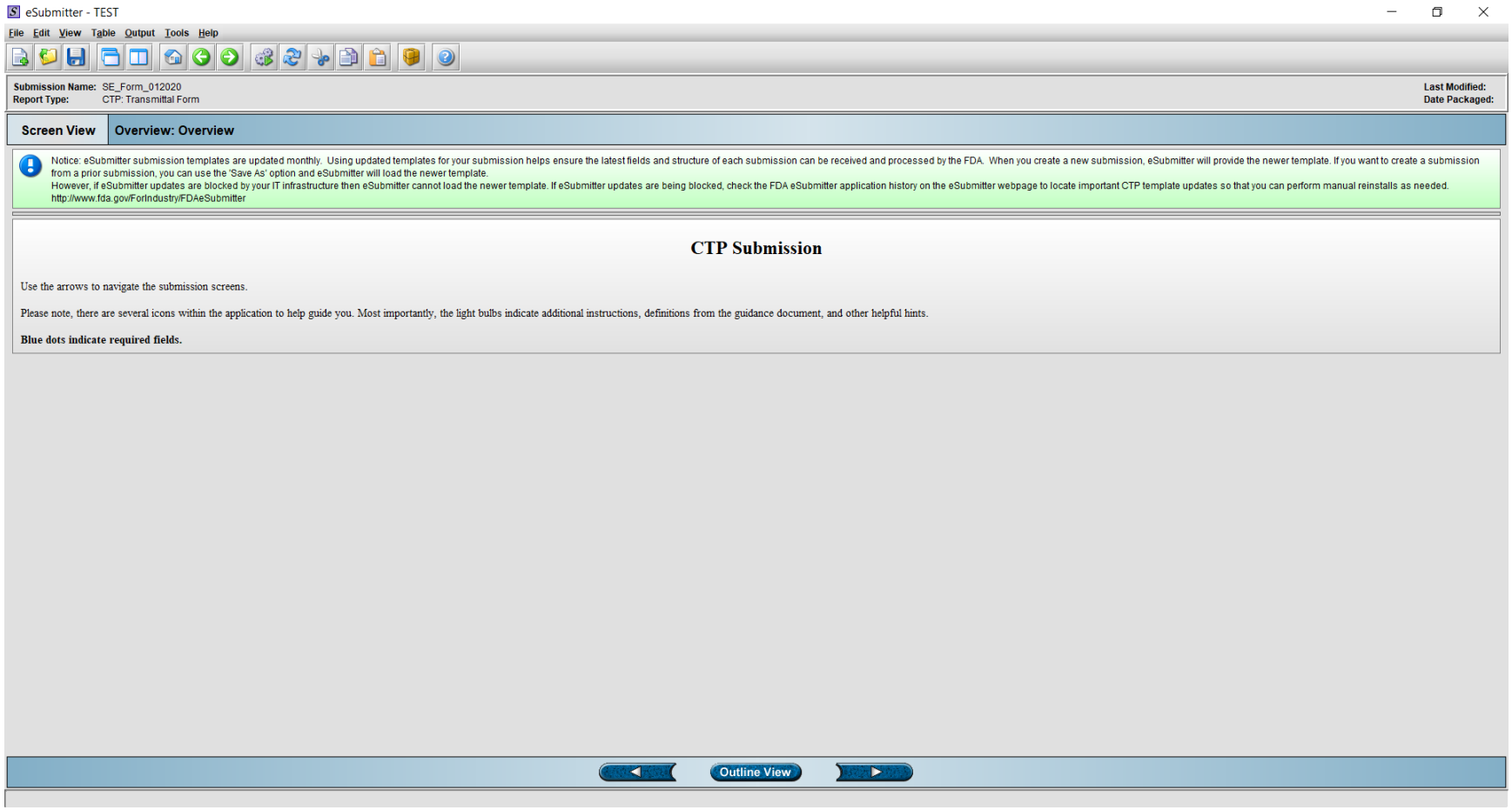
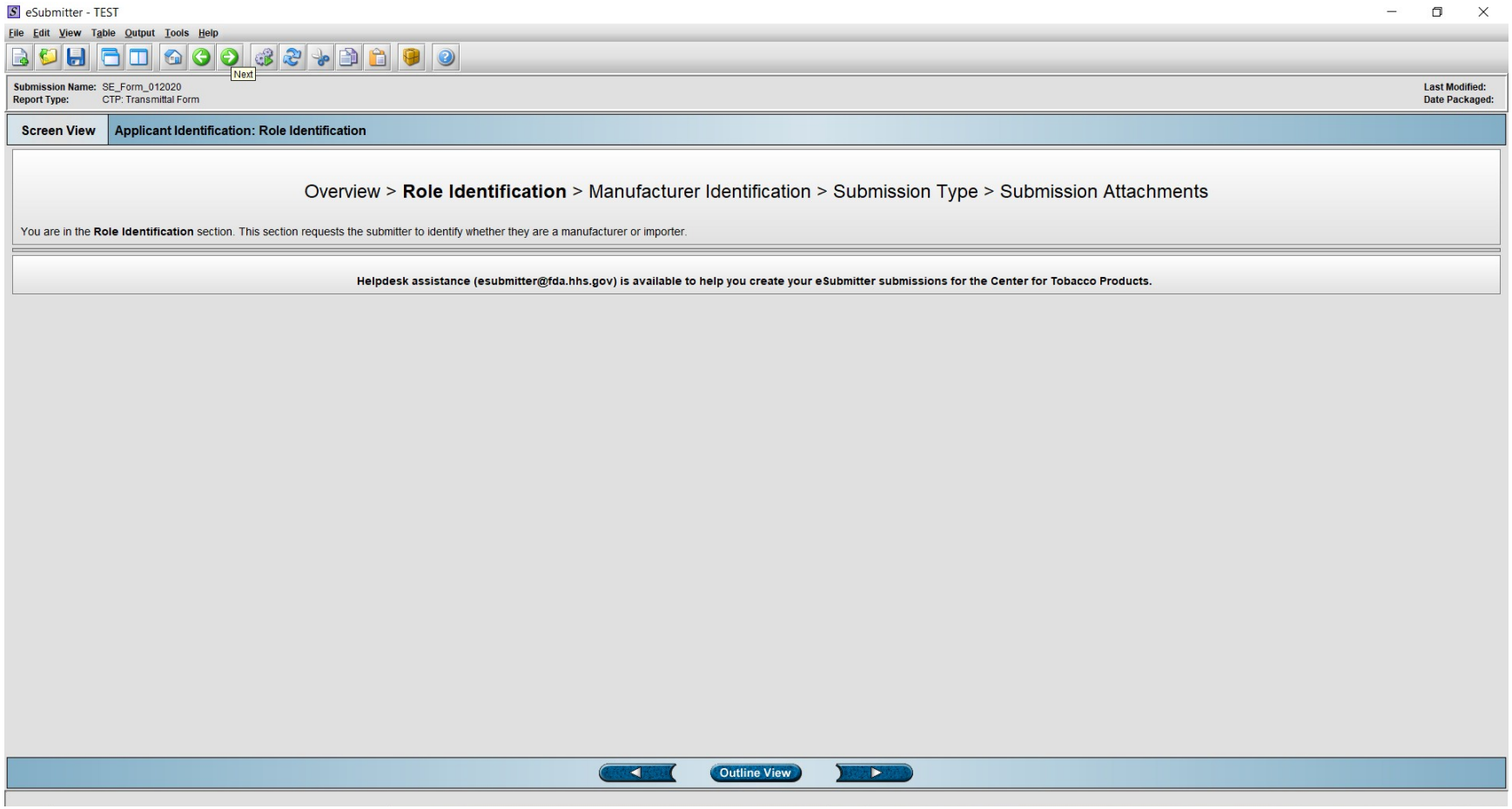
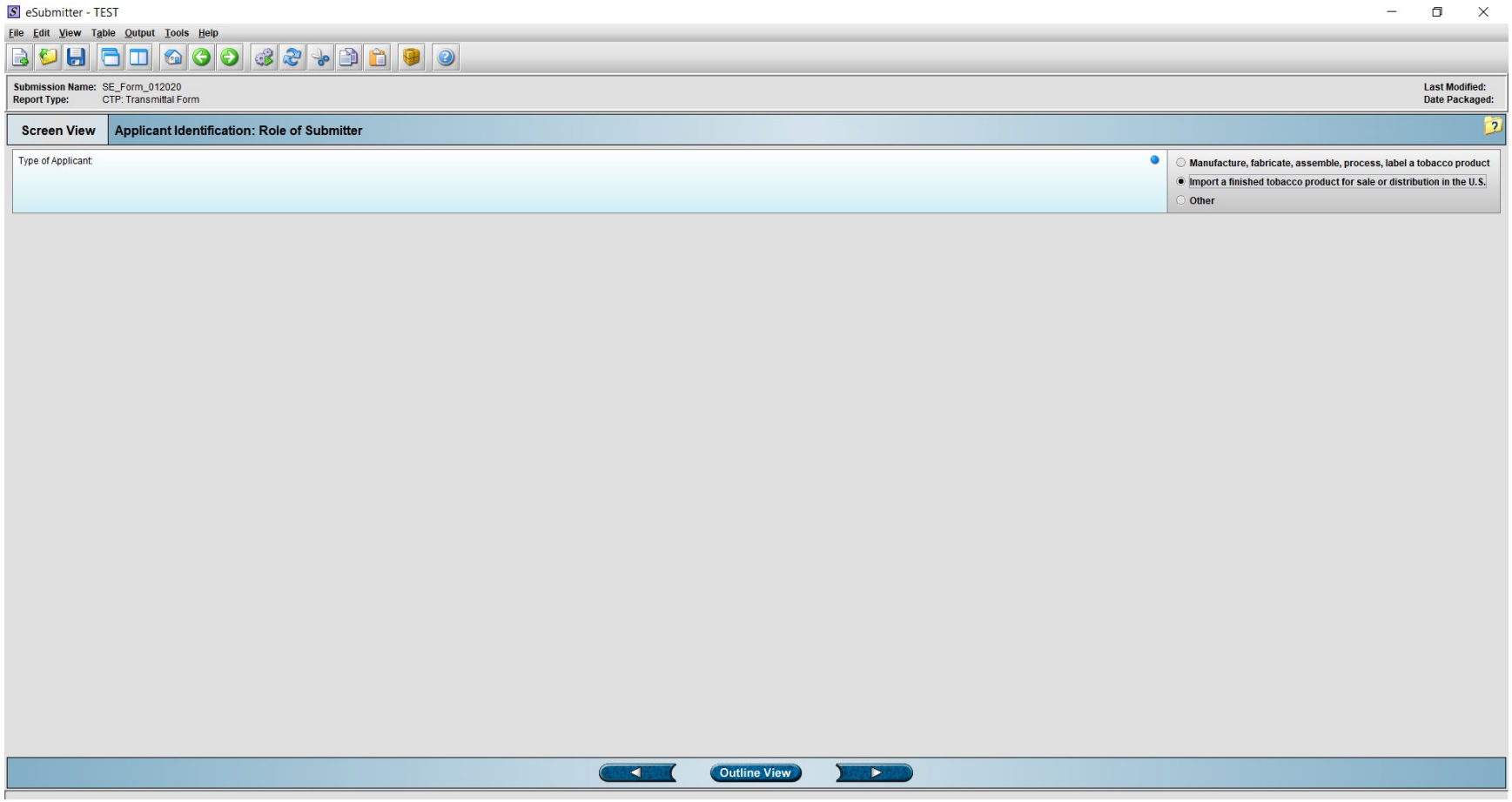
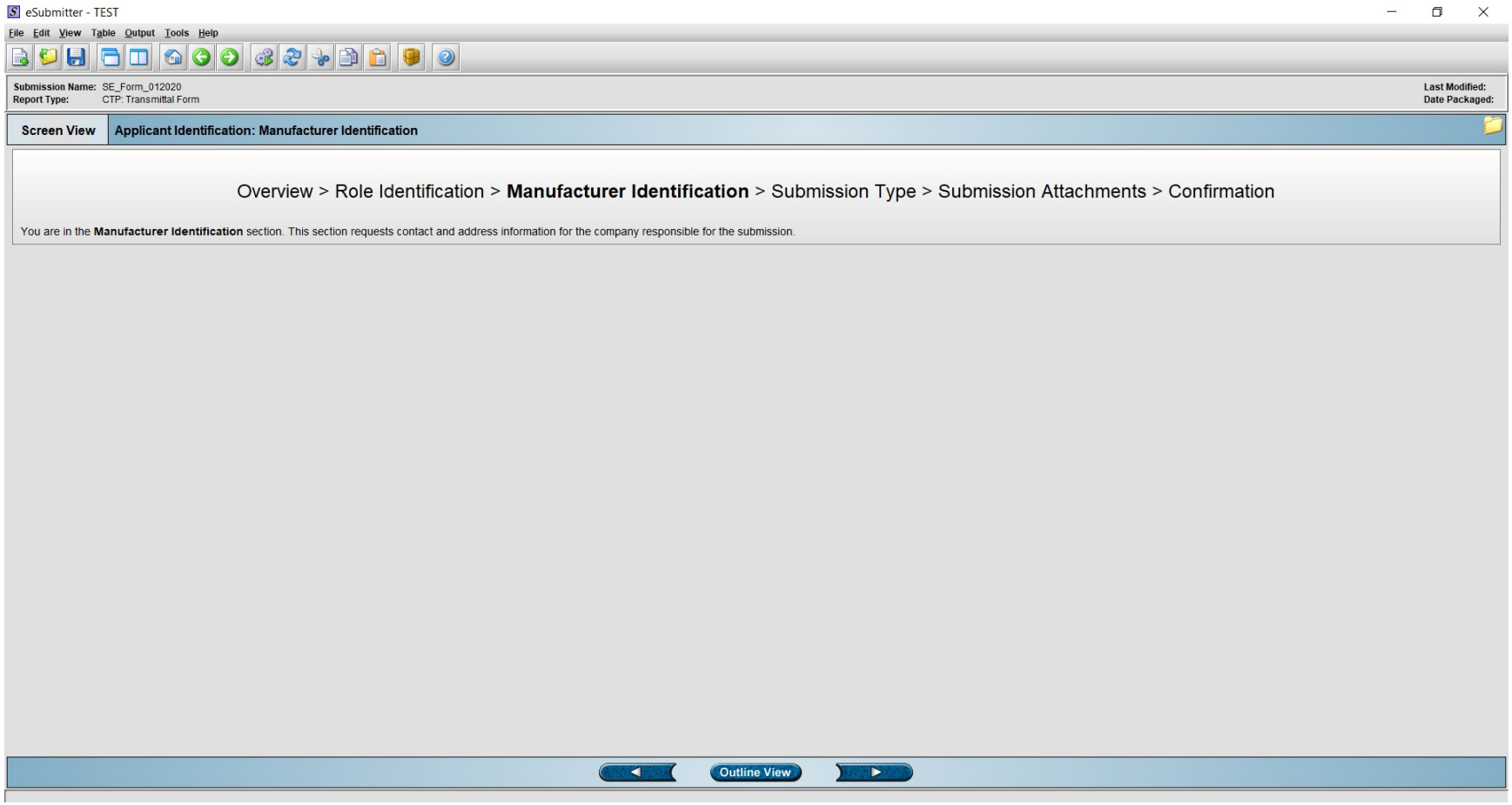
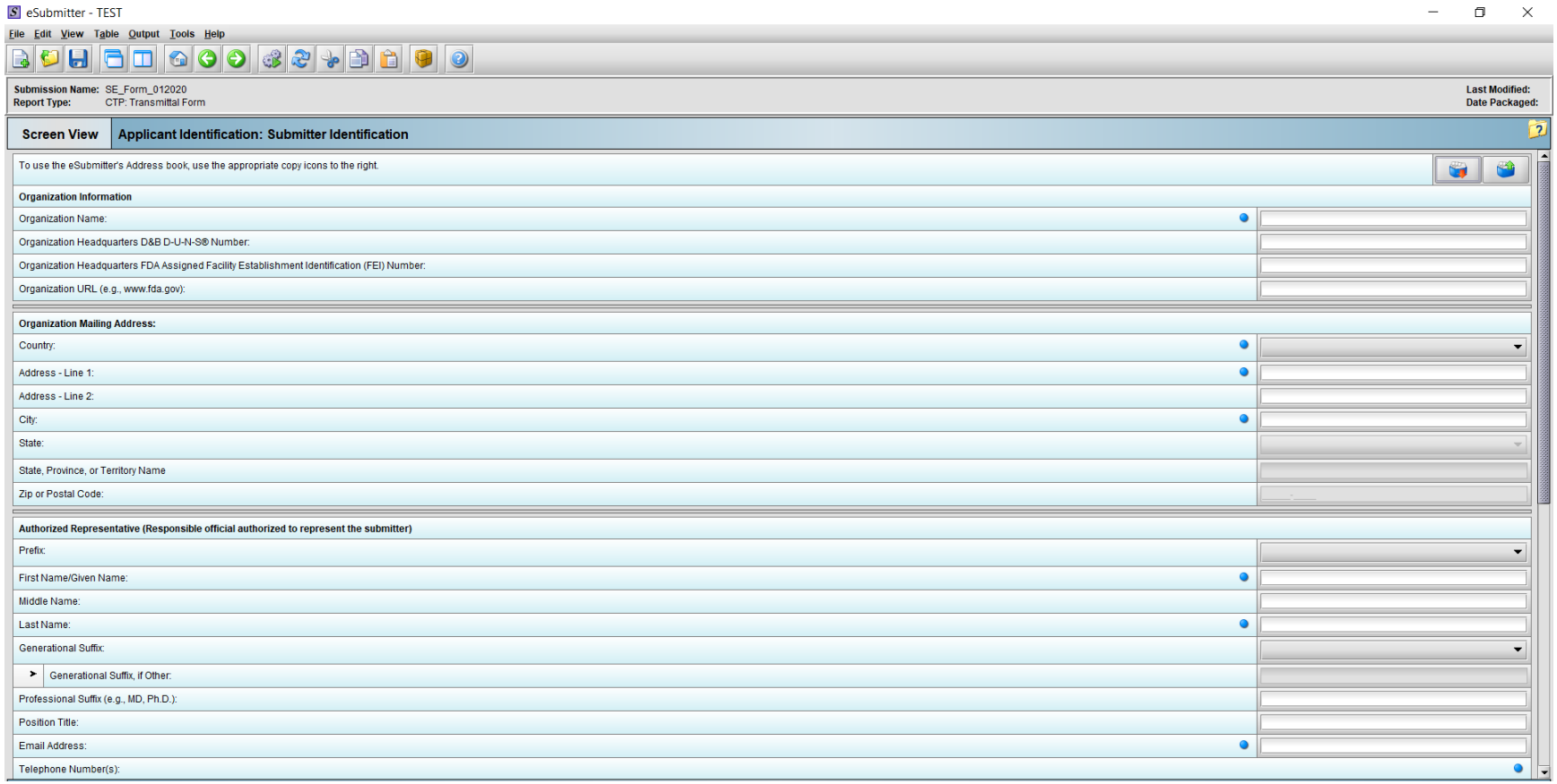
Substantial Equivalence (SE) Form

