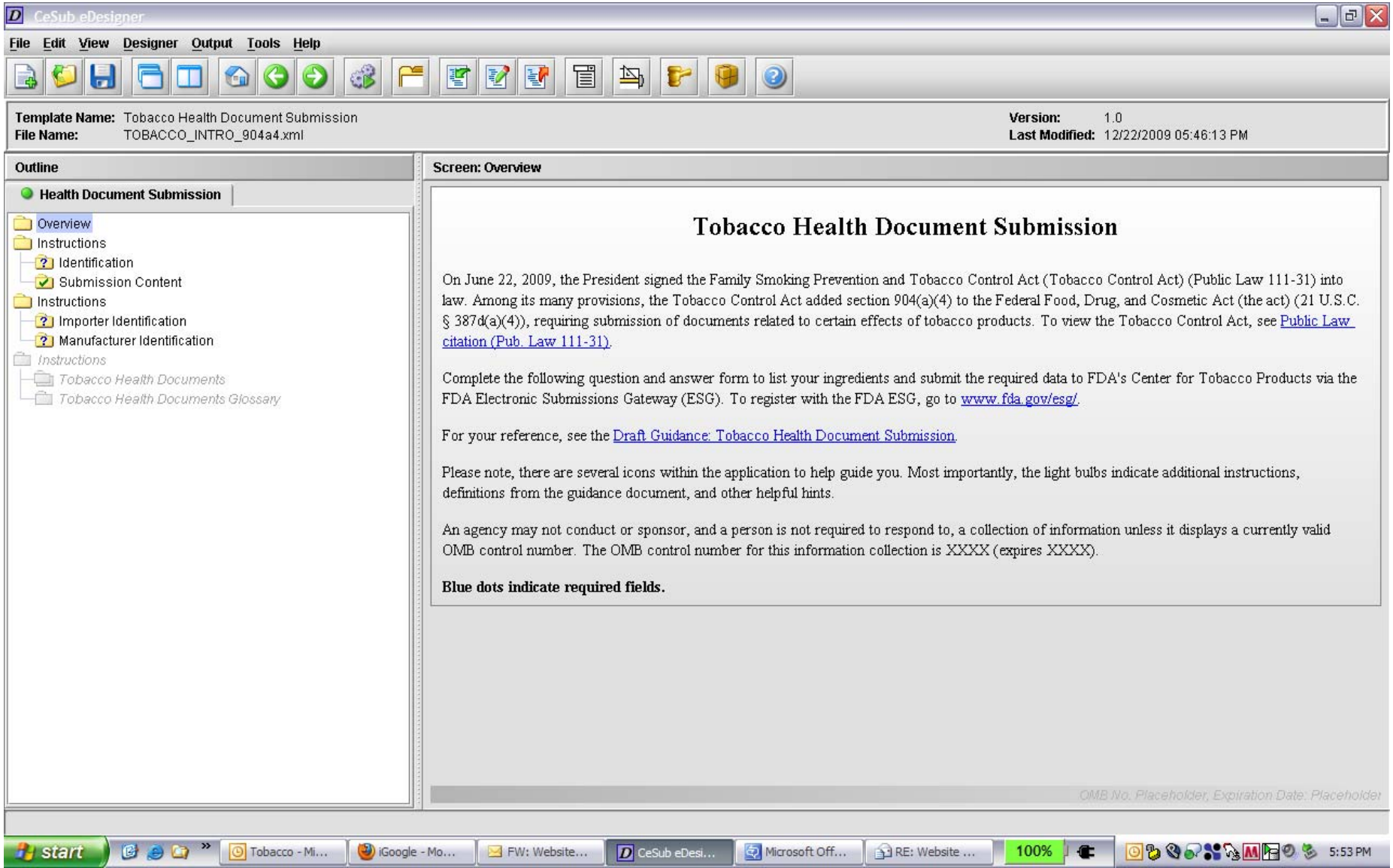
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 05:46:13 PM
Outline
Health Document Submission
Overview
Instructions
Identification
Submission Content
Instructions
Importer Identification
Manufacturer Identification
Instructions
Tobacco Health Documents
Tobacco Health Documents Glossary
Screen: Overview
Tobacco Health Document Submission
On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. Among its many provisions, the Tobacco Control Act added section 904(a)(4) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 387d(a)(4)), requiring submission of documents related to certain effects of tobacco products. To view the Tobacco Control Act, see Public Law citation (Pub. Law 111-31).
Complete the following question and answer form to list your ingredients and submit the required data to FDA's Center for Tobacco Products via the FDA Electronic Submissions Gateway (ESG). To register with the FDA ESG, go to www.fda.gov/esg/.
For your reference, see the Draft Guidance: Tobacco Health Document Submission.
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 XXXX (expires XXXX).
Blue dots indicate required fields.
OMB No. Placeholder, Expiration Date: Placeholder
start
Tobacco - Mi...
iGoogle - Mo...
FW: Website...
CeSub eDesi...
Microsoft Off...
RE: Website ...
100%
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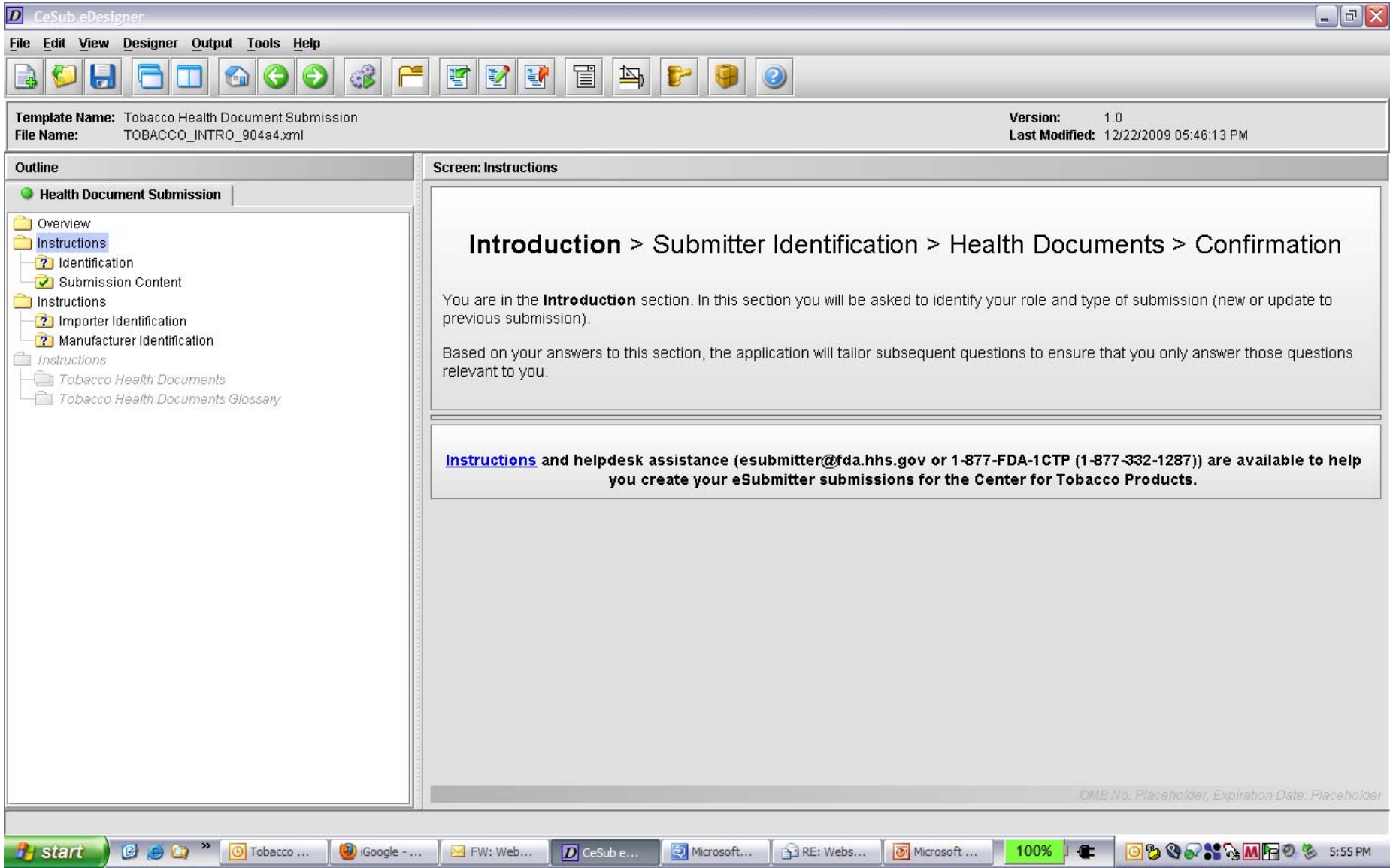
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 05:46:13 PM
Outline
Health Document Submission
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Importer Identification
Manufacturer Identification
Instructions
Tobacco Health Documents
Tobacco Health Documents Glossary
Screen: Instructions
Introduction > Submitter Identification > Health Documents > Confirmation
You are in the Introduction section. In this section you will be asked to identify your role and type of submission (new or update to previous submission).
Based on your answers to this section, the application will tailor subsequent questions to ensure that you only answer those questions relevant to you.
Instructions and helpdesk assistance (esubmitter@fda.hhs.gov or 1-877-FDA-1CTP (1-877-332-1287)) are available to help you create your eSubmitter submissions for the Center for Tobacco Products.
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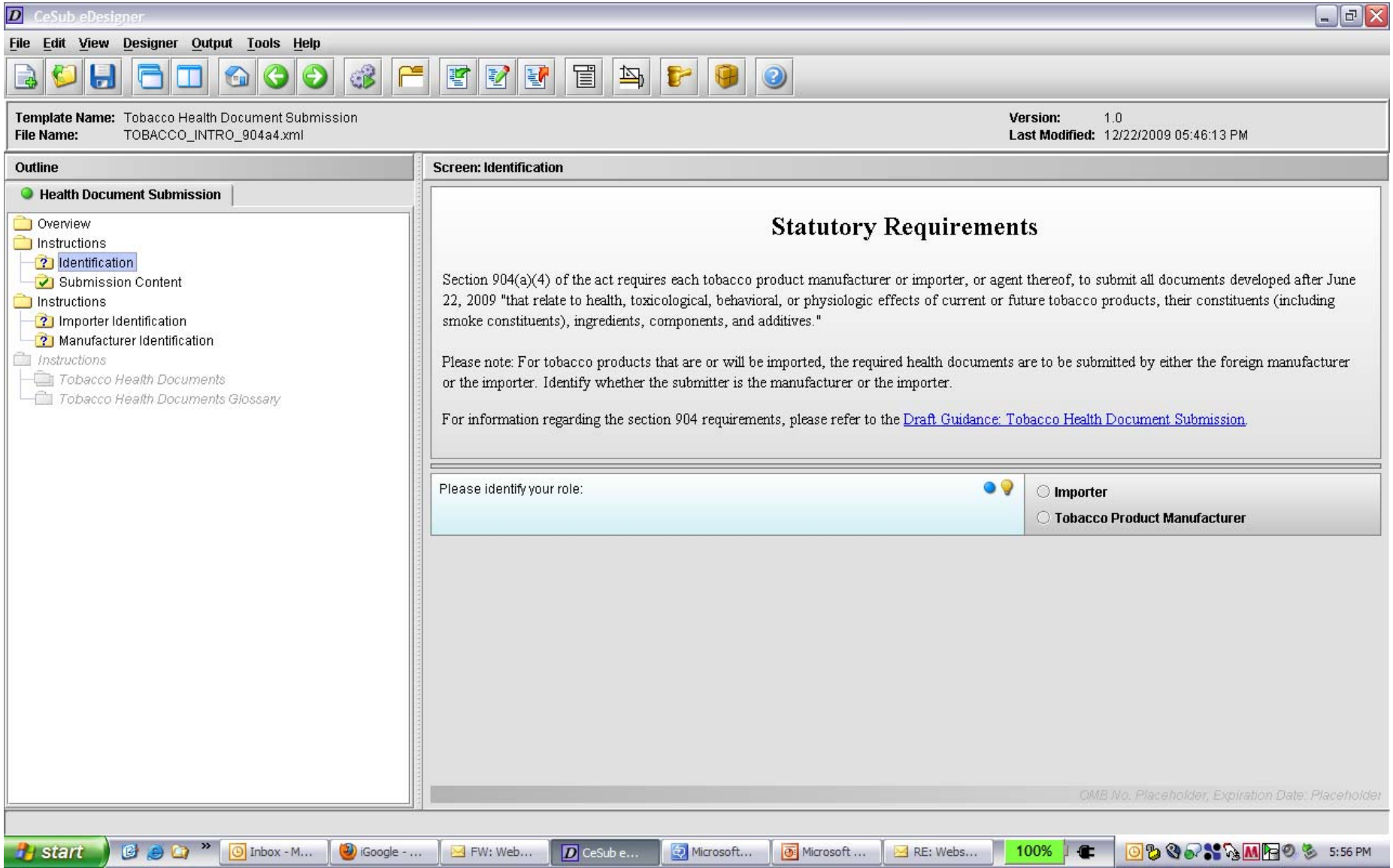
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 05:46:13 PM
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Instructions
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Manufacturer Identification
Instructions
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Screen: Identification
Statutory Requirements
Section 904(a)(4) of the act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009 "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives."
Please note: For tobacco products that are or will be imported, the required health documents are to be submitted by either the foreign manufacturer or the importer. Identify whether the submitter is the manufacturer or the importer.
For information regarding the section 904 requirements, please refer to the Draft Guidance: Tobacco Health Document Submission.
Please identify your role:
Importer
Tobacco Product Manufacturer
OMB No. Placeholder, Expiration Date: Placeholder
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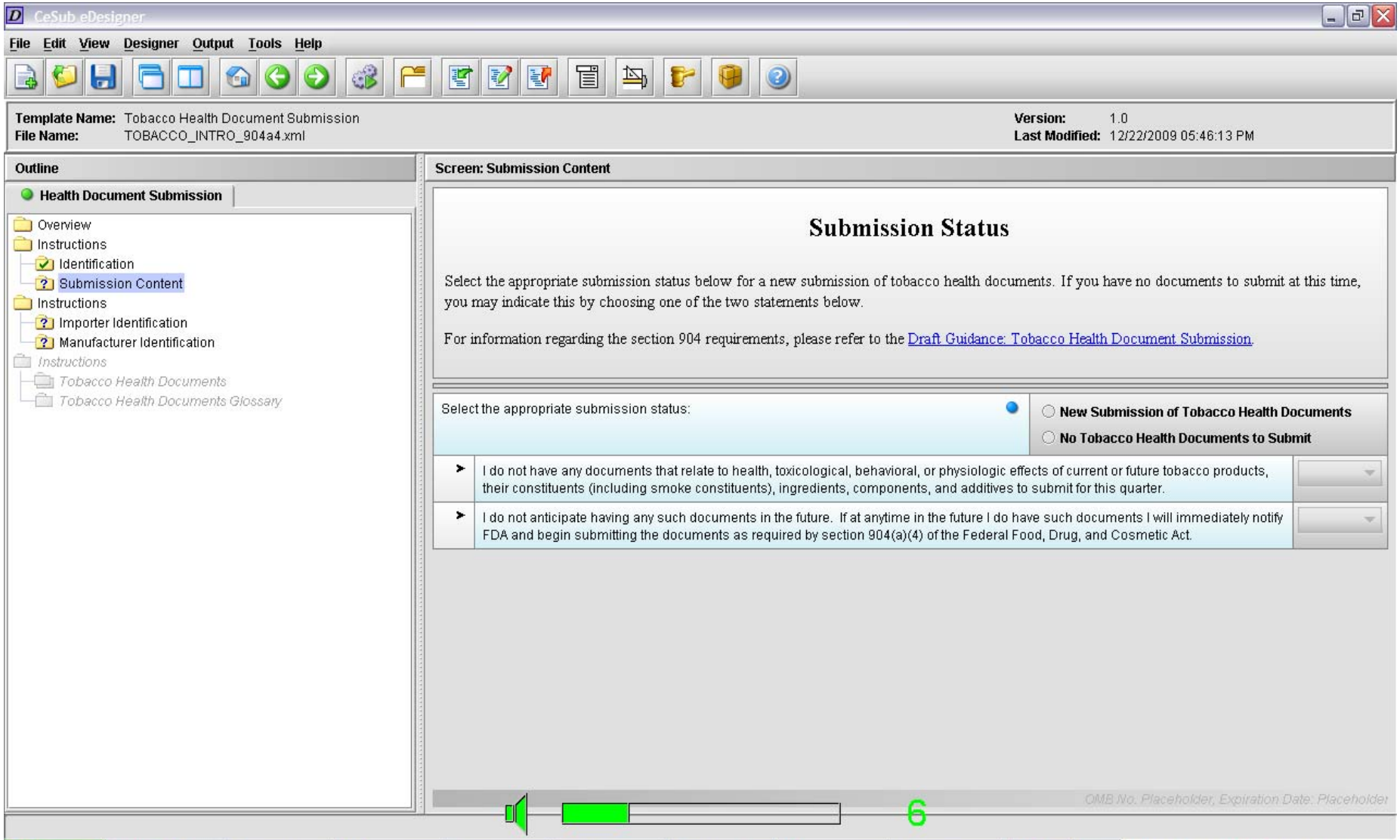
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 05:46:13 PM
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Screen: Submission Content
Submission Status