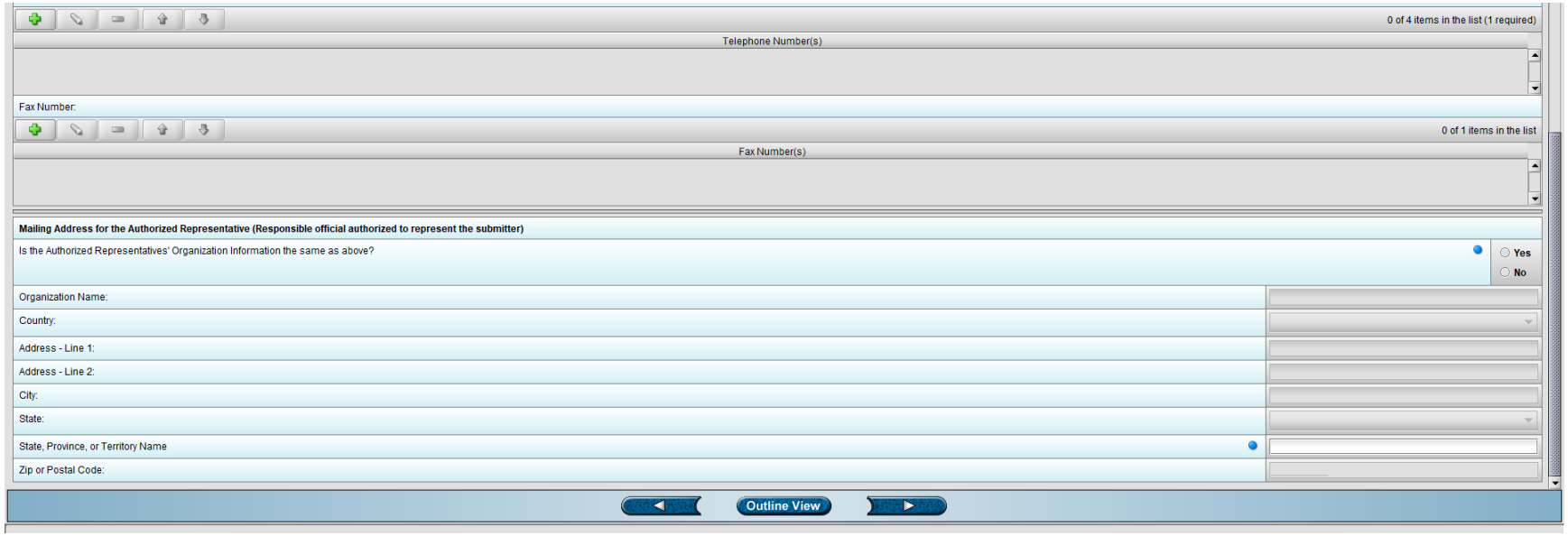


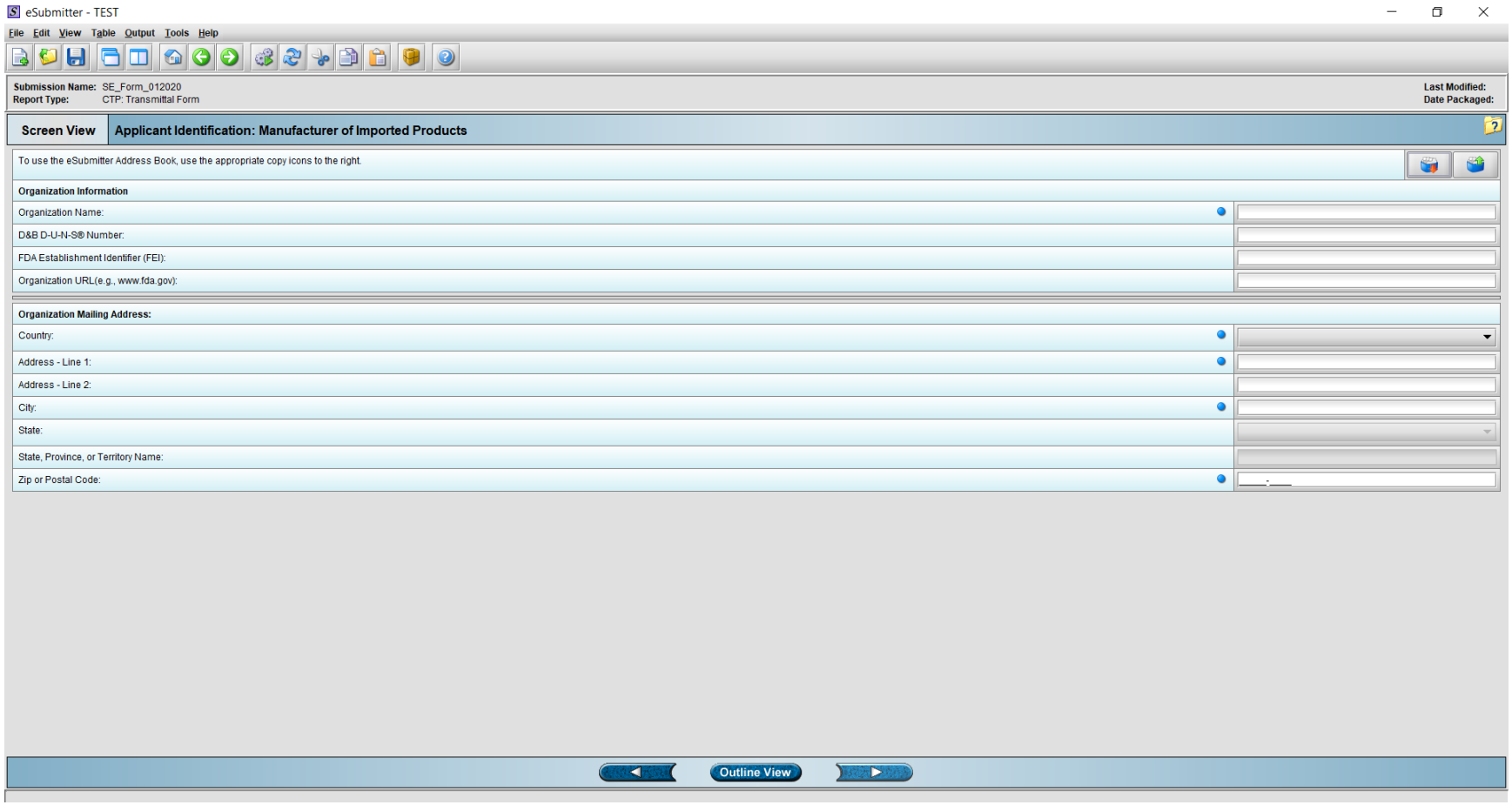

eSubmitter - TEST
File Edit View Table Output Tools Help
Next
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Applicant Identification: Role Identification
Overview > Role Identification > Manufacturer Identification > Submission Type > Submission Attachments
You are in the Role Identification section. This section requests the submitter to identify whether they are a manufacturer or importer.
Helpdesk assistance (esubmitter@fda.hhs.gov) is available to help you create your eSubmitter submissions for the Center for Tobacco Products.
Outline View

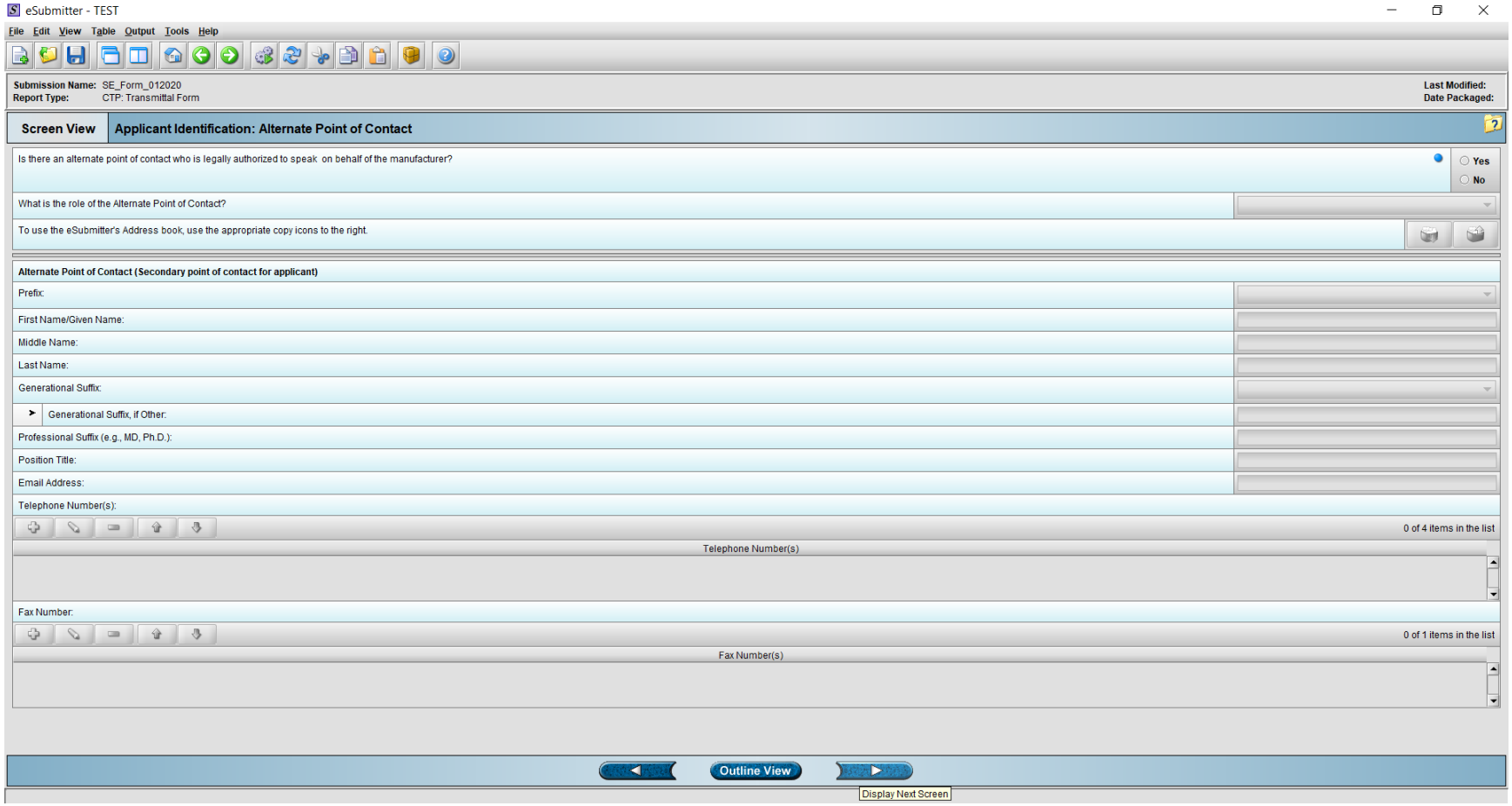

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Applicant Identification: Role of Submitter
Type of Applicant:
Manufacture, fabricate, assemble, process, label a tobacco product
Import a finished tobacco product for sale or distribution in the U.S.
Other
Outline View

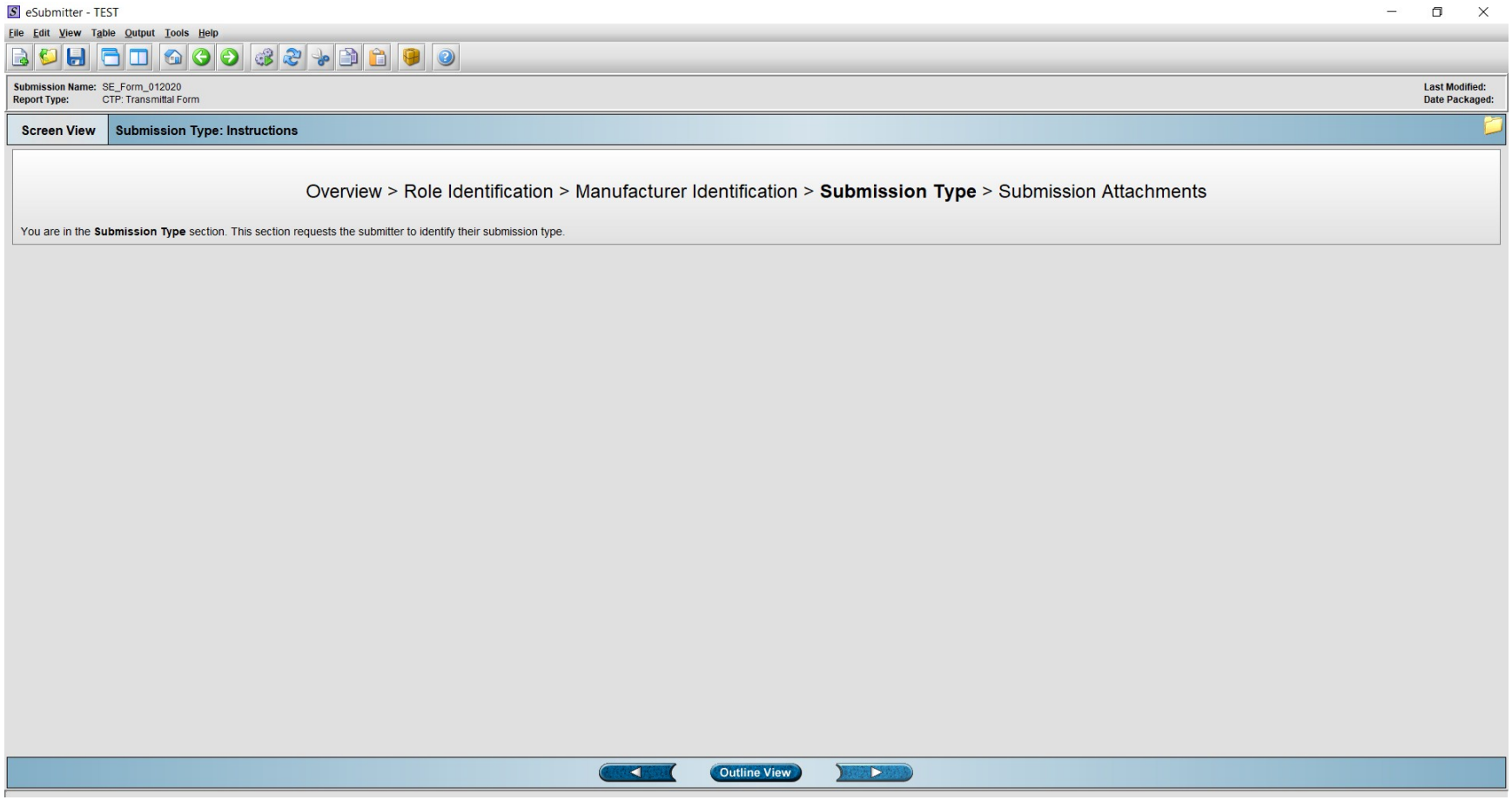

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Applicant Identification: Manufacturer Identification
Overview > Role Identification > Manufacturer Identification > Submission Type > Submission Attachments > Confirmation
You are in the Manufacturer Identification section. This section requests contact and address information for the company responsible for the submission.
Outline View