Select the appropriate submission status below for a new submission of tobacco health documents. If you have no documents to submit at this time, you may indicate this by choosing one of the two statements below.
For information regarding the section 904 requirements, please refer to the Draft Guidance: Tobacco Health Document Submission.
Select the appropriate submission status:
New Submission of Tobacco Health Documents
No Tobacco Health Documents to Submit
I do not have any documents that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives to submit for this quarter.
I do not anticipate having any such documents in the future. If at anytime in the future I do have such documents I will immediately notify FDA and begin submitting the documents as required by section 904(a)(4) of the Federal Food, Drug, and Cosmetic Act.
OMB No. Placeholder, Expiration Date: Placeholder
6
start
Inbox - M...
iGoogle - ...
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RE: Webs...
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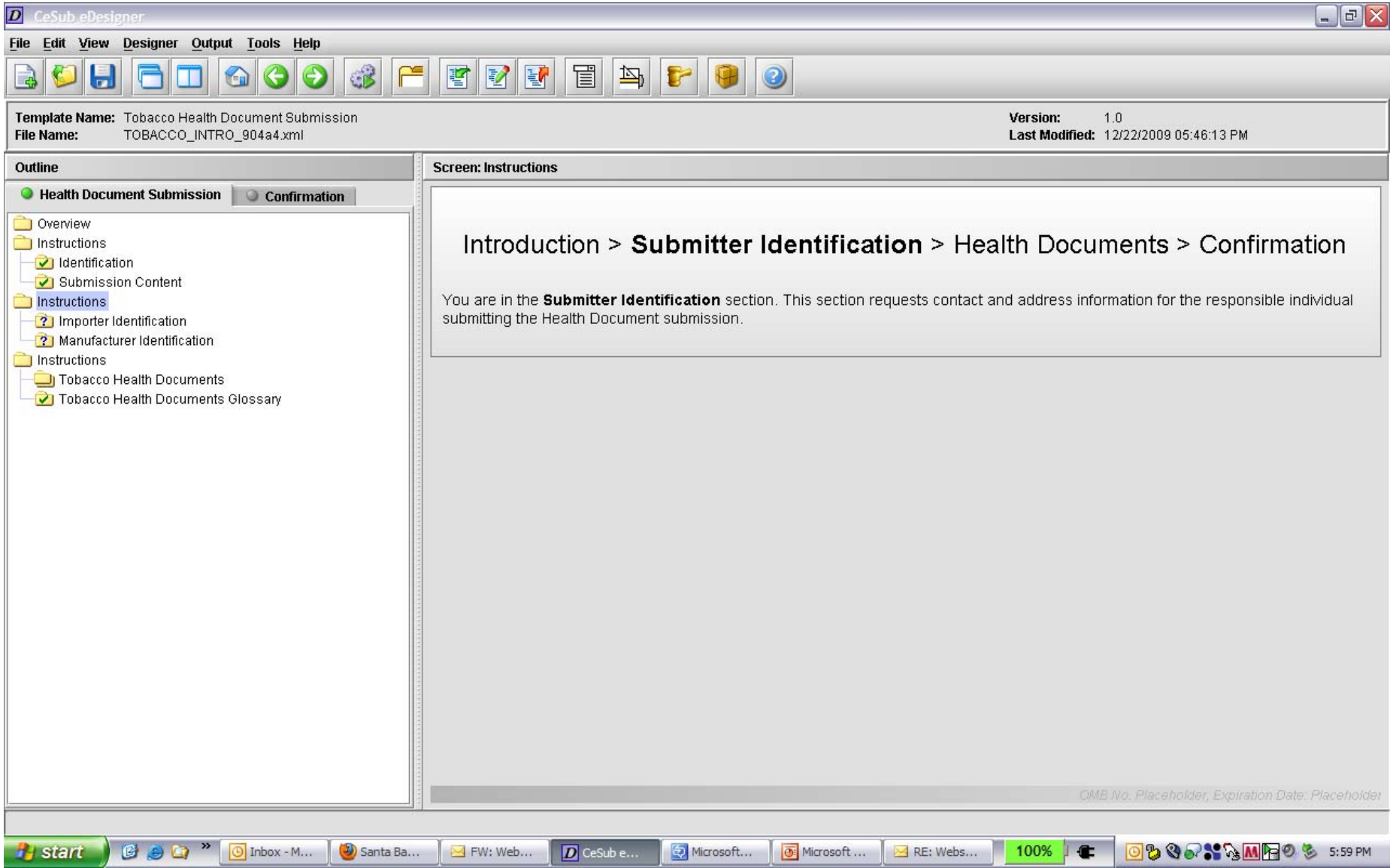
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 05:46:13 PM
Outline
Health Document Submission
Confirmation
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Submission Content
Instructions
Importer Identification
Manufacturer Identification
Instructions
Tobacco Health Documents
Tobacco Health Documents Glossary
Screen: Instructions
Introduction > Submitter Identification > Health Documents > Confirmation
You are in the Submitter Identification section. This section requests contact and address information for the responsible individual submitting the Health Document submission.
OMB No. Placeholder, Expiration Date: Placeholder
start
Inbox - M...
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File Edit View Designer Output Tools Help