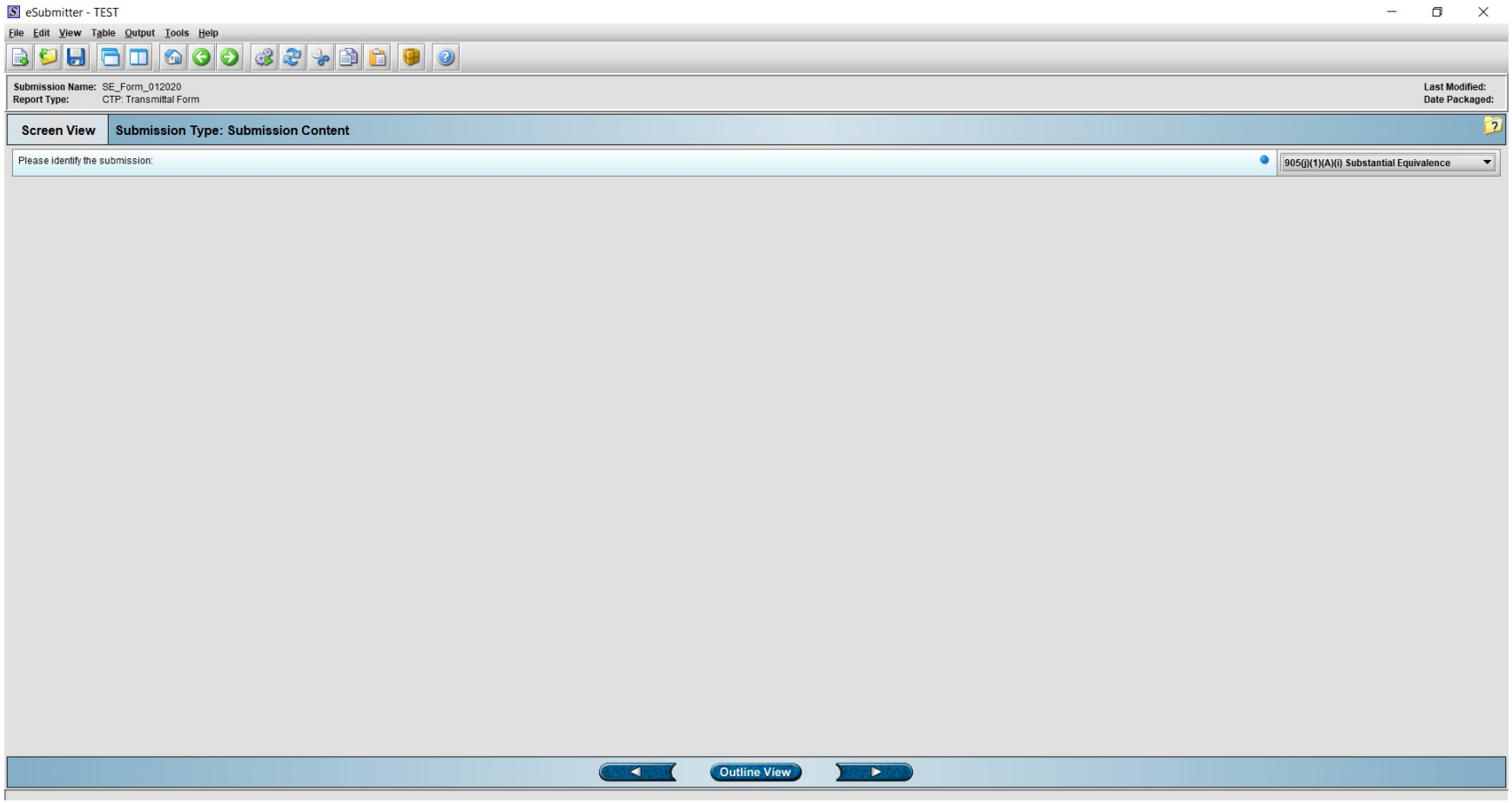

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Applicant Identification: Submitter Identification
To use the eSubmitter's Address book, use the appropriate copy icons to the right.
Organization Information
Organization Name:
Organization Headquarters D&B D-U-N-S® Number:
Organization Headquarters FDA Assigned Facility Establishment Identification (FEI) Number:
Organization URL (e.g., www.fda.gov):
Organization Mailing Address:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code:
Authorized Representative (Responsible official authorized to represent the submitter)
Prefix:
First Name/Given Name:
Middle Name:
Last Name:
Generational Suffix:
Generational Suffix, if Other:
Professional Suffix (e.g., MD, Ph.D.):
Position Title:
Email Address:
Telephone Number(s):

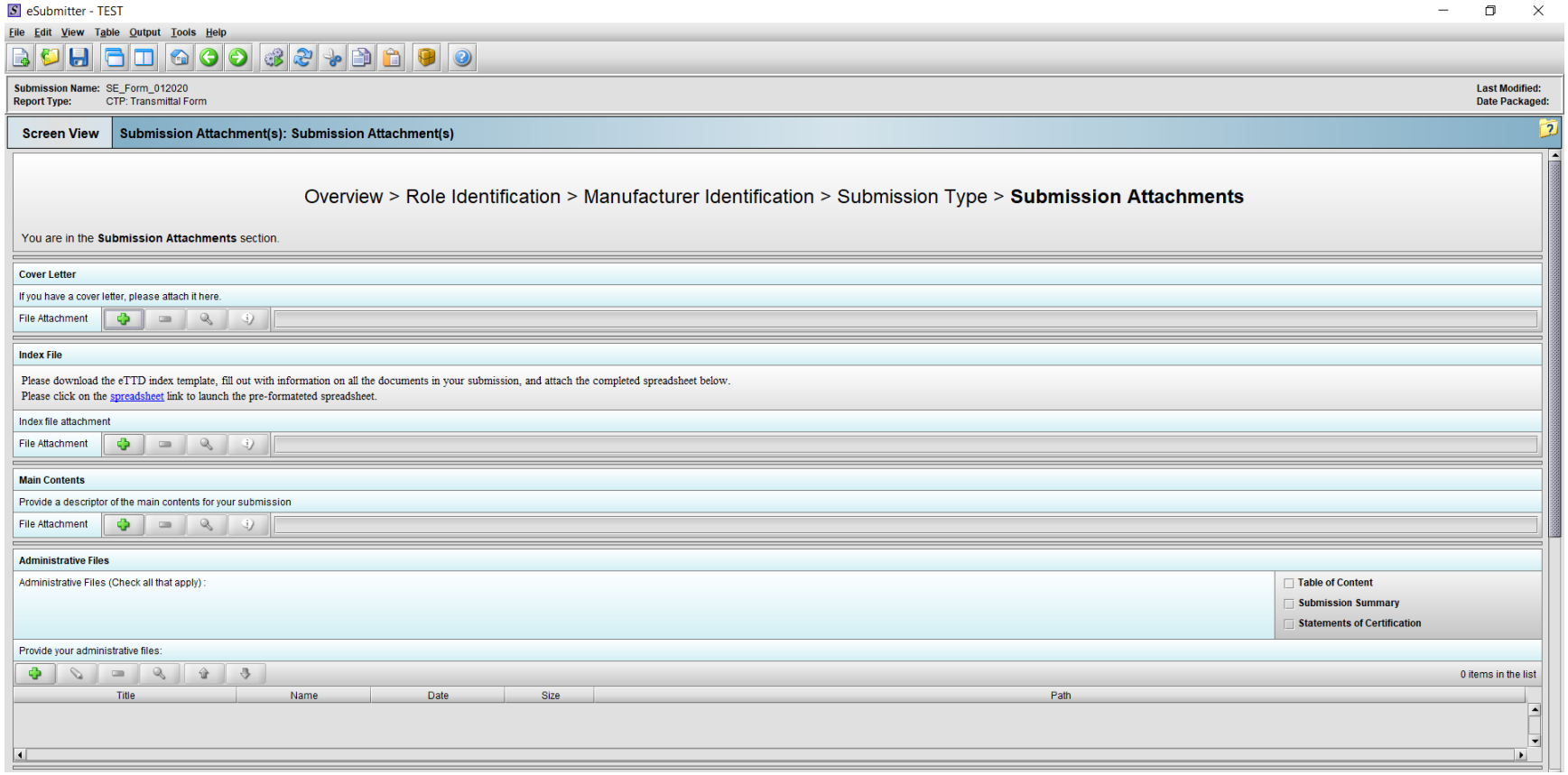

0 of 4 items in the list (1 required)
Telephone Number(s)
Fax Number:
0 of 1 items in the list
Fax Number(s)
Mailing Address for the Authorized Representative (Responsible official authorized to represent the submitter)
Is the Authorized Representatives' Organization Information the same as above?
Yes
No
Organization Name:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code:
Outline View

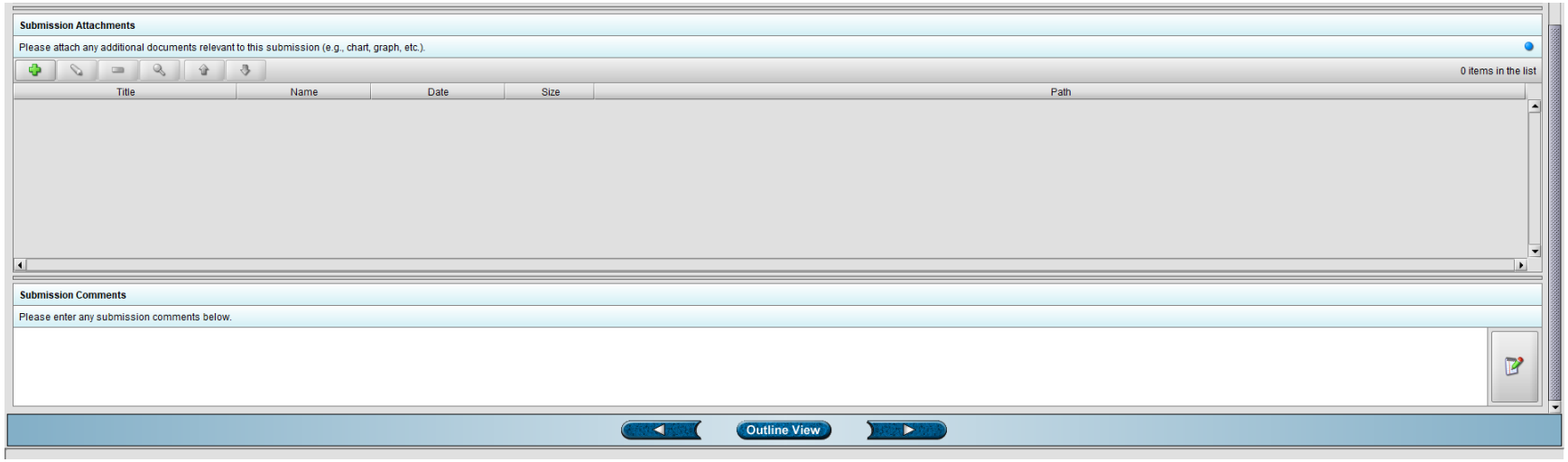

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Applicant Identification: Manufacturer of Imported Products
To use the eSubmitter Address Book, use the appropriate copy icons to the right.
Organization Information
Organization Name:
D&B D-U-N-S® Number:
FDA Establishment Identifier (FEI):
Organization URL(e.g., www.fda.gov):
Organization Mailing Address:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name:
Zip or Postal Code:
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Applicant Identification: Alternate Point of Contact
Is there an alternate point of contact who is legally authorized to speak on behalf of the manufacturer?
Yes
No
What is the role of the Alternate Point of Contact?
To use the eSubmitter's Address book, use the appropriate copy icons to the right.
Alternate Point of Contact (Secondary point of contact for applicant)
Prefix:
First Name/Given Name:
Middle Name:
Last Name:
Generational Suffix:
Generational Suffix, if Other:
Professional Suffix (e.g., MD, Ph.D.):
Position Title:
Email Address:
Telephone Number(s):
0 of 4 items in the list
Telephone Number(s)
Fax Number:
0 of 1 items in the list
Fax Number(s)
Outline View
Display Next Screen


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Submission Type: Instructions
Overview > Role Identification > Manufacturer Identification > Submission Type > Submission Attachments
You are in the Submission Type section. This section requests the submitter to identify their submission type.
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Submission Type: Submission Content
Please identify the submission:
905(j)(1)(A)(i) Substantial Equivalence
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Submission Attachment(s): Submission Attachment(s)
Overview > Role Identification > Manufacturer Identification > Submission Type > Submission Attachments
You are in the Submission Attachments section.
Cover Letter
If you have a cover letter, please attach it here.
File Attachment
Index File
Please download the eTTD index template, fill out with information on all the documents in your submission, and attach the completed spreadsheet below.
Please click on the spreadsheet link to launch the pre-formateted spreadsheet.
Index file attachment
File Attachment
Main Contents
Provide a descriptor of the main contents for your submission
File Attachment
Administrative Files
Administrative Files (Check all that apply) :
Table of Content
Submission Summary
Statements of Certification
Provide your administrative files:
0 items in the list
Title
Name
Date
Size
Path


Submission Attachments
Please attach any additional documents relevant to this submission (e.g., chart, graph, etc.).
0 items in the list
Title
Name
Date
Size
Path
Submission Comments
Please enter any submission comments below.
Outline View

eSubmitter - TEST

File Edit View Table Output Tools Help

Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form

Last Modified:
Date Packaged:

Screen View | **Substantially Equivalent Submission: Overview**

Tobacco Substantial Equivalence Report Submission

Family Smoking Prevention and Tobacco Control Act

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Statutory Requirements

Section 910(a)(1) of the FD&C Act defines a new tobacco product as "(A)any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or (B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007."

Section 910(a)(2) of the FD&C Act states that premarket review is required for new tobacco products. There are three pathways to receive marketing authorization. Substantial equivalence is one of the three pathways.

Section 910(a)(3) of the FD&C Act states that "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product "(i) has the same characteristics as the predicate tobacco product; or (ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health."

Section 905(j)(1)(A)(i) of the FD&C Act includes the timeframe and basis for submission of a substantial equivalence Report (SE Report).

Complete the following question and answer form for the Substantial Equivalence Report and submit the required data to FDA's Center for Tobacco Products via the CTP Portal or FDA Electronic Submissions Gateway (ESG). To register with the FDA ESG, go to www.fda.gov/esg/.

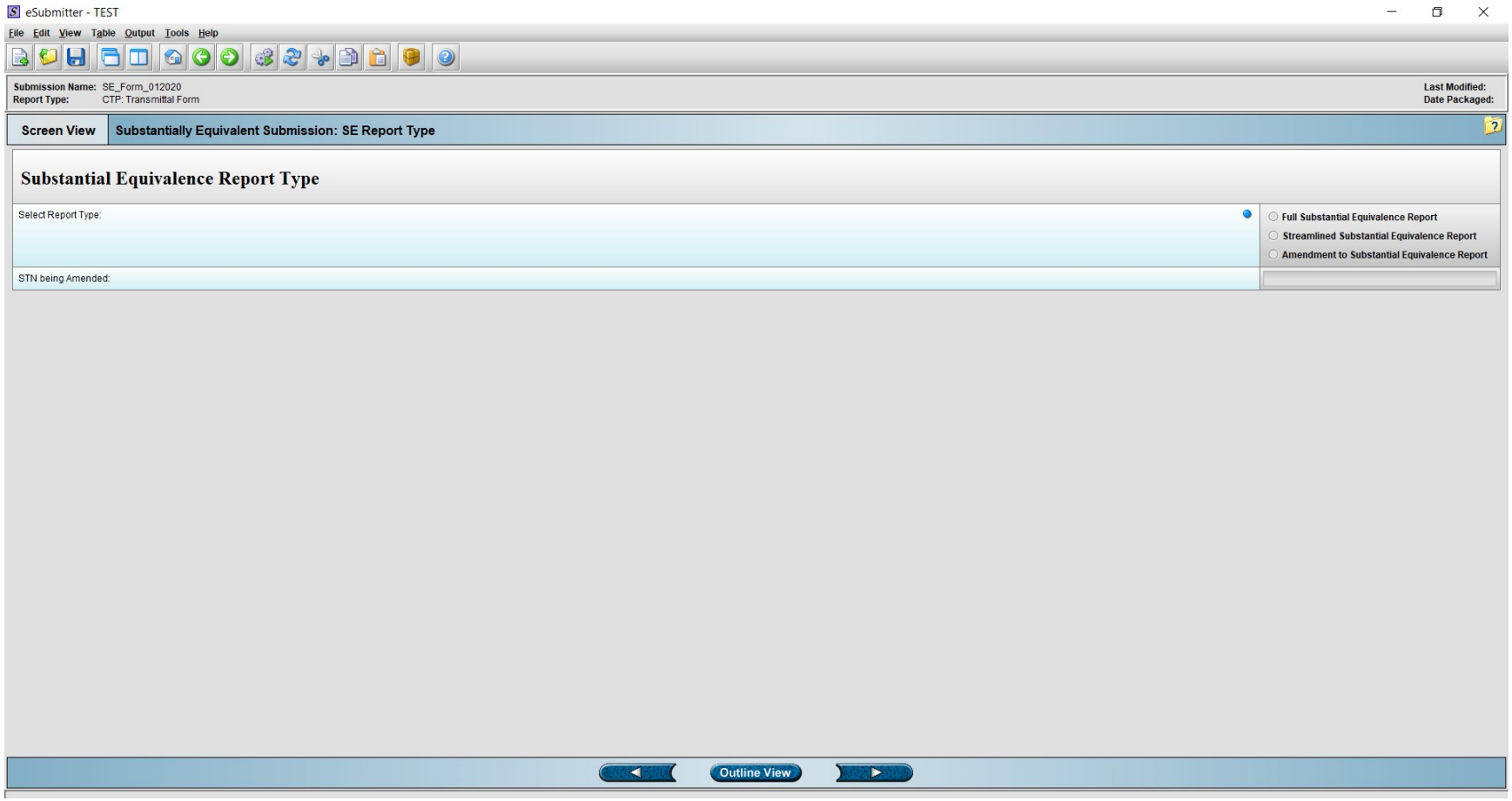
For your reference, see the Overview of Substantial Equivalence (SE) .