**Template Name:** Tobacco Health Document Submission
**File Name:** TOBACCO_INTRO_904a4.xml

**Version:** 1.0
**Last Modified:** 12/22/2009 05:46:13 PM

**Outline**

Health Document Submission | Confirmation

- Overview
- Instructions
  - Identification
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- Instructions
  - Importer Identification
  - Manufacturer Identification
- Instructions
  - Tobacco Health Documents
  - Tobacco Health Documents Glossary

**Screen: Importer Identification**

If you are submitting as an importer, you must complete a separate submission for each manufacturer whose products you import. For each submission, you are also to identify the manufacturer whose documents you are submitting.

Please provide the importer's contact information below:

| Contact | |
|---|---|
| Title (Mr., Ms., Dr.): | |
| First/Given Name: | |
| Middle Name: | |
| Last Name: | |
| Position Title: | |
| Email Address: | |

| Address | |
|---|---|
| Company Name: | |
| Country: | (•) United States of America ( ) Other (select below) |
| Address - Line 1: | |
| Address - Line 2: | |
| City: | |
| State, Province, or Territory: | |
| Post Office or Zip Code: | _____-____ |

| Phone Numbers | |
|---|---|
| Telephone number: | (___) ___-____ Ext: ____ |
| Fax number: | (___) ___-____ |

| Reference Numbers (for the Company Name specified above) | |
|---|---|
| D&B D-U-N-S Number: | |

OMB No. Placeholder, Expiration Date: Placeholder

start | Inbox - Mi... | Santa Bab... | FW: Web... | CeSub eD... | Microsoft ... | Microsoft ... | RE: Websi... | 100% | 6:01 PM

File Edit View Designer Output Tools Help

**Template Name:** Tobacco Health Document Submission
**File Name:** TOBACCO_INTRO_904a4.xml

**Version:** 1.0
**Last Modified:** 12/22/2009 05:46:13 PM

**Outline**

Health Document Submission | Confirmation

- Overview
- Instructions
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- Instructions
  - Importer Identification
  - Manufacturer Identification
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**Screen: Manufacturer Identification**

If you are submitting as an importer, you must complete a separate submission for each manufacturer whose products you import. For each submission, you are also to identify the manufacturer whose documents you are submitting.

Please provide the manufacturer's contact information below:

| **Contact** | |
|---|---|
| Title (Mr., Ms., Dr.): | |
| First/Given Name: | |
| Middle Name: | |
| Last Name: | |
| Position Title: | |
| Email Address: | |

| **Address** | |
|---|---|
| Company Name: | |
| Country: | (•) United States of America ( ) Other (select below) |
| Address - Line 1: | |
| Address - Line 2: | |
| City: | |
| State, Province, or Territory: | |
| Post Office or Zip Code: | ____-____ |

| **Phone Numbers** | |
|---|---|
| Telephone number: | (___) ___-____ Ext: ____ |
| Fax number: | (___) ___-____ |

| **Reference Numbers (for the Company Name specified above)** | |
|---|---|
| D&B D-U-N-S Number: | |

OMB No. Placeholder, Expiration Date: Placeholder

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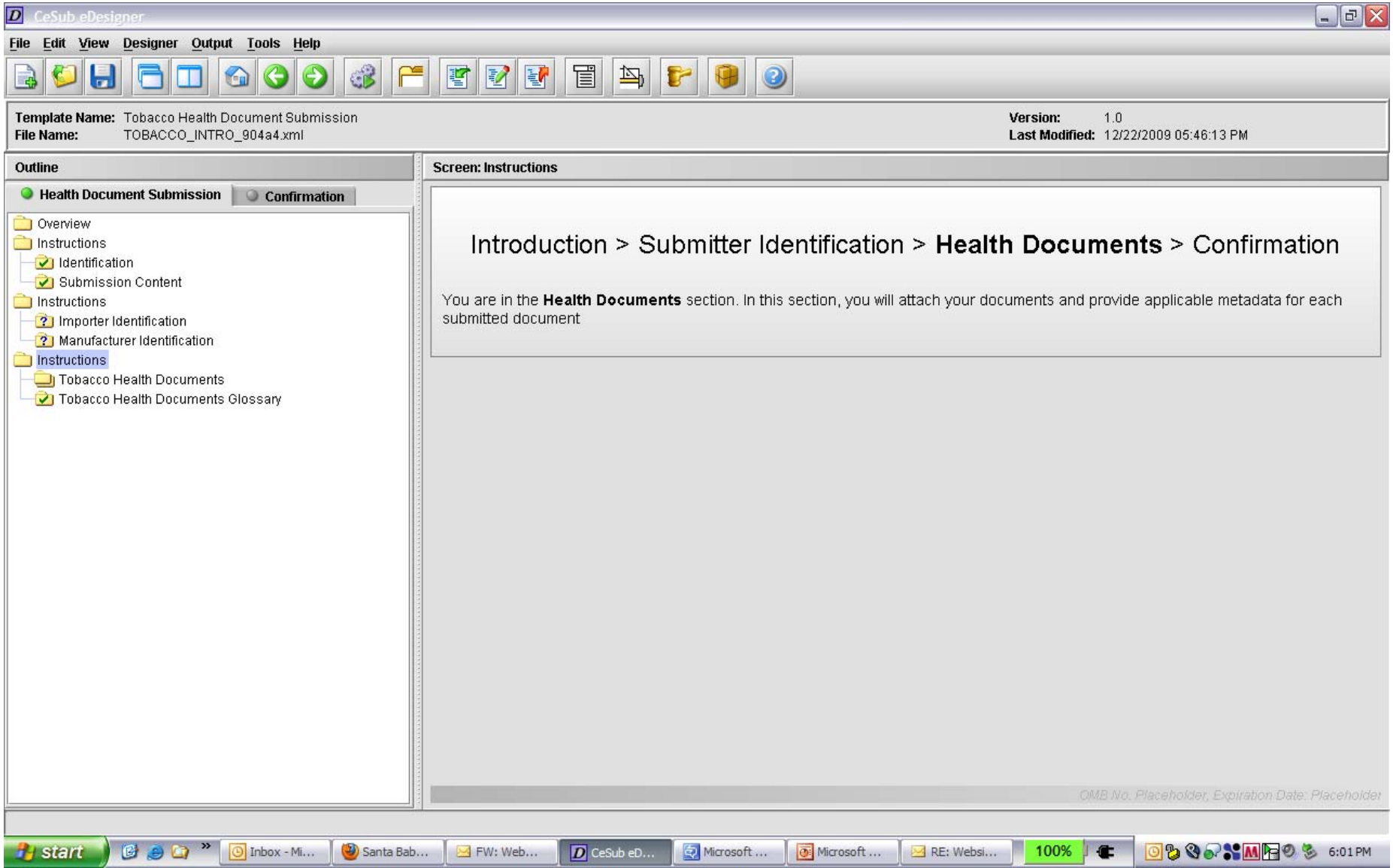
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 05:46:13 PM
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Confirmation
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Instructions
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Instructions
Importer Identification
Manufacturer Identification
Instructions
Tobacco Health Documents
Tobacco Health Documents Glossary
Screen: Instructions
Introduction > Submitter Identification > Health Documents > Confirmation
You are in the Health Documents section. In this section, you will attach your documents and provide applicable metadata for each submitted document
OMB No. Placeholder, Expiration Date: Placeholder
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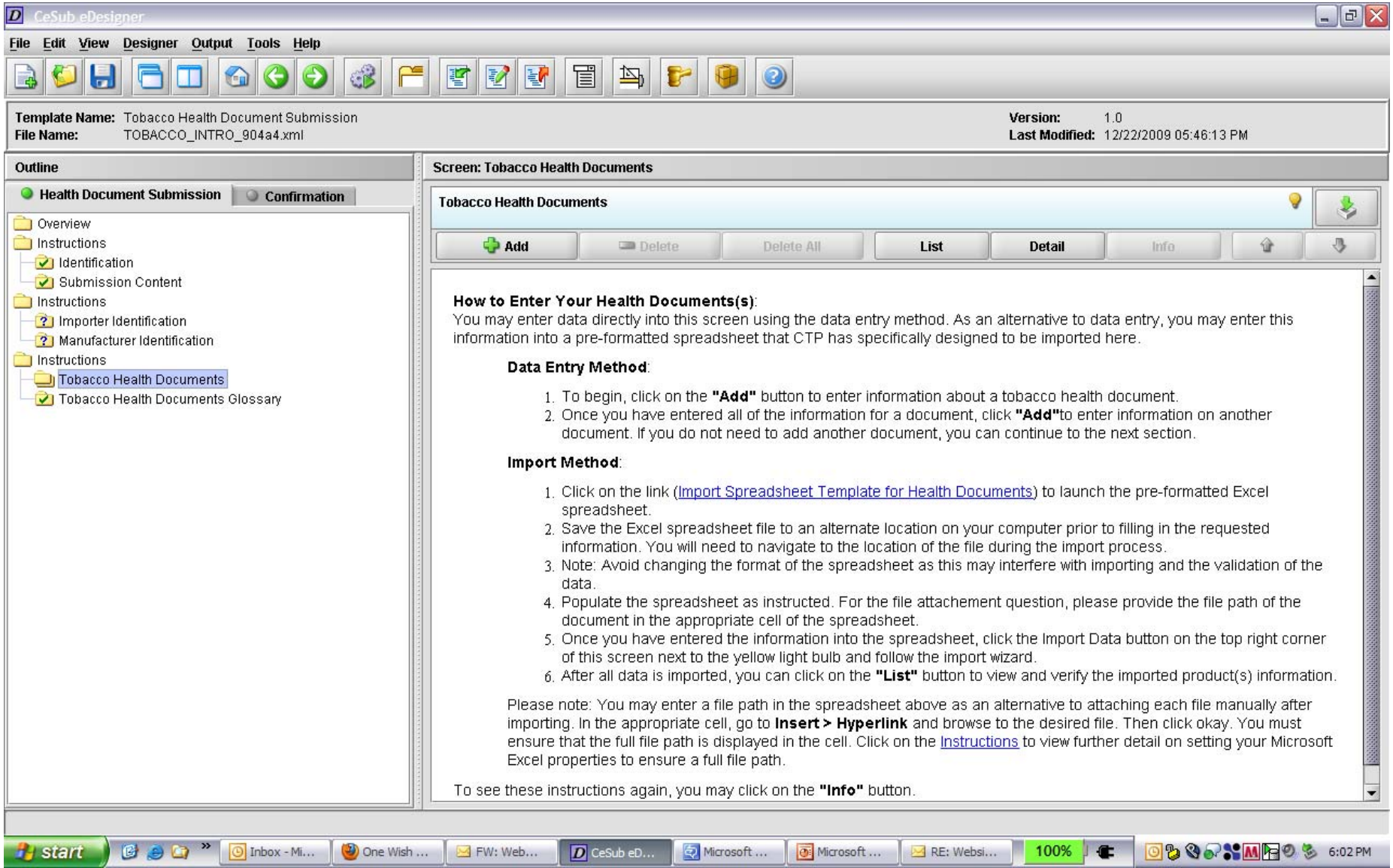
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 05:46:13 PM
Outline
Health Document Submission
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Instructions
Tobacco Health Documents
Tobacco Health Documents Glossary
Screen: Tobacco Health Documents
Tobacco Health Documents
Add
Delete
Delete All
List
Detail
Info
How to Enter Your Health Documents(s):
You may enter data directly into this screen using the data entry method. As an alternative to data entry, you may enter this information into a pre-formatted spreadsheet that CTP has specifically designed to be imported here.
Data Entry Method:
1. To begin, click on the "Add" button to enter information about a tobacco health document.
2. Once you have entered all of the information for a document, click "Add"to enter information on another document. If you do not need to add another document, you can continue to the next section.
Import Method:
1. Click on the link (Import Spreadsheet Template for Health Documents) to launch the pre-formatted Excel spreadsheet.
2. Save the Excel spreadsheet file to an alternate location on your computer prior to filling in the requested information. You will need to navigate to the location of the file during the import process.
3. Note: Avoid changing the format of the spreadsheet as this may interfere with importing and the validation of the data.
4. Populate the spreadsheet as instructed. For the file attachement question, please provide the file path of the document in the appropriate cell of the spreadsheet.
5. Once you have entered the information into the spreadsheet, click the Import Data button on the top right corner of this screen next to the yellow light bulb and follow the import wizard.
6. After all data is imported, you can click on the "List" button to view and verify the imported product(s) information.
Please note: You may enter a file path in the spreadsheet above as an alternative to attaching each file manually after importing. In the appropriate cell, go to Insert > Hyperlink and browse to the desired file. Then click okay. You must ensure that the full file path is displayed in the cell. Click on the Instructions to view further detail on setting your Microsoft Excel properties to ensure a full file path.
To see these instructions again, you may click on the "Info" button.
start
Inbox - Mi...
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File Edit View Designer Output Tools Help

**Template Name:** Tobacco Health Document Submission
**File Name:** TOBACCO_INTRO_904a4.xml

**Version:** 1.0
**Last Modified:** 12/22/2009 06:03:29 PM

**Outline**

Health Document Submission | Confirmation

- Overview
- Instructions
  - Identification
  - Submission Content
- Instructions
  - Importer Identification
  - Manufacturer Identification
- Instructions
  - Tobacco Health Documents
  - Tobacco Health Documents Glossary


- Importer Identification
- Manufacturer Identification
- Instructions
  - Tobacco Health Documents
  - Tobacco Health Documents Glossary


**Screen: Tobacco Health Documents**

**Tobacco Health Documents**

Add | Delete | Delete All | List | Detail | Info

**Item: 1**

**DOCUMENT IDENTIFICATION**

Attach the tobacco health document.

File

Indicate the following effects that this document relates to:

- Health
- Toxicological
- Behavioral
- Physiologic

If this document references specific current or future tobacco product(s), you are required to enter the name of all such products below.

0 of 100 items in the list

If this document references a class of current or future tobacco products (e.g., menthol cigarettes), you are required to enter the name of all such classes below.