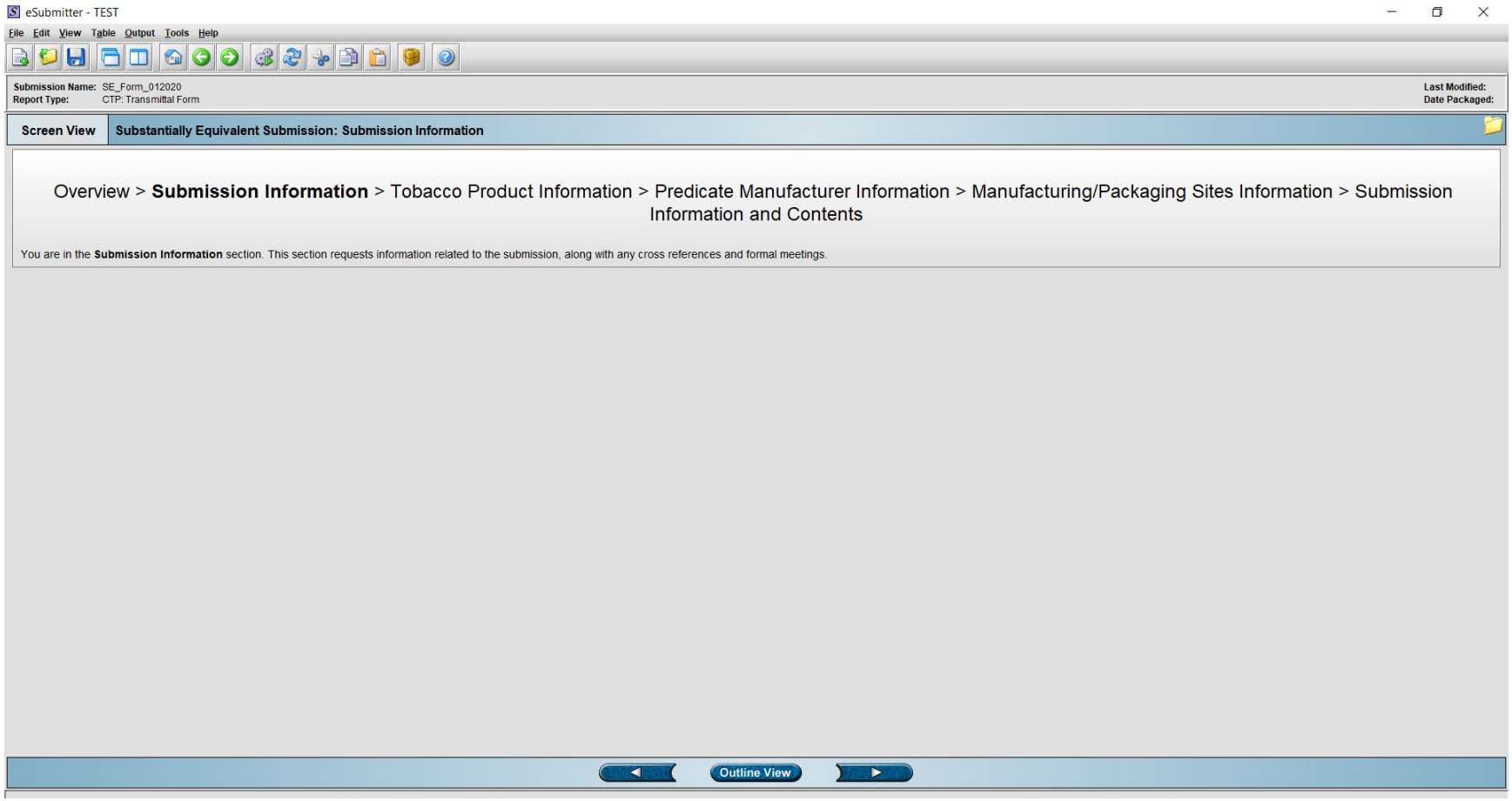
Please note, there are several icons within the application to help guide you. Most importantly, the light bulbs indicate additional instructions, definitions from the guidance document, and other helpful hints.

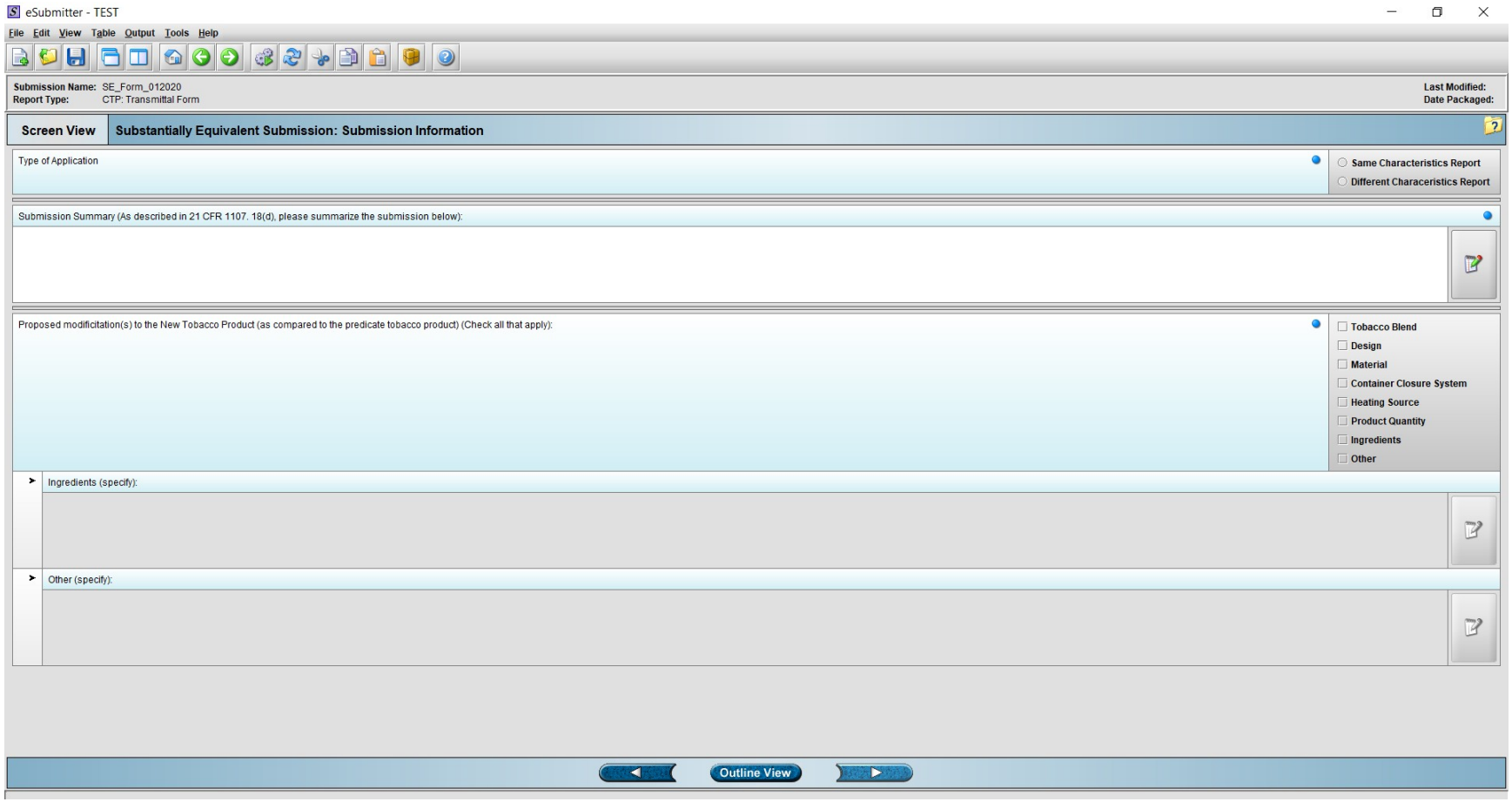
An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0650 (expires 6/30/2019).

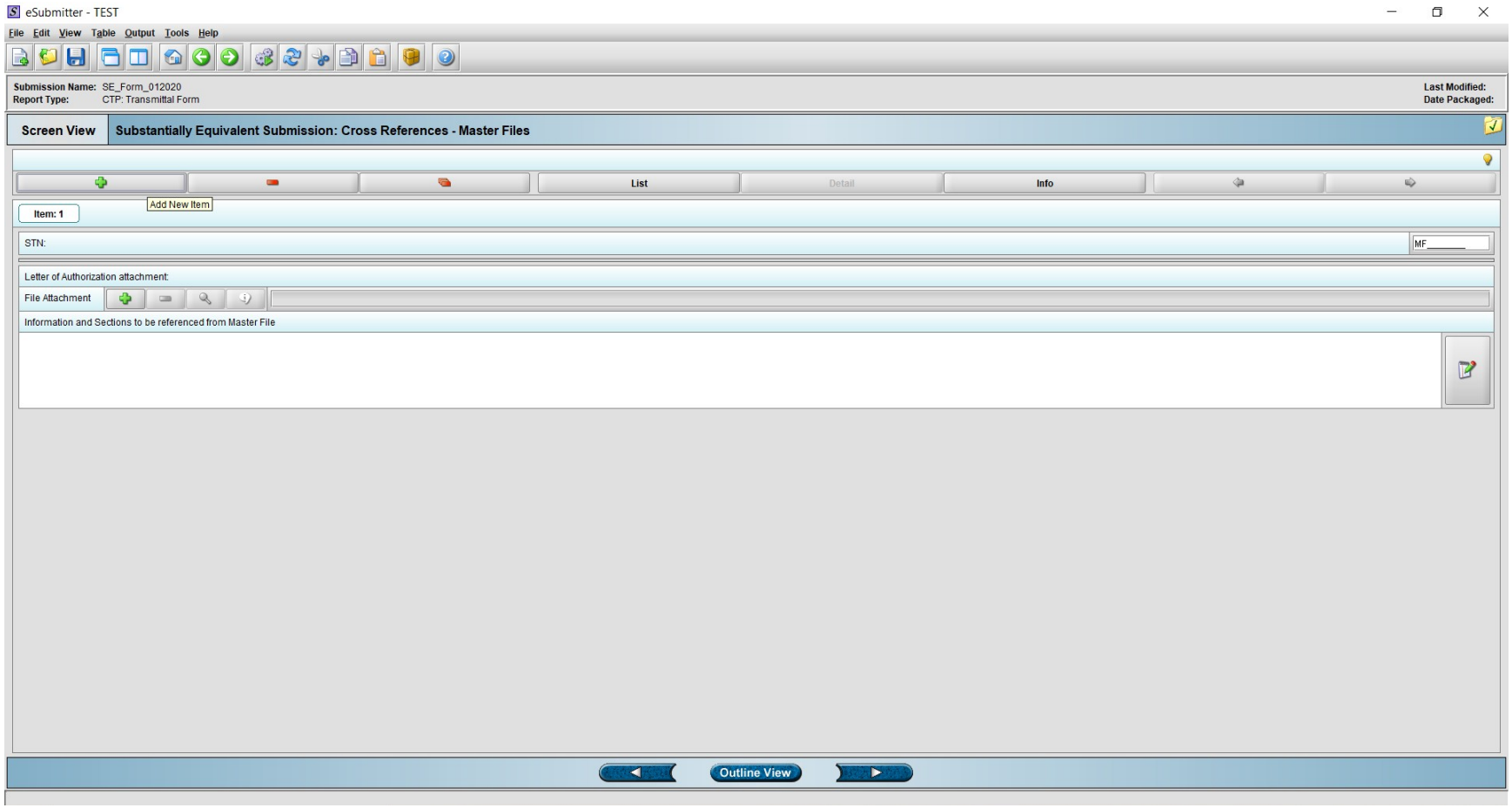
Blue dots indicate required fields.

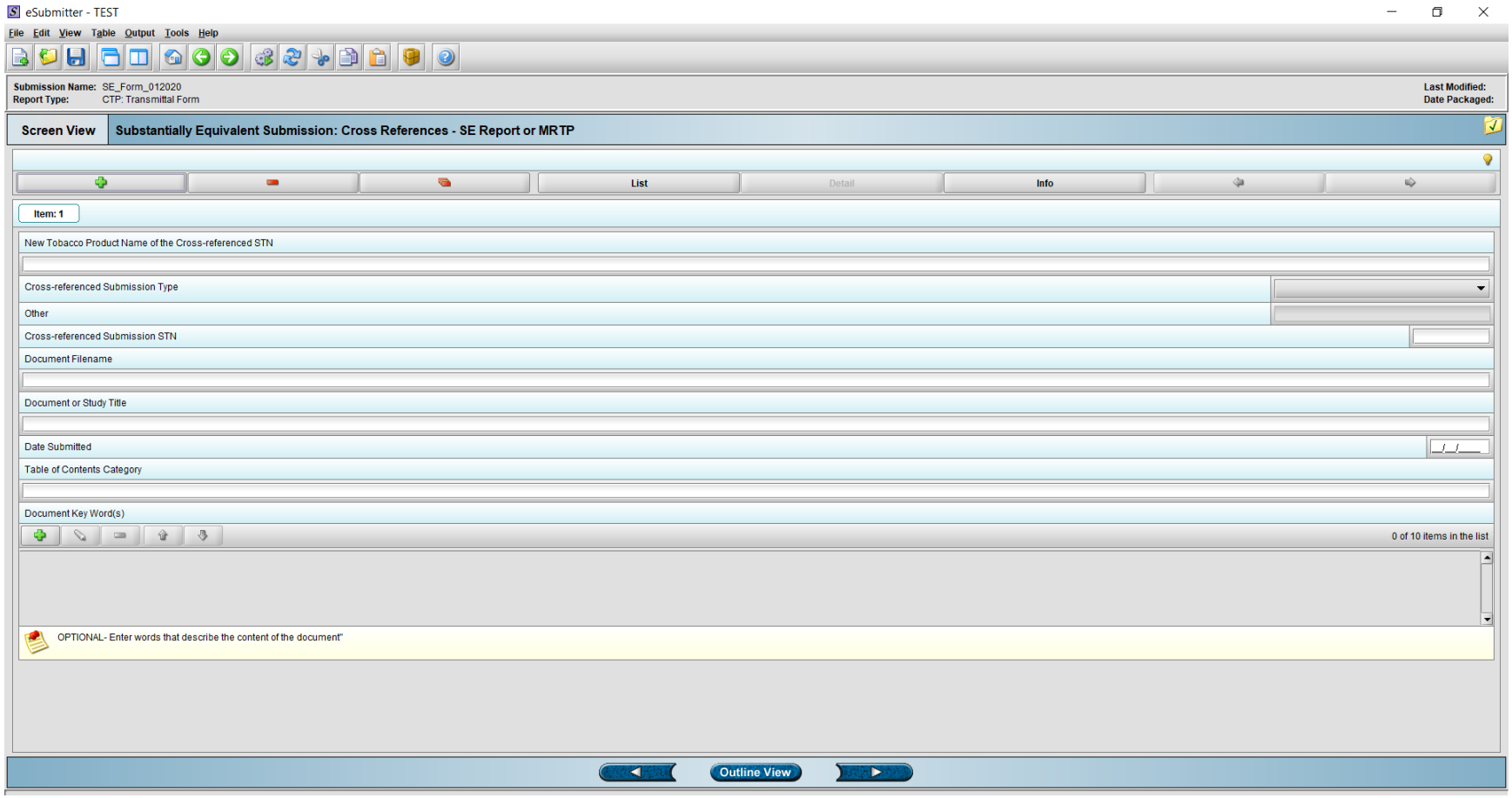
◄ Outline View ►

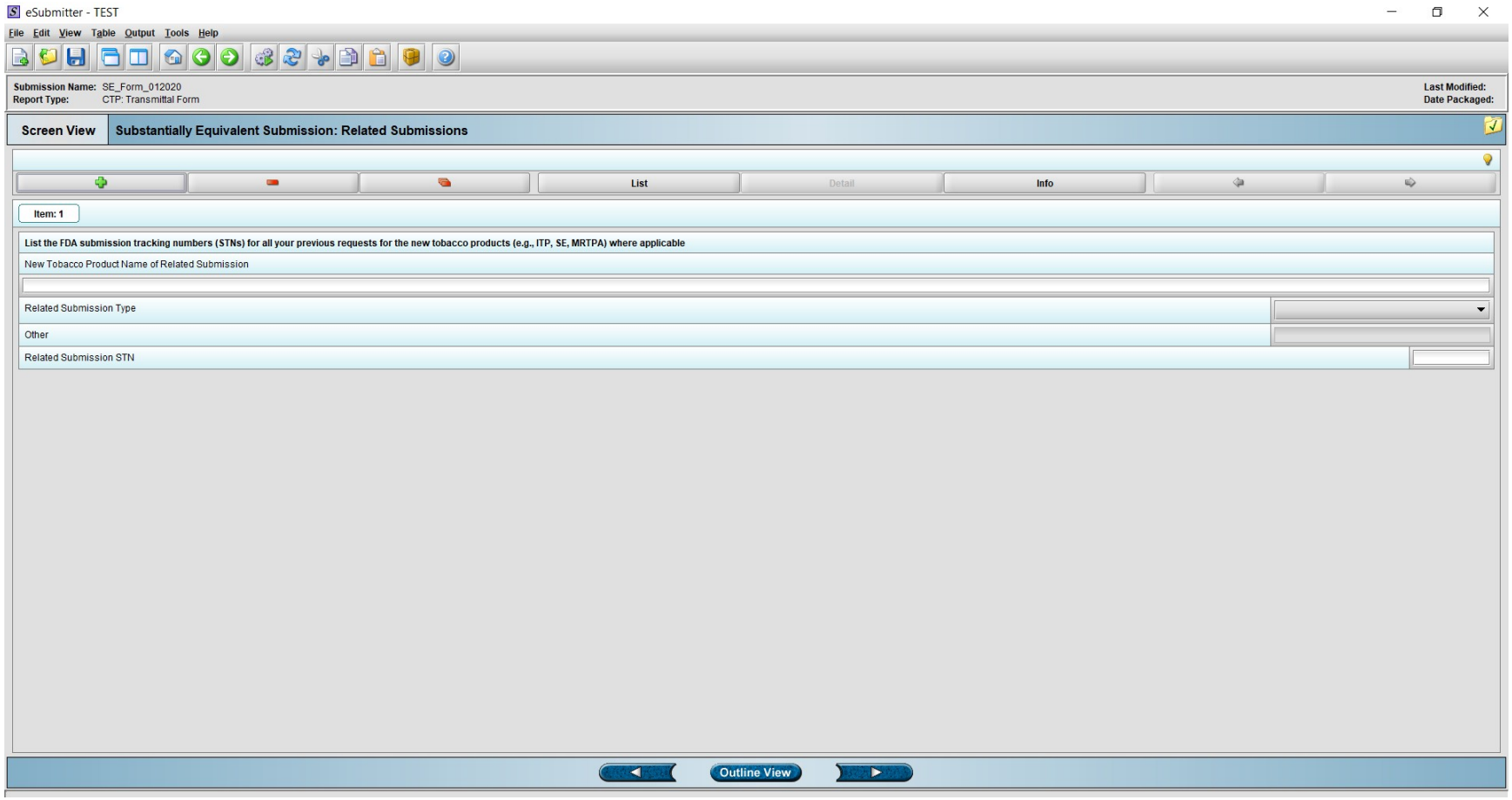

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: SE Report Type
Substantial Equivalence Report Type
Select Report Type:
Full Substantial Equivalence Report
Streamlined Substantial Equivalence Report
Amendment to Substantial Equivalence Report
STN being Amended:
Outline View