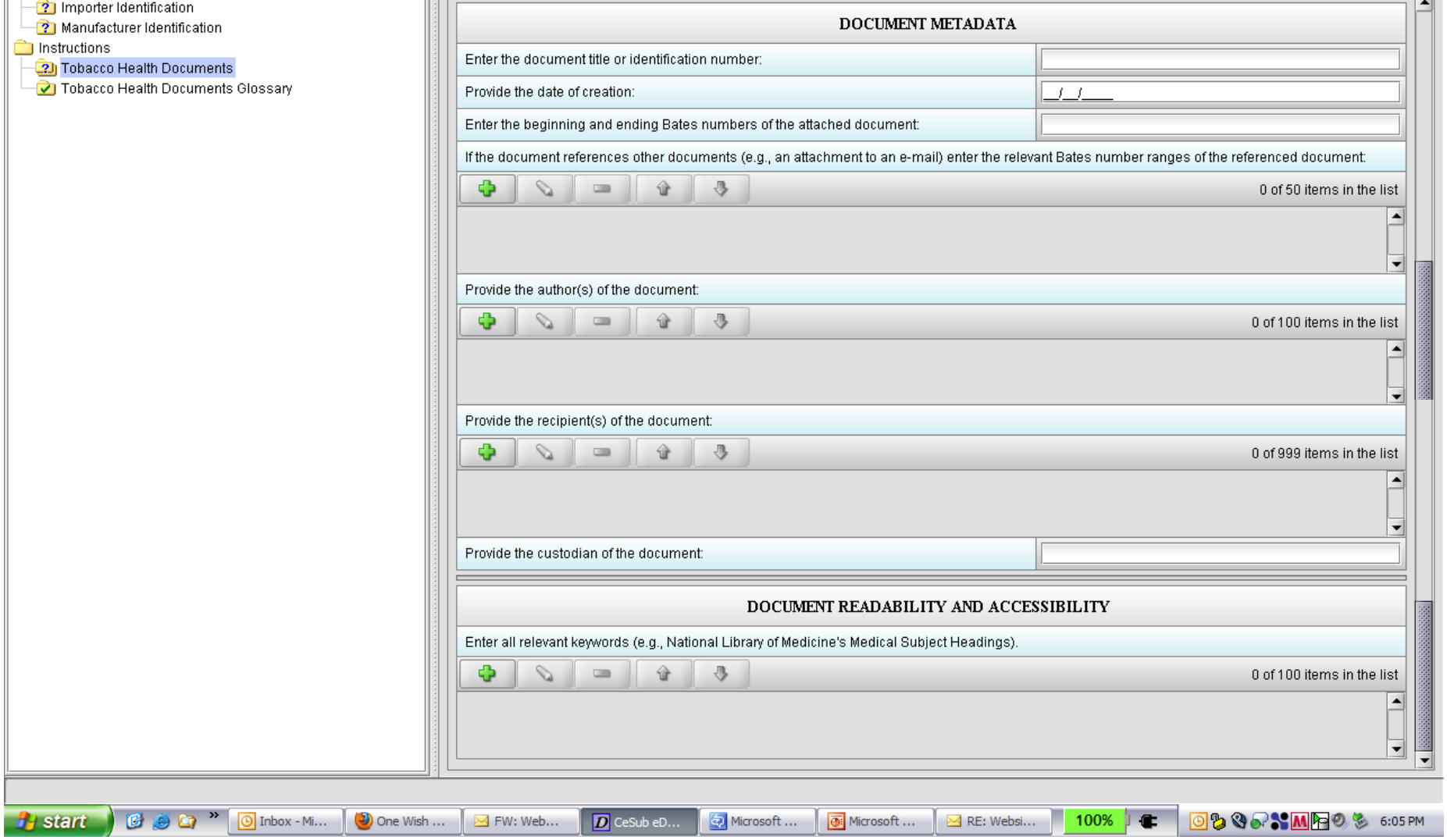
0 of 100 items in the list

If this document references specific ingredient(s), constituent(s), component(s), or additive(s), you are required to enter the name of all such ingredient(s), constituent(s), component(s), or additive(s) below.

0 of 100 items in the list

If this document references a class of ingredients, constituents, components, or additives (e.g., tobacco specific nitrosamines), you are required to enter the name of all such classes below.

0 of 100 items in the list


Importer Identification
Manufacturer Identification
Instructions
Tobacco Health Documents
Tobacco Health Documents Glossary
DOCUMENT METADATA
Enter the document title or identification number:
Provide the date of creation:
__/__/____
Enter the beginning and ending Bates numbers of the attached document:
If the document references other documents (e.g., an attachment to an e-mail) enter the relevant Bates number ranges of the referenced document:
0 of 50 items in the list
Provide the author(s) of the document:
0 of 100 items in the list
Provide the recipient(s) of the document:
0 of 999 items in the list
Provide the custodian of the document:
DOCUMENT READABILITY AND ACCESSIBILITY
Enter all relevant keywords (e.g., National Library of Medicine's Medical Subject Headings).
0 of 100 items in the list
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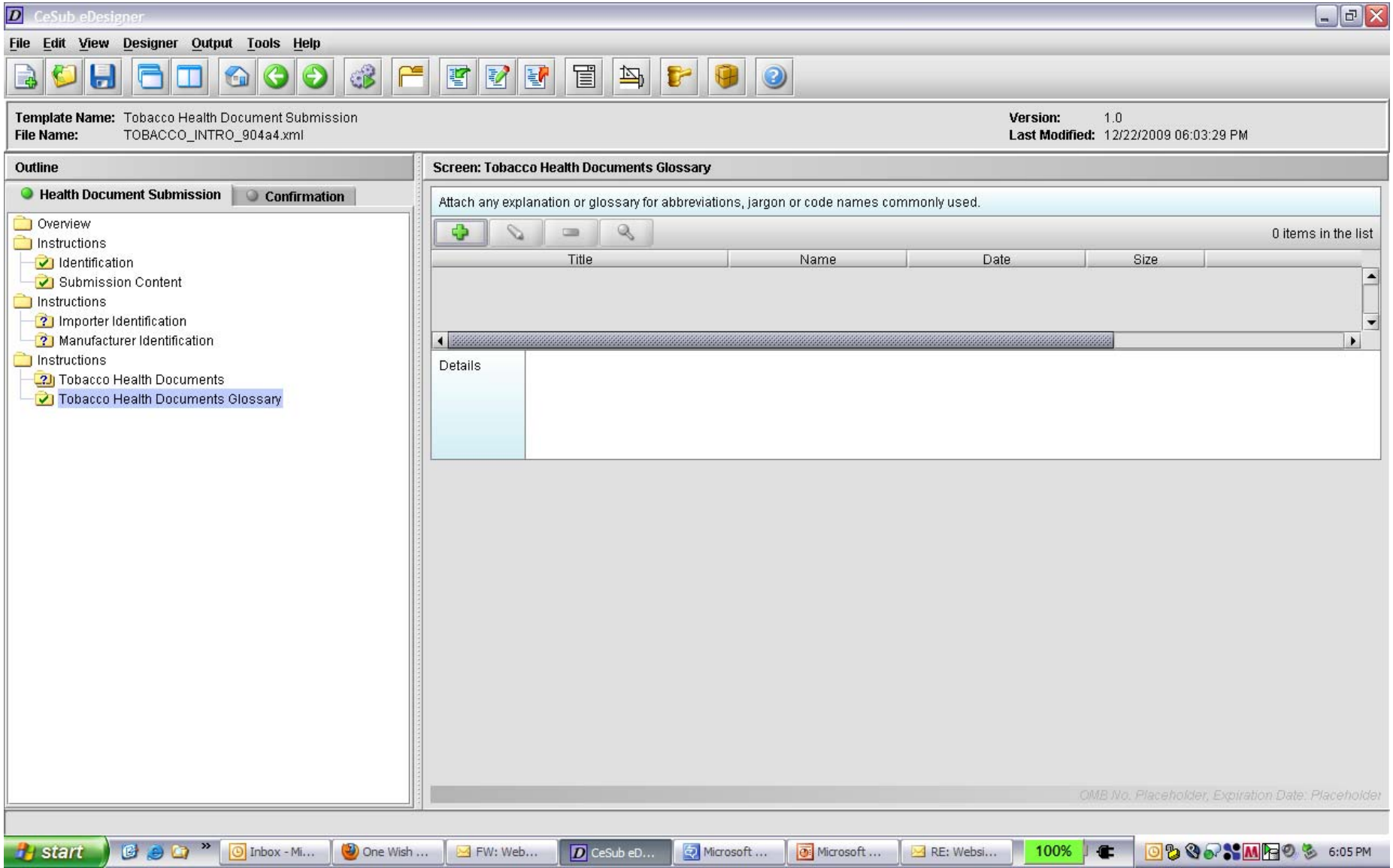
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 06:03:29 PM
Outline
Health Document Submission
Confirmation
Overview
Instructions
Identification
Submission Content
Instructions
Importer Identification
Manufacturer Identification
Instructions
Tobacco Health Documents
Tobacco Health Documents Glossary
Screen: Tobacco Health Documents Glossary
Attach any explanation or glossary for abbreviations, jargon or code names commonly used.
0 items in the list
Title
Name
Date
Size
Details
OMB No. Placeholder, Expiration Date: Placeholder
start
Inbox - Mi...
One Wish ...
FW: Web...
CeSub eD...
Microsoft ...
Microsoft ...
RE: Websi...
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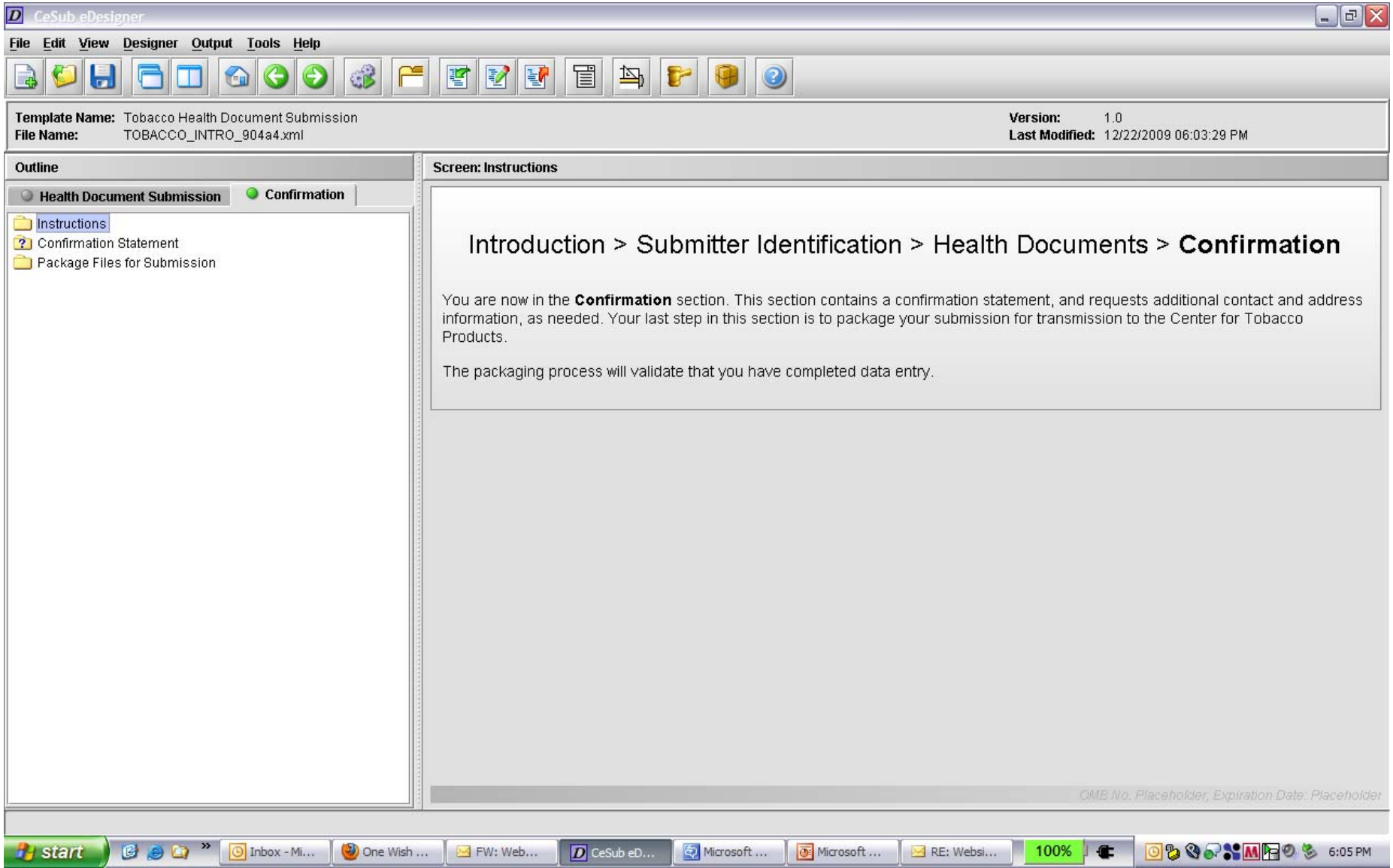
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 06:03:29 PM
Outline
Health Document Submission
Confirmation
Instructions
Confirmation Statement
Package Files for Submission
Screen: Instructions
Introduction > Submitter Identification > Health Documents > Confirmation
You are now in the Confirmation section. This section contains a confirmation statement, and requests additional contact and address information, as needed. Your last step in this section is to package your submission for transmission to the Center for Tobacco Products.