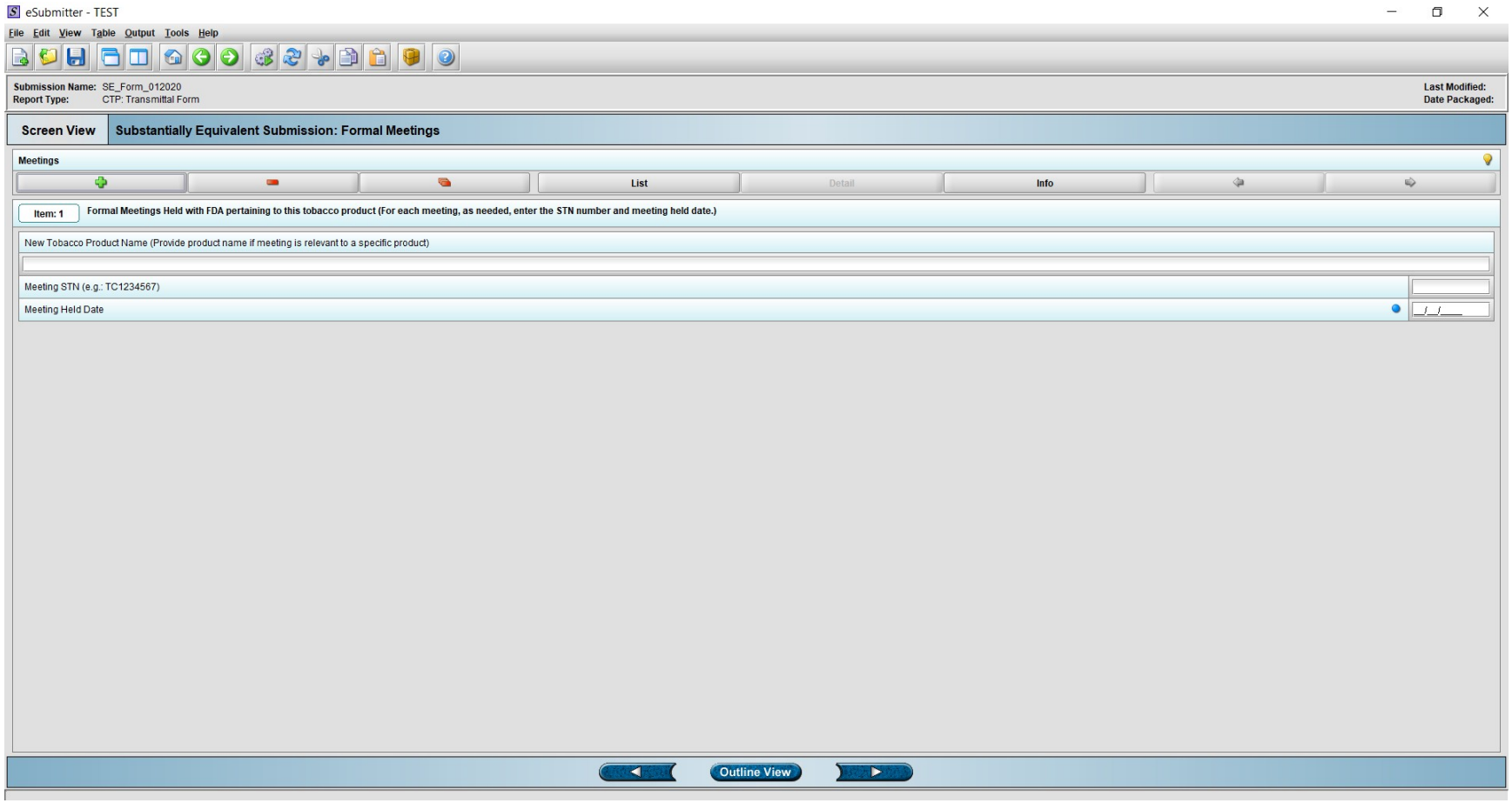

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Submission Information
Overview > Submission Information > Tobacco Product Information > Predicate Manufacturer Information > Manufacturing/Packaging Sites Information > Submission Information and Contents
You are in the Submission Information section. This section requests information related to the submission, along with any cross references and formal meetings.
Outline View

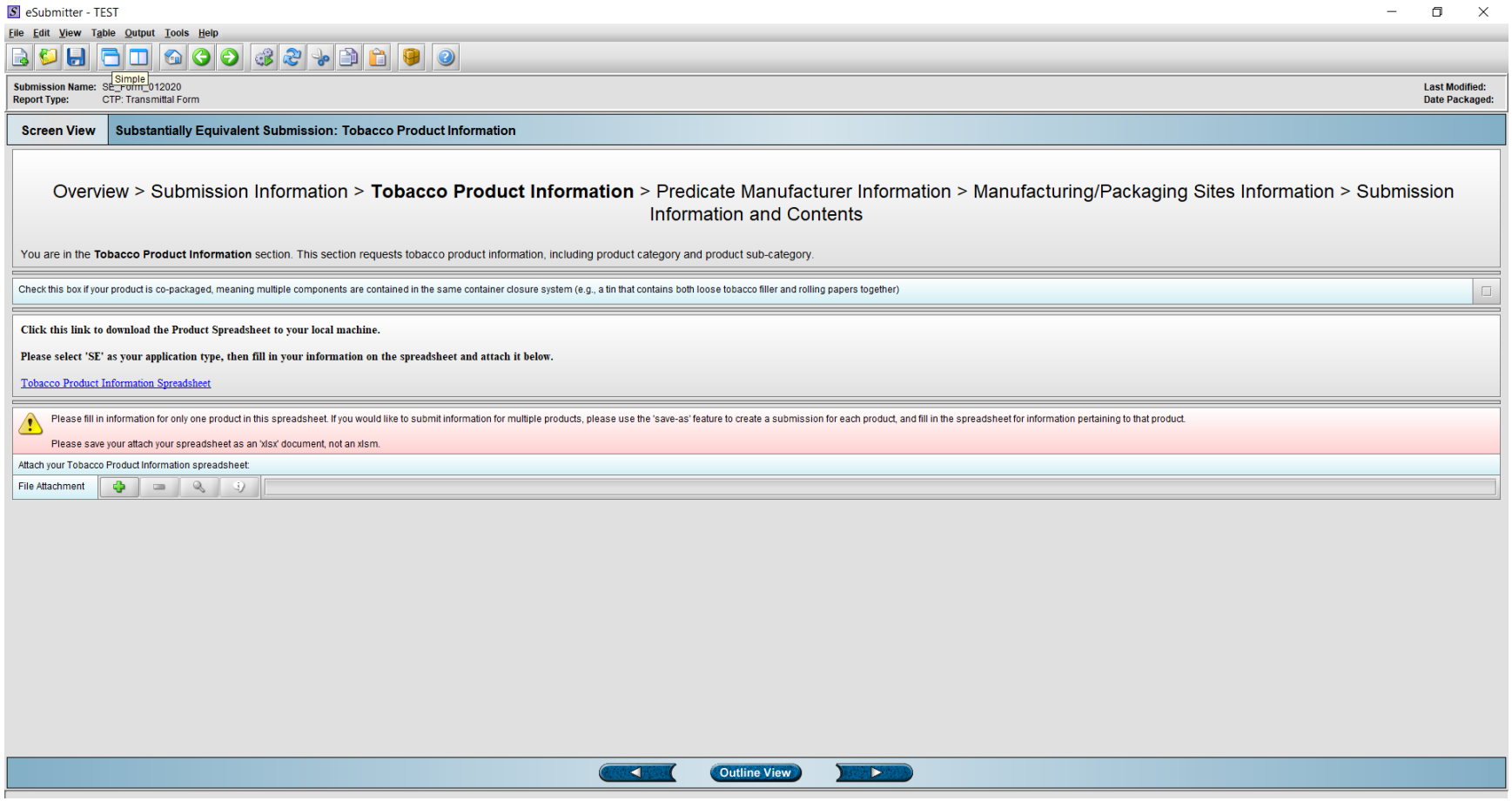

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Submission Information
Type of Application
Same Characteristics Report
Different Characeristics Report
Submission Summary (As described in 21 CFR 1107. 18(d), please summarize the submission below):
Proposed modificitation(s) to the New Tobacco Product (as compared to the predicate tobacco product) (Check all that apply):
Tobacco Blend
Design
Material
Container Closure System
Heating Source
Product Quantity
Ingredients
Other
Ingredients (specify):
Other (specify):
Outline View

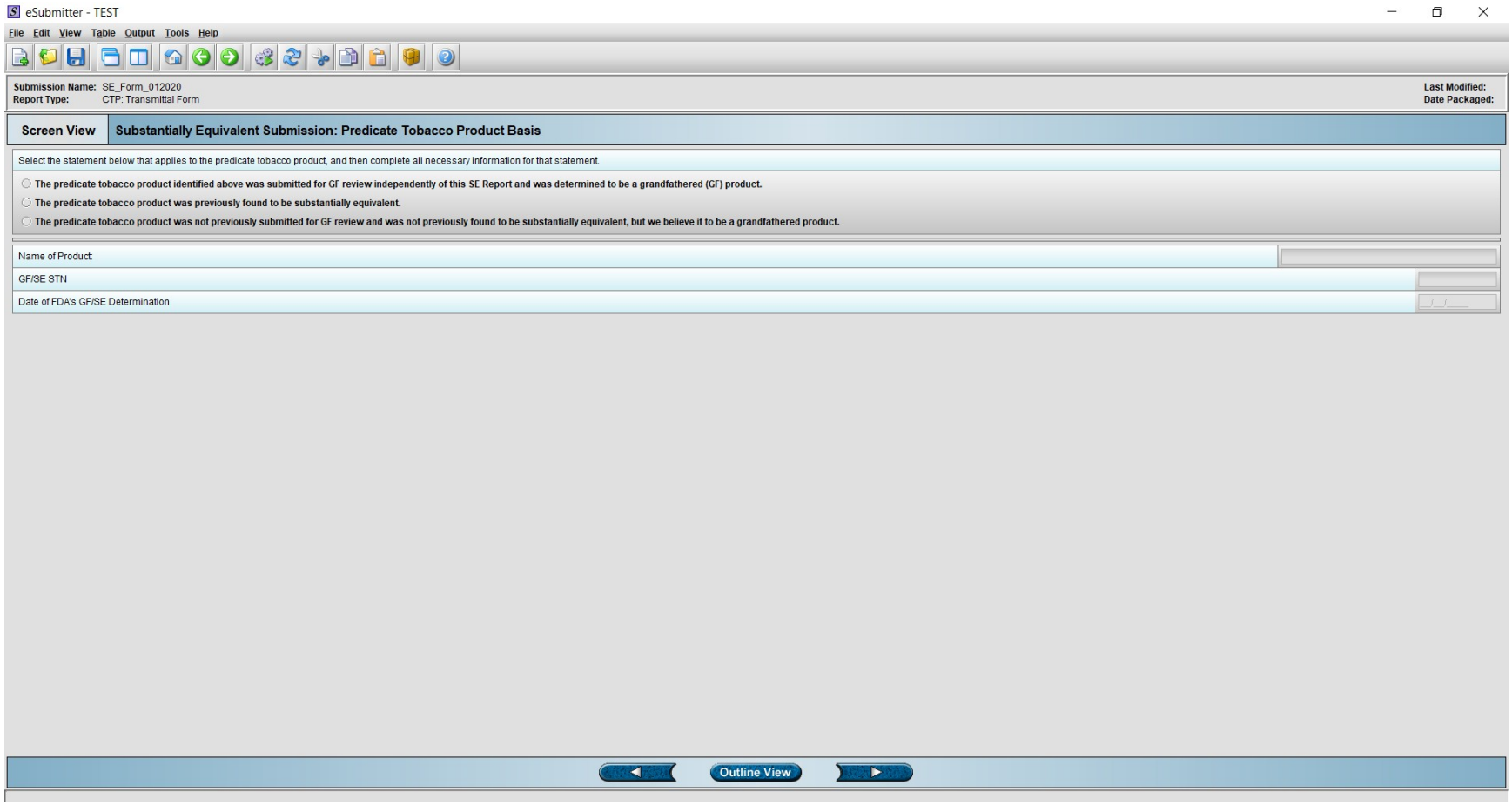

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Cross References - Master Files
List
Detail
Info
Add New Item
Item: 1
STN:
MF_____
Letter of Authorization attachment:
File Attachment
Information and Sections to be referenced from Master File
Outline View

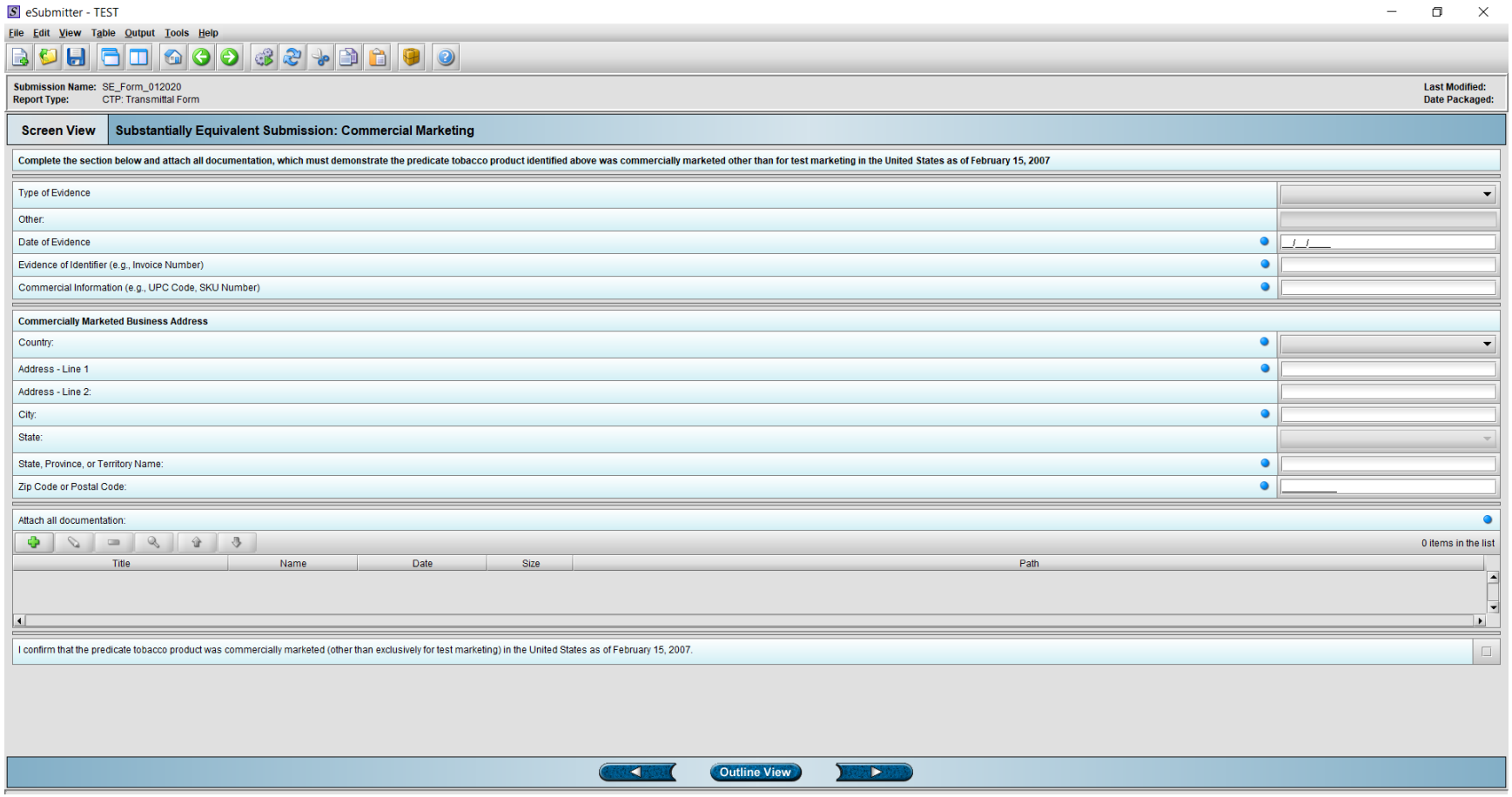

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Cross References - SE Report or MRTP
List
Detail
Info
Item: 1
New Tobacco Product Name of the Cross-referenced STN
Cross-referenced Submission Type
Other
Cross-referenced Submission STN
Document Filename
Document or Study Title
Date Submitted
__/__/____
Table of Contents Category
Document Key Word(s)
0 of 10 items in the list
OPTIONAL- Enter words that describe the content of the document"
Outline View