The packaging process will validate that you have completed data entry.
OMB No. Placeholder, Expiration Date: Placeholder
start
Inbox - Mi...
One Wish ...
FW: Web...
CeSub eD...
Microsoft ...
Microsoft ...
RE: Websi...
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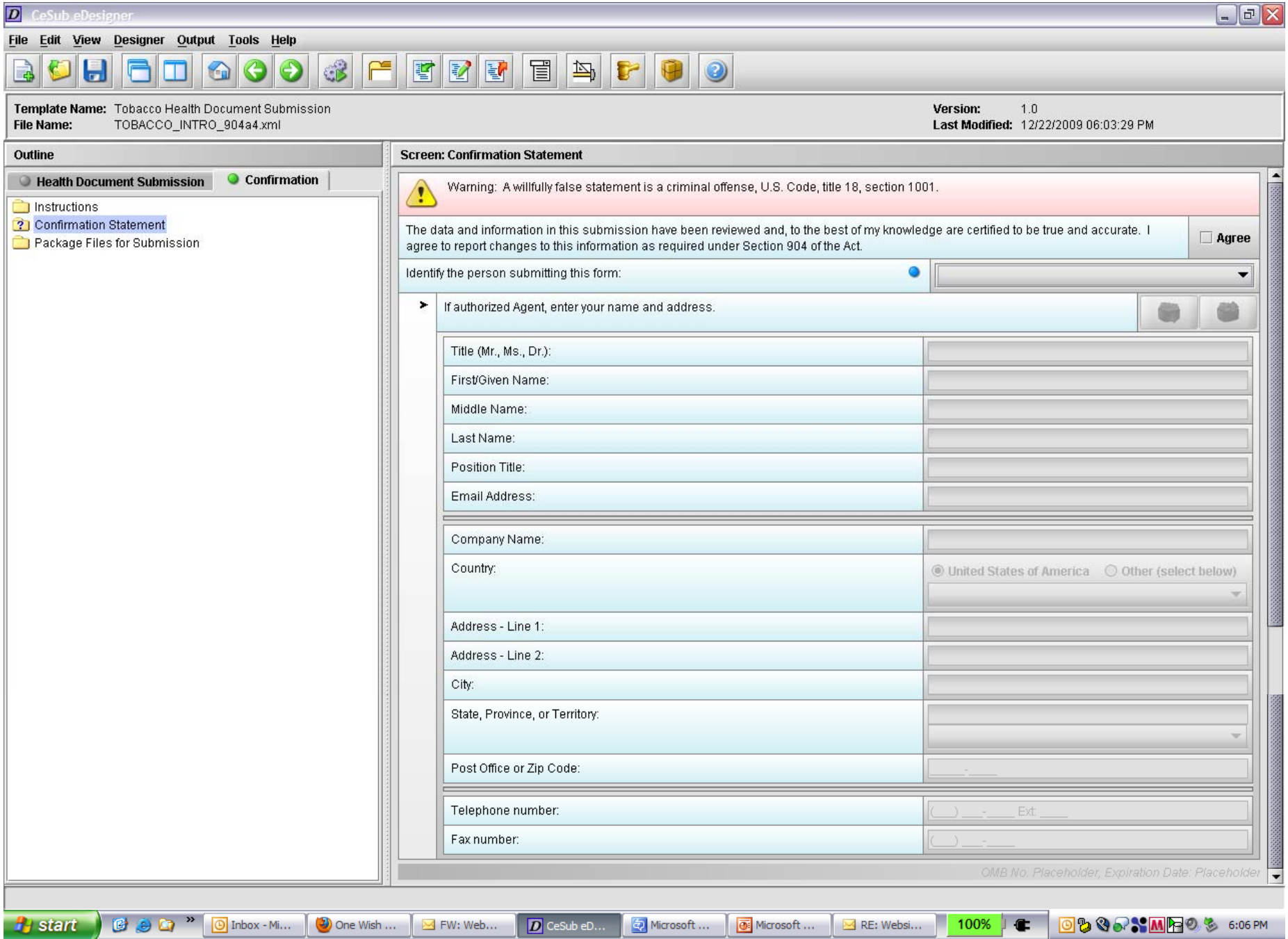
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 06:03:29 PM
Outline
Health Document Submission
Confirmation
Instructions
Confirmation Statement
Package Files for Submission
Screen: Confirmation Statement
Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.
The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate. I agree to report changes to this information as required under Section 904 of the Act.
Agree
Identify the person submitting this form:
If authorized Agent, enter your name and address.
Title (Mr., Ms., Dr.):
First/Given Name:
Middle Name:
Last Name:
Position Title:
Email Address:
Company Name:
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Telephone number:
Fax number:
OMB No. Placeholder, Expiration Date: Placeholder
start
Inbox - Mi...
One Wish ...
FW: Web...
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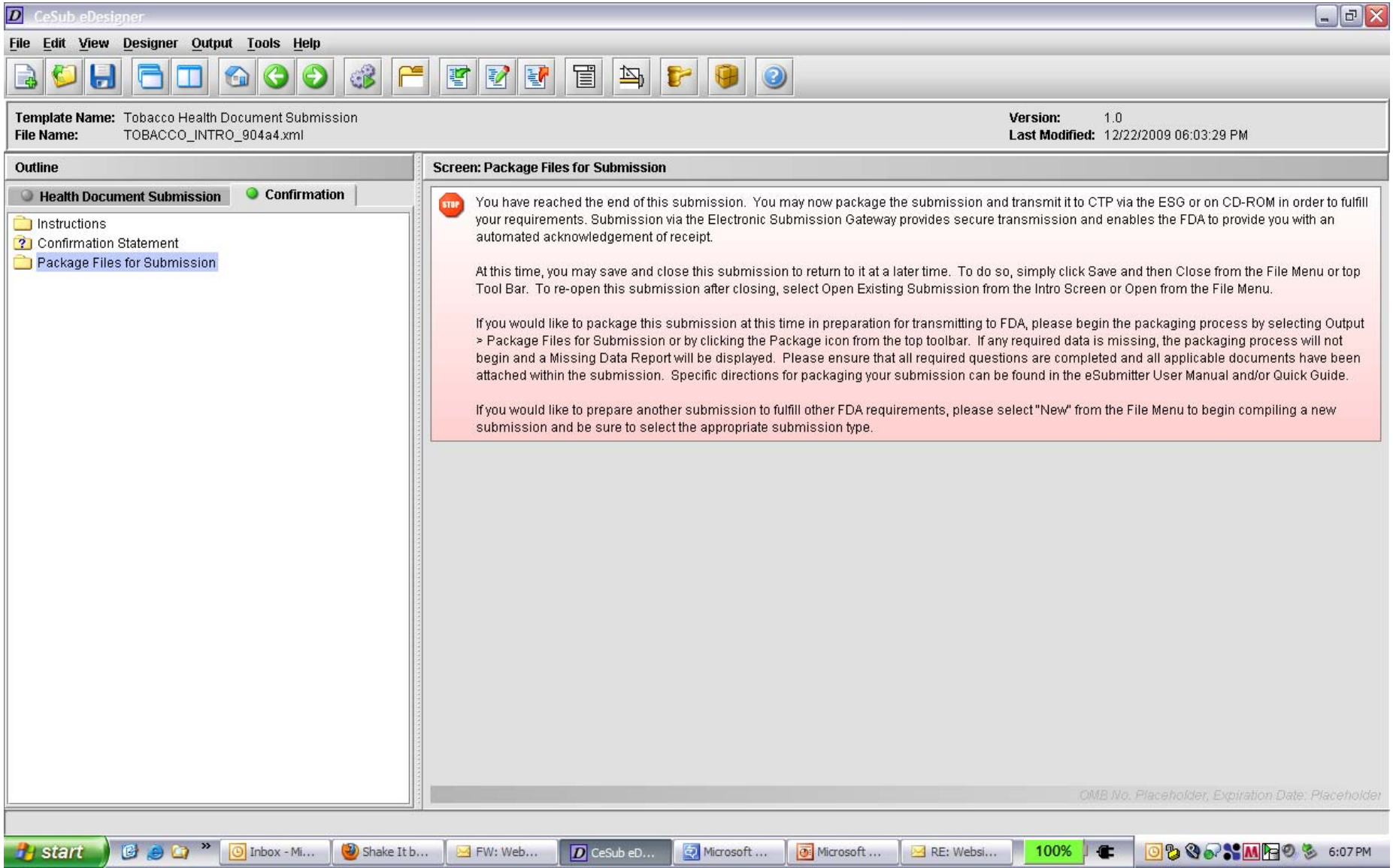
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Health Document Submission
File Name: TOBACCO_INTRO_904a4.xml
Version: 1.0
Last Modified: 12/22/2009 06:03:29 PM
Outline
Health Document Submission
Confirmation
Instructions
Confirmation Statement
Package Files for Submission
Screen: Package Files for Submission
STOP
You have reached the end of this submission. You may now package the submission and transmit it to CTP via the ESG or on CD-ROM in order to fulfill your requirements. Submission via 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.
OMB No. Placeholder, Expiration Date: Placeholder
start
Inbox - Mi...
Shake It b...
FW: Web...
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Microsoft ...
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