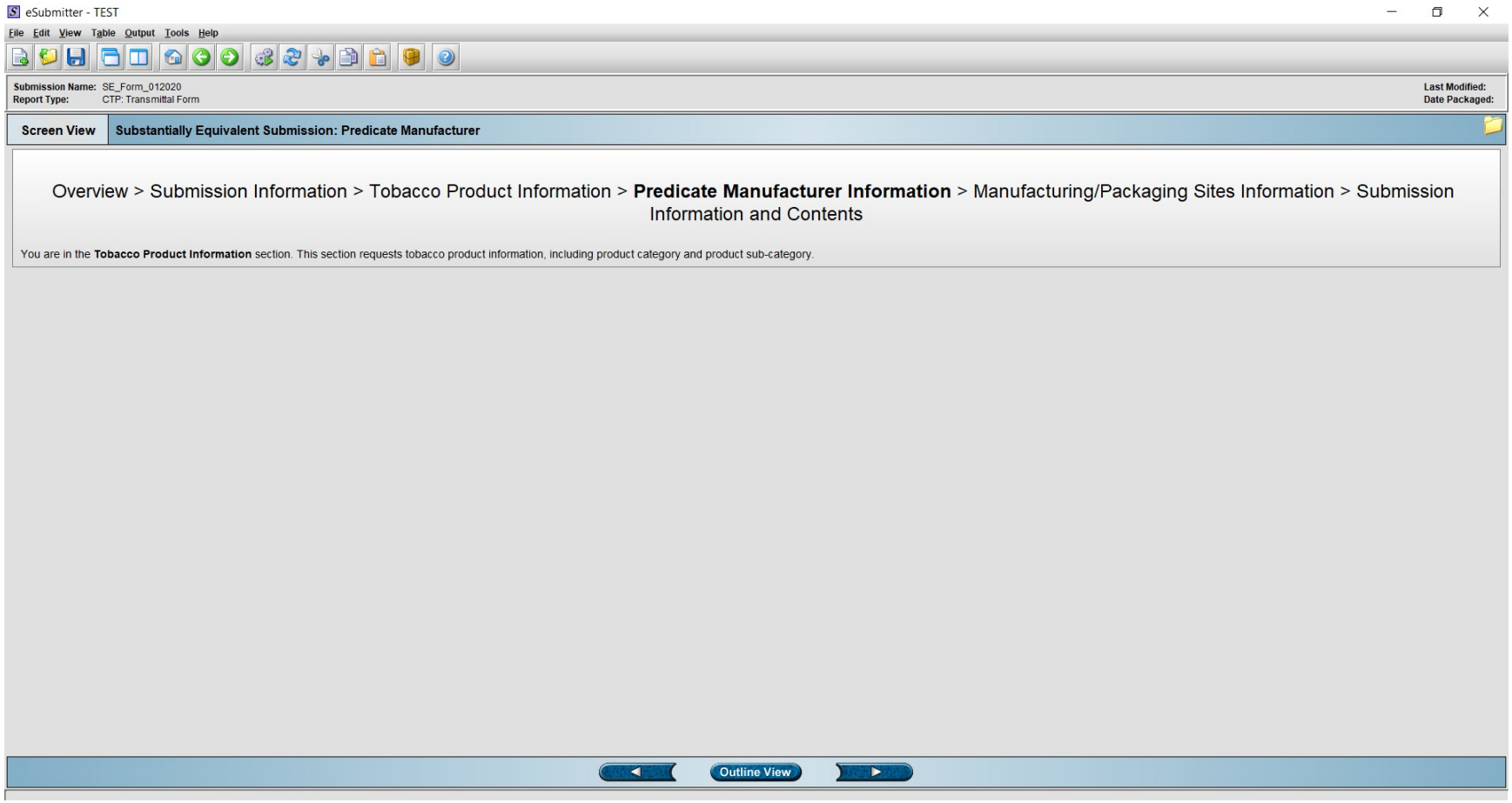

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Related Submissions
List
Detail
Info
Item: 1
List the FDA submission tracking numbers (STNs) for all your previous requests for the new tobacco products (e.g., ITP, SE, MRTPA) where applicable
New Tobacco Product Name of Related Submission
Related Submission Type
Other
Related Submission STN
Outline View

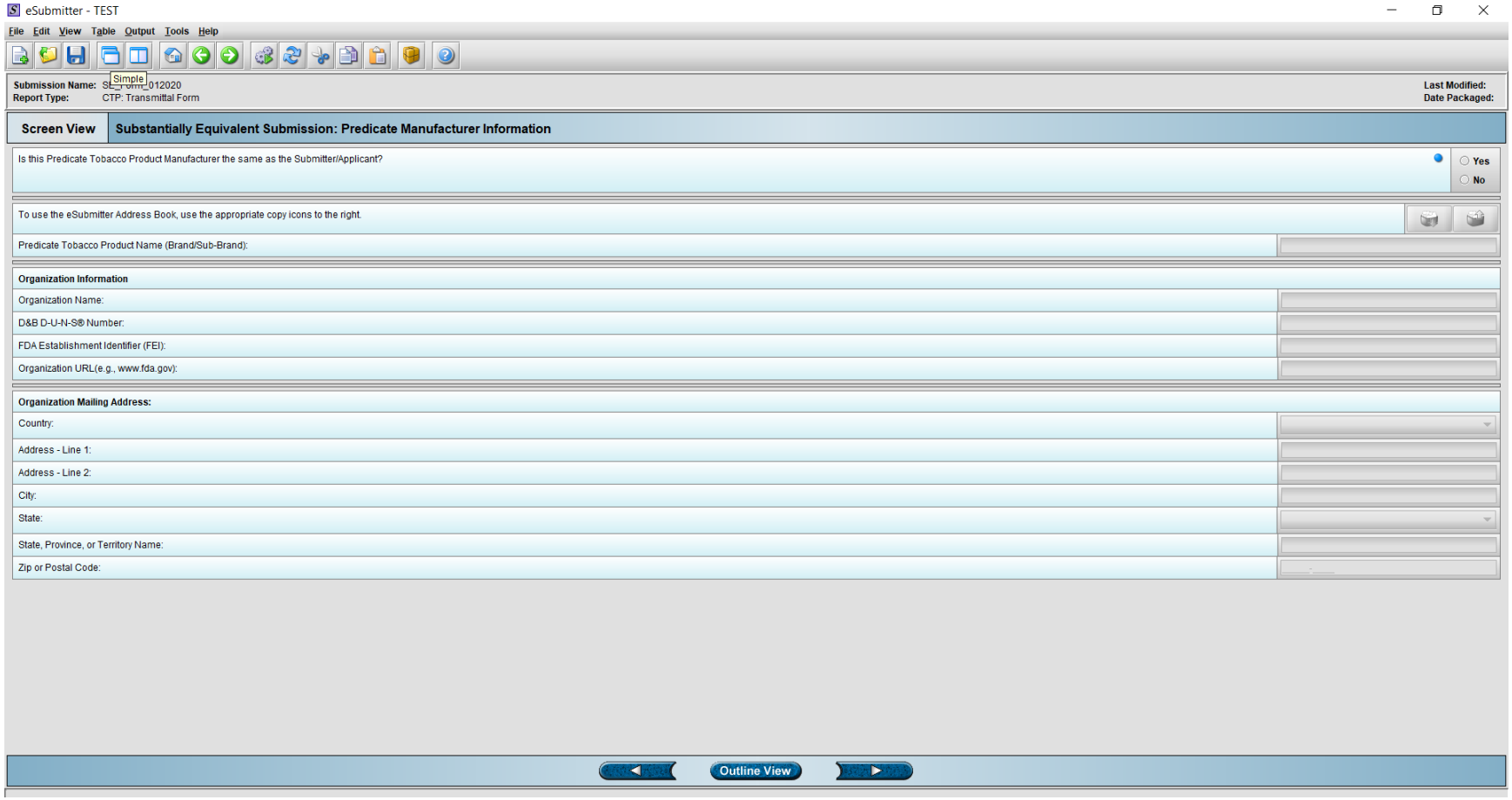

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Formal Meetings
Meetings
List
Detail
Info
Item: 1
Formal Meetings Held with FDA pertaining to this tobacco product (For each meeting, as needed, enter the STN number and meeting held date.)
New Tobacco Product Name (Provide product name if meeting is relevant to a specific product)
Meeting STN (e.g.: TC1234567)
Meeting Held Date
__/__/____
Outline View

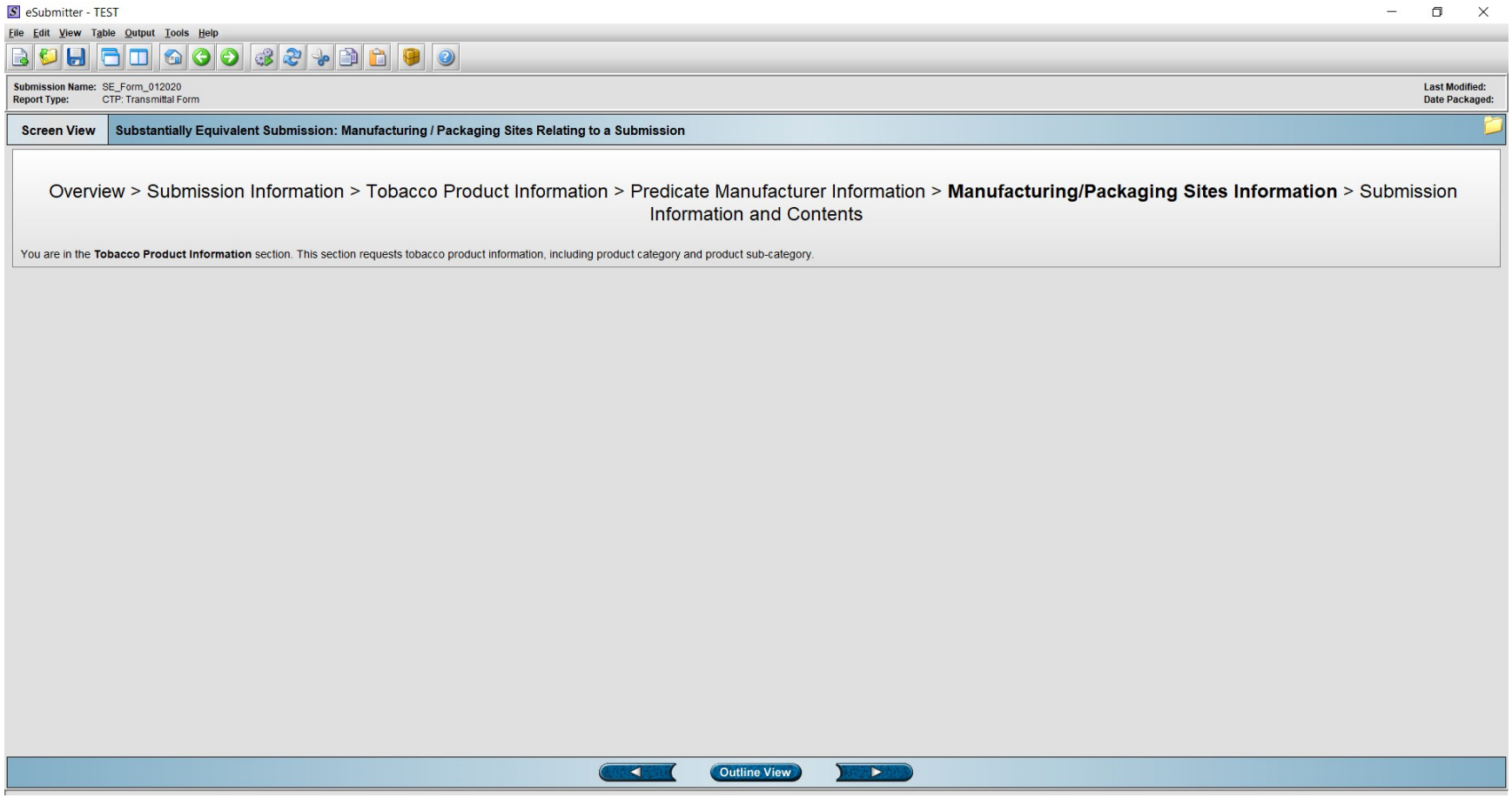

eSubmitter - TEST
File Edit View Table Output Tools Help
Simple
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Tobacco Product Information
Overview > Submission Information > Tobacco Product Information > Predicate Manufacturer Information > Manufacturing/Packaging Sites Information > Submission Information and Contents
You are in the Tobacco Product Information section. This section requests tobacco product information, including product category and product sub-category.
Check this box if your product is co-packaged, meaning multiple components are contained in the same container closure system (e.g., a tin that contains both loose tobacco filler and rolling papers together)
Click this link to download the Product Spreadsheet to your local machine.
Please select 'SE' as your application type, then fill in your information on the spreadsheet and attach it below.
Tobacco Product Information Spreadsheet
Please fill in information for only one product in this spreadsheet. If you would like to submit information for multiple products, please use the 'save-as' feature to create a submission for each product, and fill in the spreadsheet for information pertaining to that product.
Please save your attach your spreadsheet as an 'xlsx' document, not an xlsm.
Attach your Tobacco Product Information spreadsheet:
File Attachment
Outline View

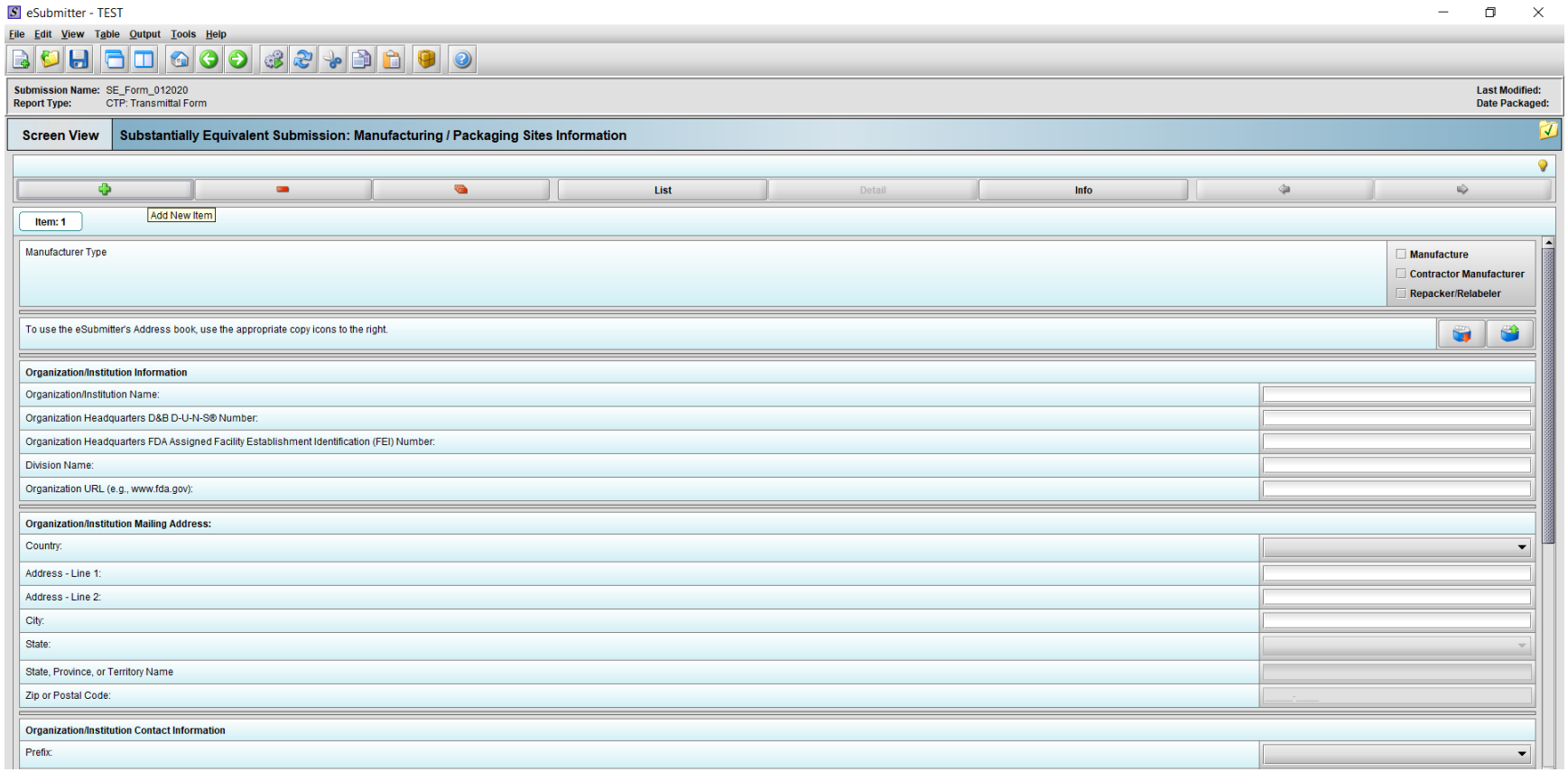

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Predicate Tobacco Product Basis
Select the statement below that applies to the predicate tobacco product, and then complete all necessary information for that statement.
The predicate tobacco product identified above was submitted for GF review independently of this SE Report and was determined to be a grandfathered (GF) product.
The predicate tobacco product was previously found to be substantially equivalent.
The predicate tobacco product was not previously submitted for GF review and was not previously found to be substantially equivalent, but we believe it to be a grandfathered product.
Name of Product:
GF/SE STN
Date of FDA's GF/SE Determination
Outline View

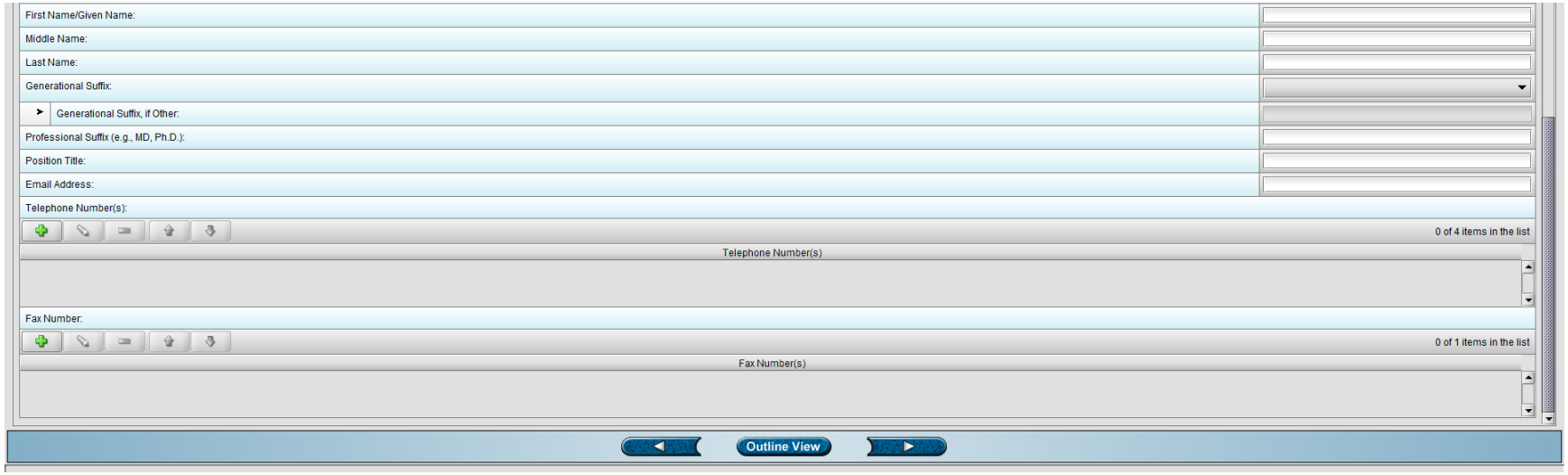

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Commercial Marketing
Complete the section below and attach all documentation, which must demonstrate the predicate tobacco product identified above was commercially marketed other than for test marketing in the United States as of February 15, 2007
Type of Evidence
Other:
Date of Evidence
__/__/____
Evidence of Identifier (e.g., Invoice Number)
Commercial Information (e.g., UPC Code, SKU Number)
Commercially Marketed Business Address
Country:
Address - Line 1
Address - Line 2:
City:
State:
State, Province, or Territory Name:
Zip Code or Postal Code:
Attach all documentation:
0 items in the list
Title
Name
Date
Size
Path
I confirm that the predicate tobacco product was commercially marketed (other than exclusively for test marketing) in the United States as of February 15, 2007.
Outline View

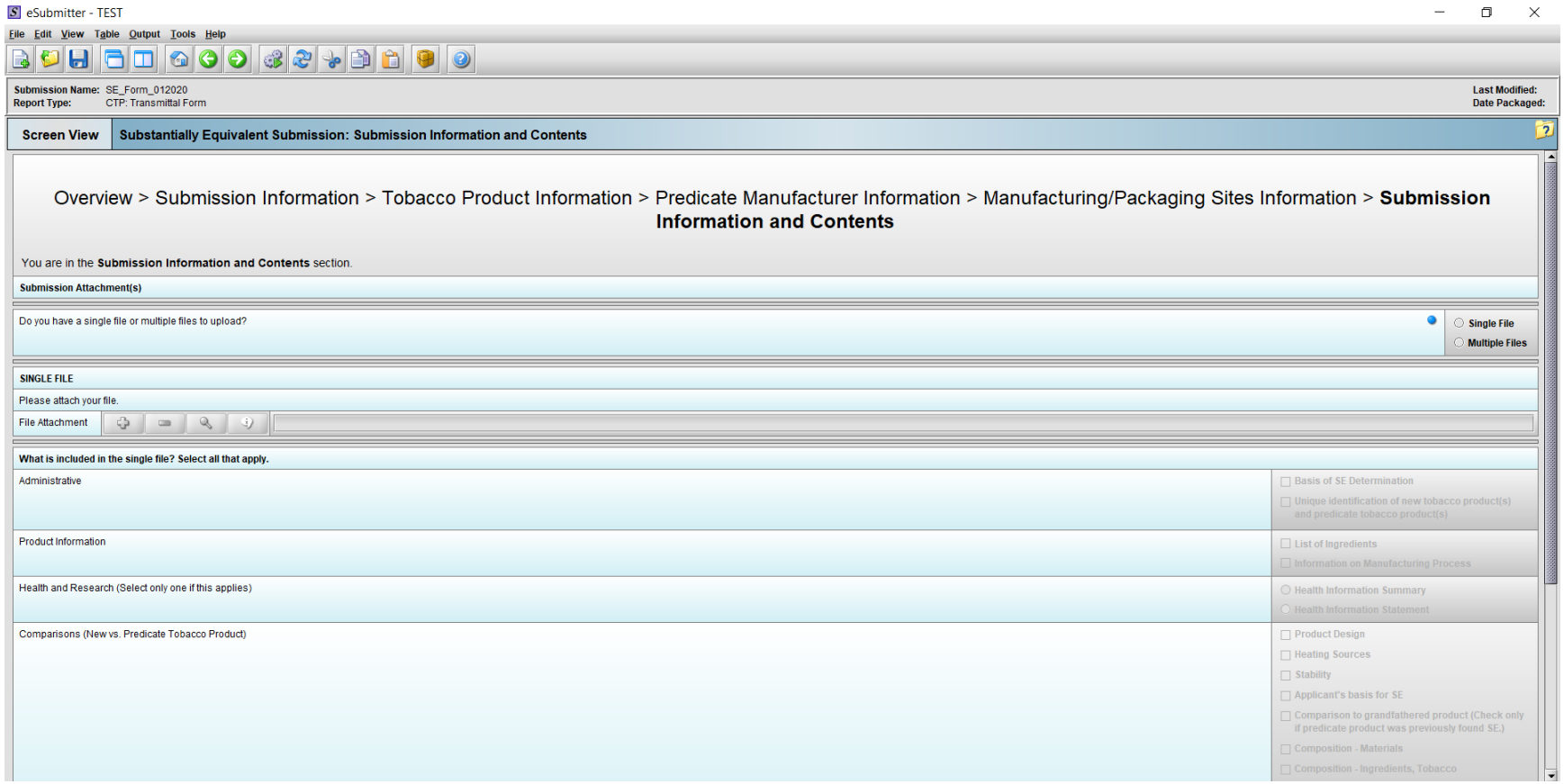

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Predicate Manufacturer
Overview > Submission Information > Tobacco Product Information > Predicate Manufacturer Information > Manufacturing/Packaging Sites Information > Submission Information and Contents
You are in the Tobacco Product Information section. This section requests tobacco product information, including product category and product sub-category.
Outline View

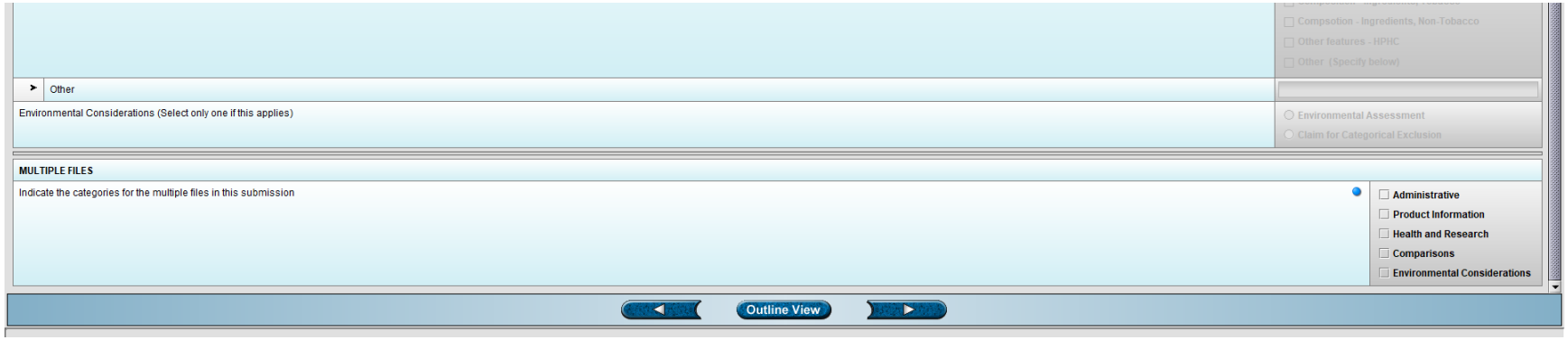

eSubmitter - TEST
File Edit View Table Output Tools Help
Simple
Submission Name: S[illegible]012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Predicate Manufacturer Information
Is this Predicate Tobacco Product Manufacturer the same as the Submitter/Applicant?
Yes
No
To use the eSubmitter Address Book, use the appropriate copy icons to the right.
Predicate Tobacco Product Name (Brand/Sub-Brand):
Organization Information
Organization Name:
D&B D-U-N-S® Number:
FDA Establishment Identifier (FEI):
Organization URL(e.g., www.fda.gov):
Organization Mailing Address:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name:
Zip or Postal Code:
Outline View

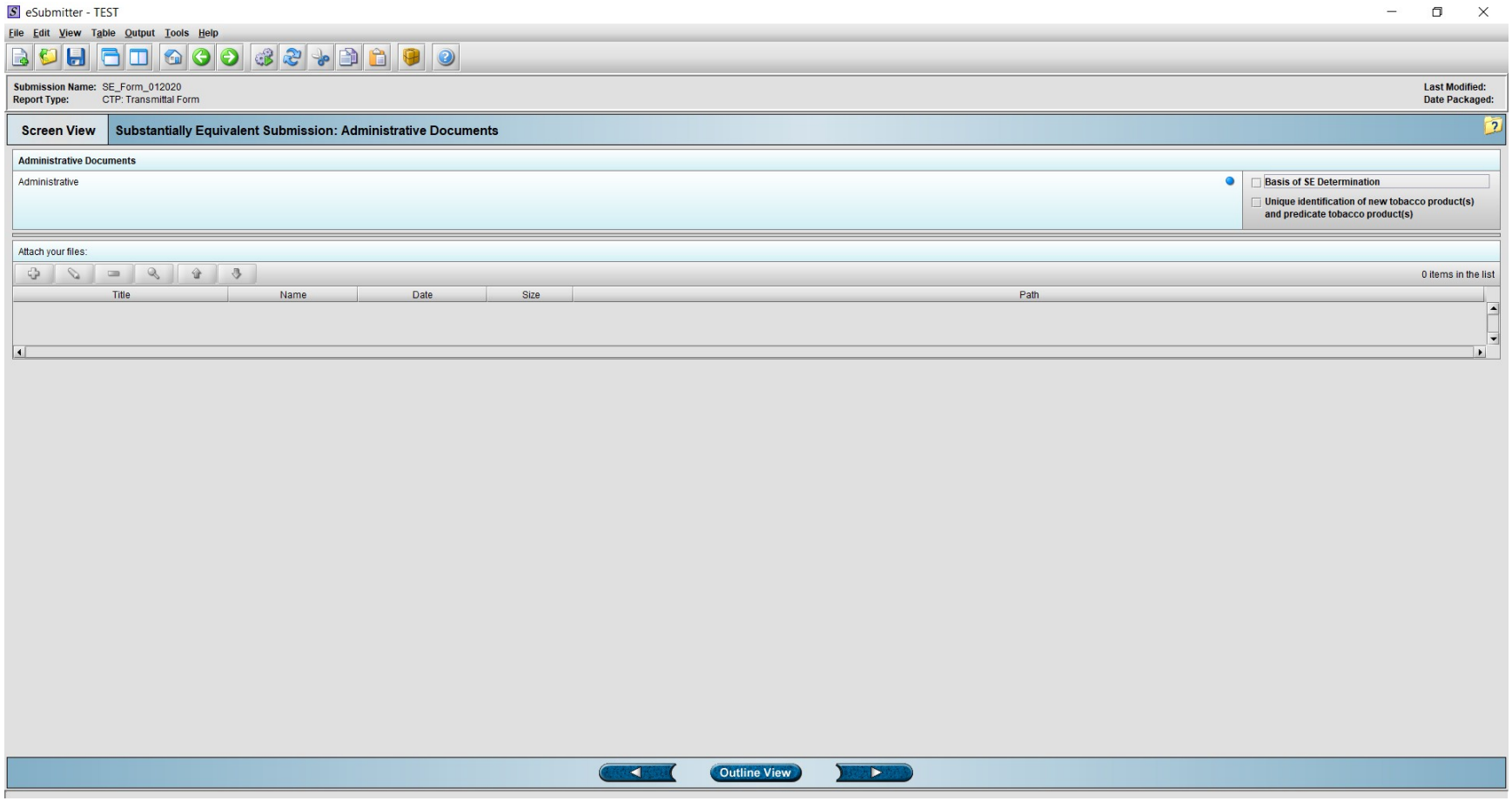

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Manufacturing / Packaging Sites Relating to a Submission
Overview > Submission Information > Tobacco Product Information > Predicate Manufacturer Information > Manufacturing/Packaging Sites Information > Submission Information and Contents
You are in the Tobacco Product Information section. This section requests tobacco product information, including product category and product sub-category.
Outline View

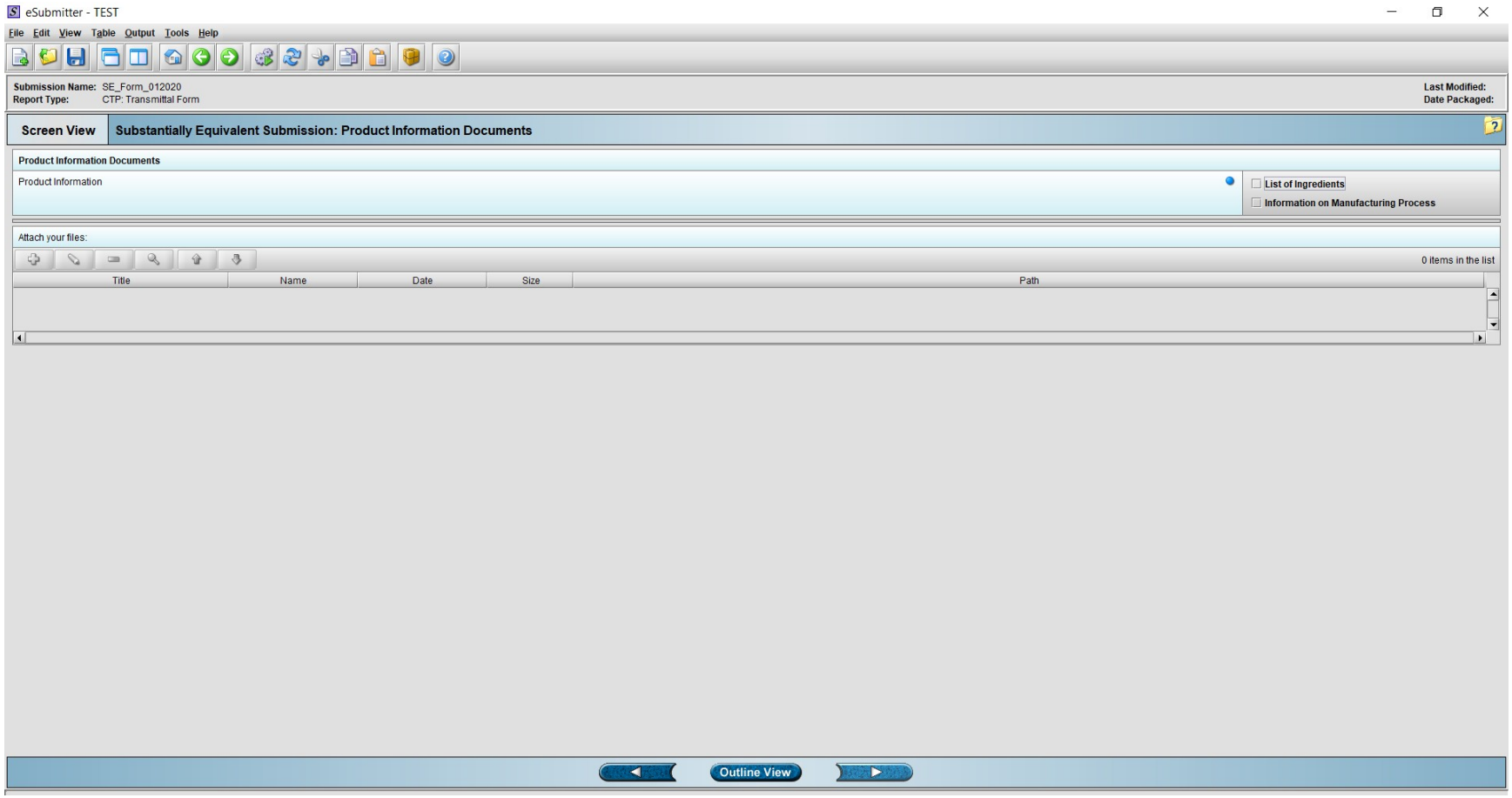

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Manufacturing / Packaging Sites Information
List
Detail
Info
Item: 1
Add New Item
Manufacturer Type
Manufacture
Contractor Manufacturer
Repacker/Relabeler
To use the eSubmitter's Address book, use the appropriate copy icons to the right.
Organization/Institution Information
Organization/Institution Name:
Organization Headquarters D&B D-U-N-S® Number:
Organization Headquarters FDA Assigned Facility Establishment Identification (FEI) Number:
Division Name:
Organization URL (e.g., www.fda.gov):
Organization/Institution Mailing Address:
Country:
Address - Line 1:
Address - Line 2:
City:
State:
State, Province, or Territory Name
Zip or Postal Code:
Organization/Institution Contact Information
Prefix:

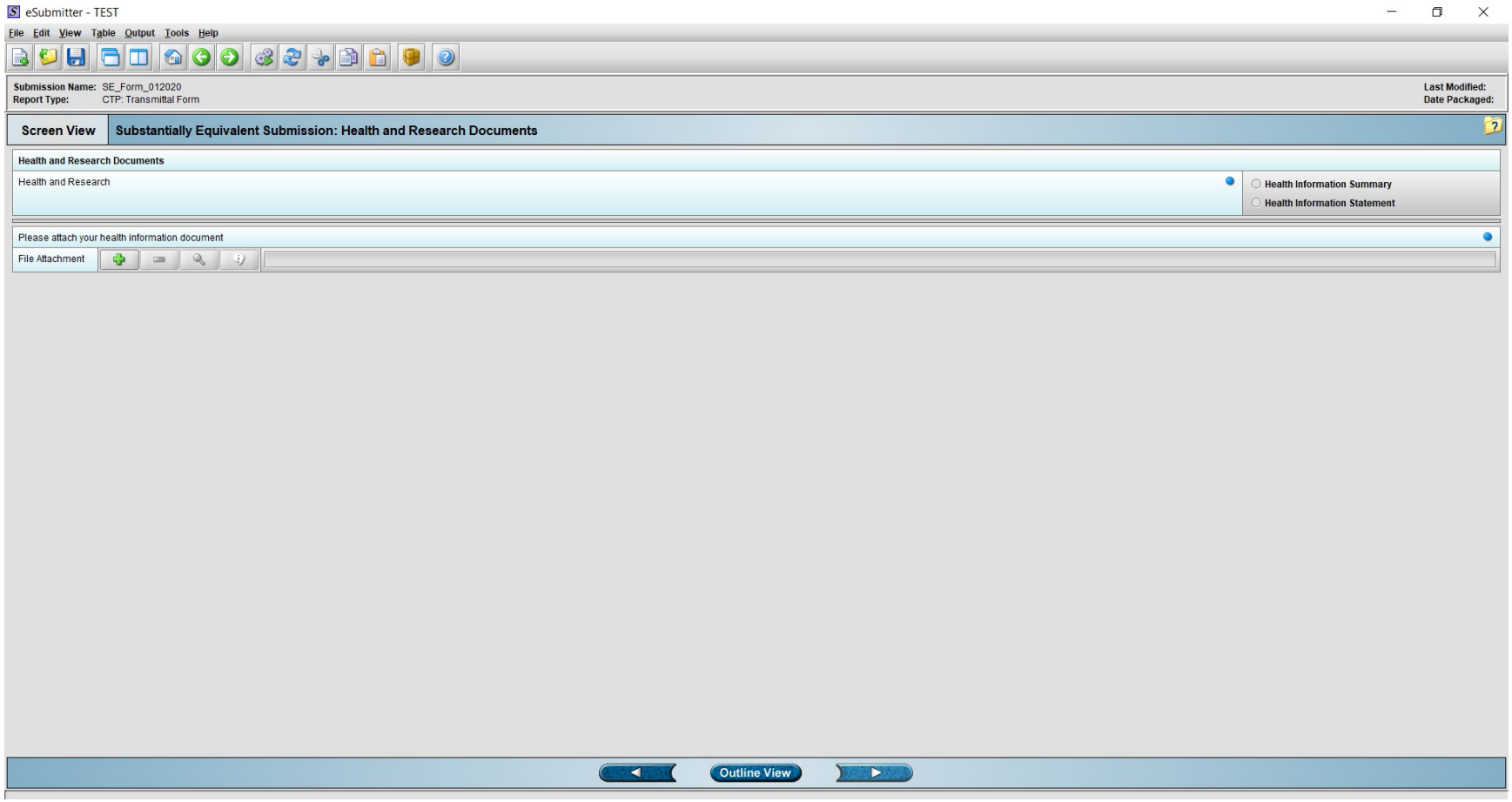

First Name/Given Name:
Middle Name:
Last Name:
Generational Suffix:
Generational Suffix, if Other:
Professional Suffix (e.g., MD, Ph.D.):
Position Title:
Email Address:
Telephone Number(s):
0 of 4 items in the list
Telephone Number(s)
Fax Number:
0 of 1 items in the list
Fax Number(s)
Outline View

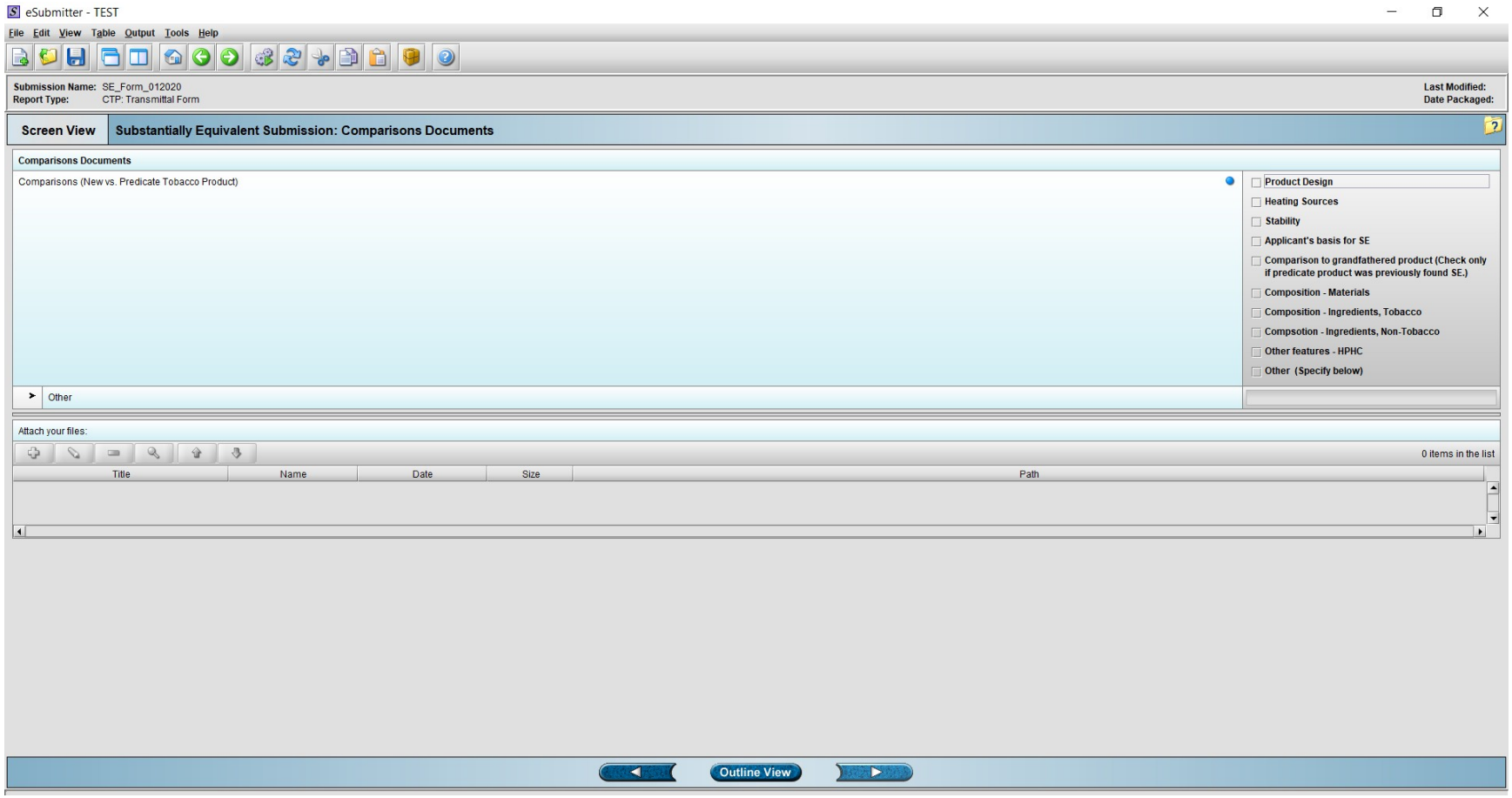

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Submission Information and Contents
Overview > Submission Information > Tobacco Product Information > Predicate Manufacturer Information > Manufacturing/Packaging Sites Information > Submission Information and Contents
You are in the Submission Information and Contents section.
Submission Attachment(s)
Do you have a single file or multiple files to upload?
Single File
Multiple Files
SINGLE FILE
Please attach your file.
File Attachment
What is included in the single file? Select all that apply.
Administrative
Basis of SE Determination
Unique identification of new tobacco product(s) and predicate tobacco product(s)
Product Information
List of Ingredients
Information on Manufacturing Process
Health and Research (Select only one if this applies)
Health Information Summary
Health Information Statement
Comparisons (New vs. Predicate Tobacco Product)
Product Design
Heating Sources
Stability
Applicant's basis for SE
Comparison to grandfathered product (Check only if predicate product was previously found SE.)
Composition - Materials
Composition - Ingredients, Tobacco

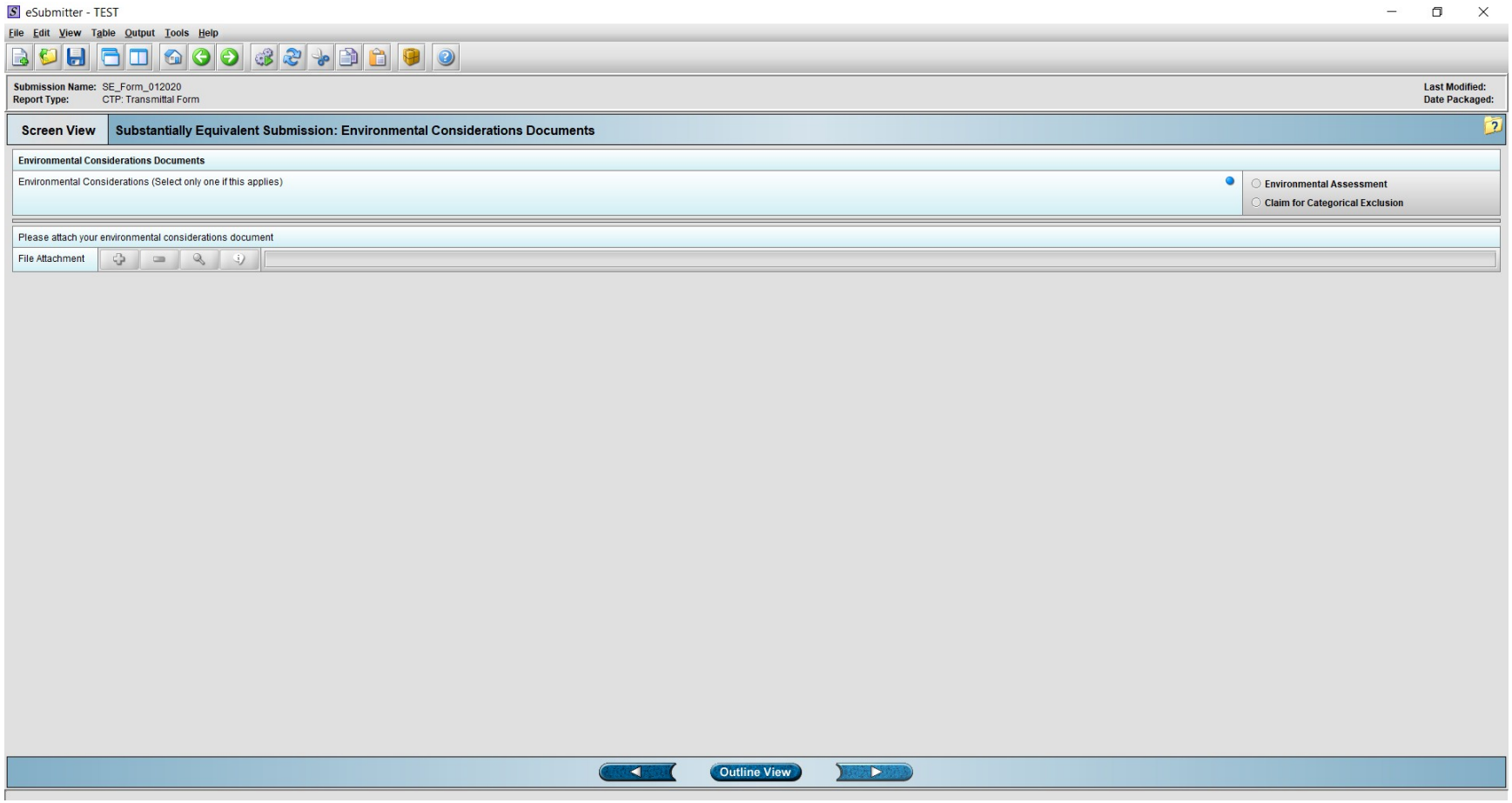

Compsotion - Ingredients, Non-Tobacco
Other features - HPHC
Other (Specify below)
Other
Environmental Considerations (Select only one if this applies)
Environmental Assessment
Claim for Categorical Exclusion
MULTIPLE FILES
Indicate the categories for the multiple files in this submission
Administrative
Product Information
Health and Research
Comparisons
Environmental Considerations
Outline View

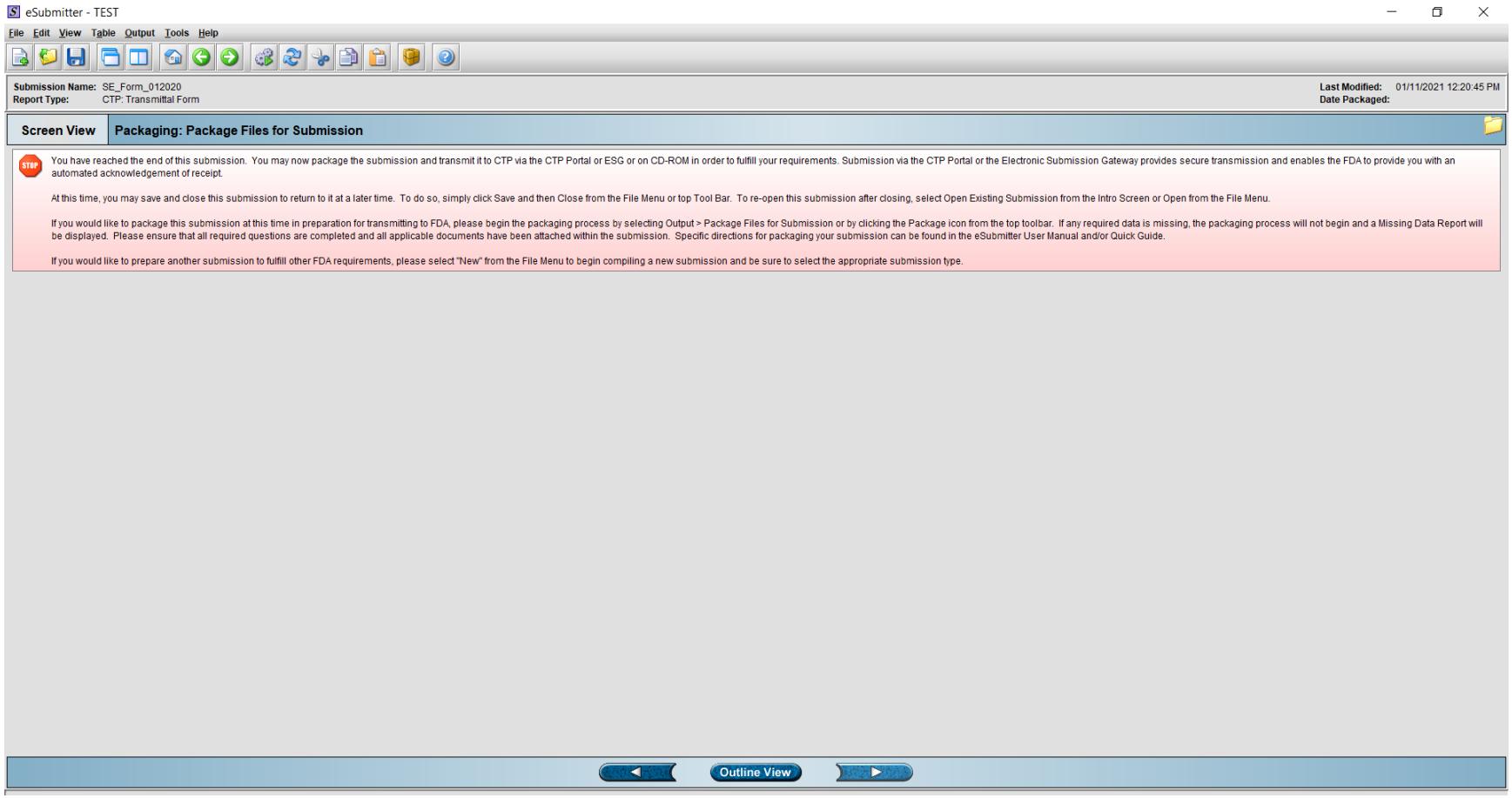

eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Administrative Documents
Administrative Documents
Administrative
Basis of SE Determination
Unique identification of new tobacco product(s) and predicate tobacco product(s)
Attach your files:
0 items in the list
Title
Name
Date
Size
Path
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Product Information Documents
Product Information Documents
Product Information
List of Ingredients
Information on Manufacturing Process
Attach your files:
0 items in the list
Title
Name
Date
Size
Path
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Health and Research Documents
Health and Research Documents
Health and Research
Health Information Summary
Health Information Statement
Please attach your health information document
File Attachment
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Comparisons Documents
Comparisons Documents
Comparisons (New vs. Predicate Tobacco Product)
Product Design
Heating Sources
Stability
Applicant's basis for SE
Comparison to grandfathered product (Check only if predicate product was previously found SE.)
Composition - Materials
Composition - Ingredients, Tobacco
Compsotion - Ingredients, Non-Tobacco
Other features - HPHC
Other (Specify below)
Other
Attach your files:
0 items in the list
Title
Name
Date
Size
Path
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified:
Date Packaged:
Screen View
Substantially Equivalent Submission: Environmental Considerations Documents
Environmental Considerations Documents
Environmental Considerations (Select only one if this applies)
Environmental Assessment
Claim for Categorical Exclusion
Please attach your environmental considerations document
File Attachment
Outline View


eSubmitter - TEST
File Edit View Table Output Tools Help
Submission Name: SE_Form_012020
Report Type: CTP: Transmittal Form
Last Modified: 01/11/2021 12:20:45 PM
Date Packaged:
Screen View
Packaging: Package Files for Submission
You have reached the end of this submission. You may now package the submission and transmit it to CTP via the CTP Portal or ESG or on CD-ROM in order to fulfill your requirements. Submission via the CTP Portal or the Electronic Submission Gateway provides secure transmission and enables the FDA to provide you with an automated acknowledgement of receipt.
At this time, you may save and close this submission to return to it at a later time. To do so, simply click Save and then Close from the File Menu or top Tool Bar. To re-open this submission after closing, select Open Existing Submission from the Intro Screen or Open from the File Menu.
If you would like to package this submission at this time in preparation for transmitting to FDA, please begin the packaging process by selecting Output > Package Files for Submission or by clicking the Package icon from the top toolbar. If any required data is missing, the packaging process will not begin and a Missing Data Report will be displayed. Please ensure that all required questions are completed and all applicable documents have been attached within the submission. Specific directions for packaging your submission can be found in the eSubmitter User Manual and/or Quick Guide.
If you would like to prepare another submission to fulfill other FDA requirements, please select "New" from the File Menu to begin compiling a new submission and be sure to select the appropriate submission type.
Outline View