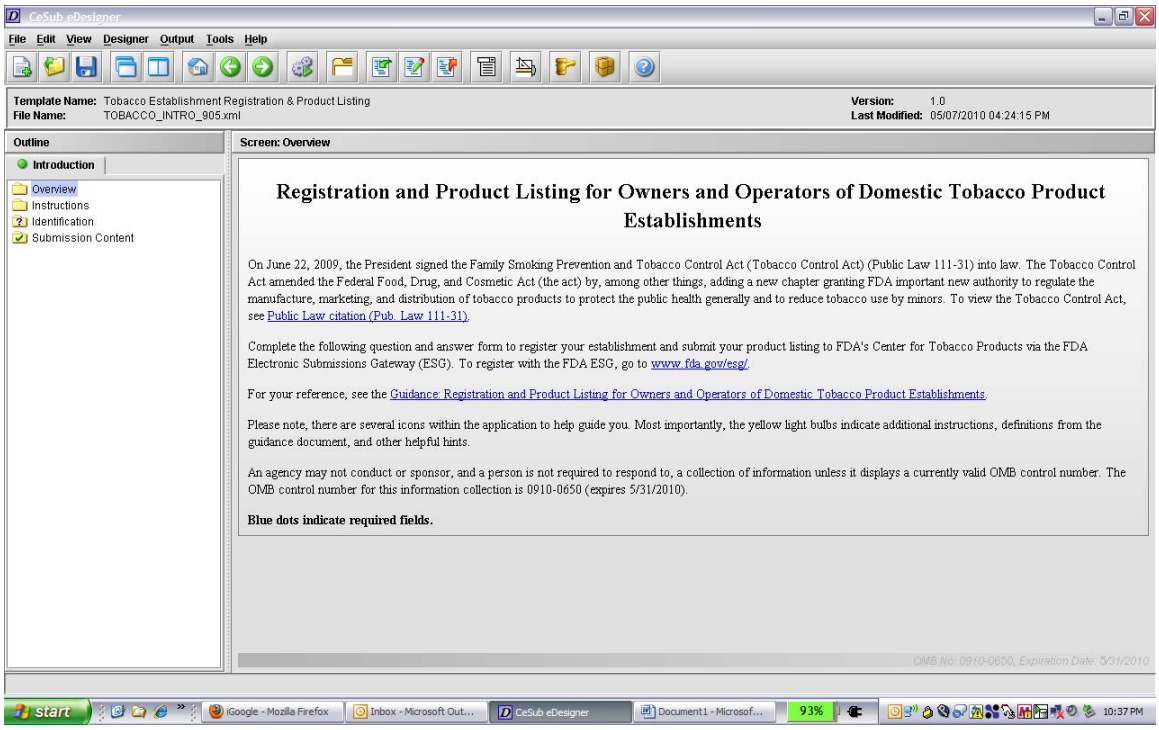
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Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Introduction
Overview
Instructions
Identification
Submission Content
Screen: Overview
Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments
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 (the act) by, among other things, adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. To view the Tobacco Control Act, see Public Law citation (Pub. Law 111-31).
Complete the following question and answer form to register your establishment and submit your product listing 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 Guidance: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.
Please note, there are several icons within the application to help guide you. Most importantly, the yellow 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 5/31/2010).
Blue dots indicate required fields.
OMB No: 0910-0650, Expiration Date: 5/31/2010
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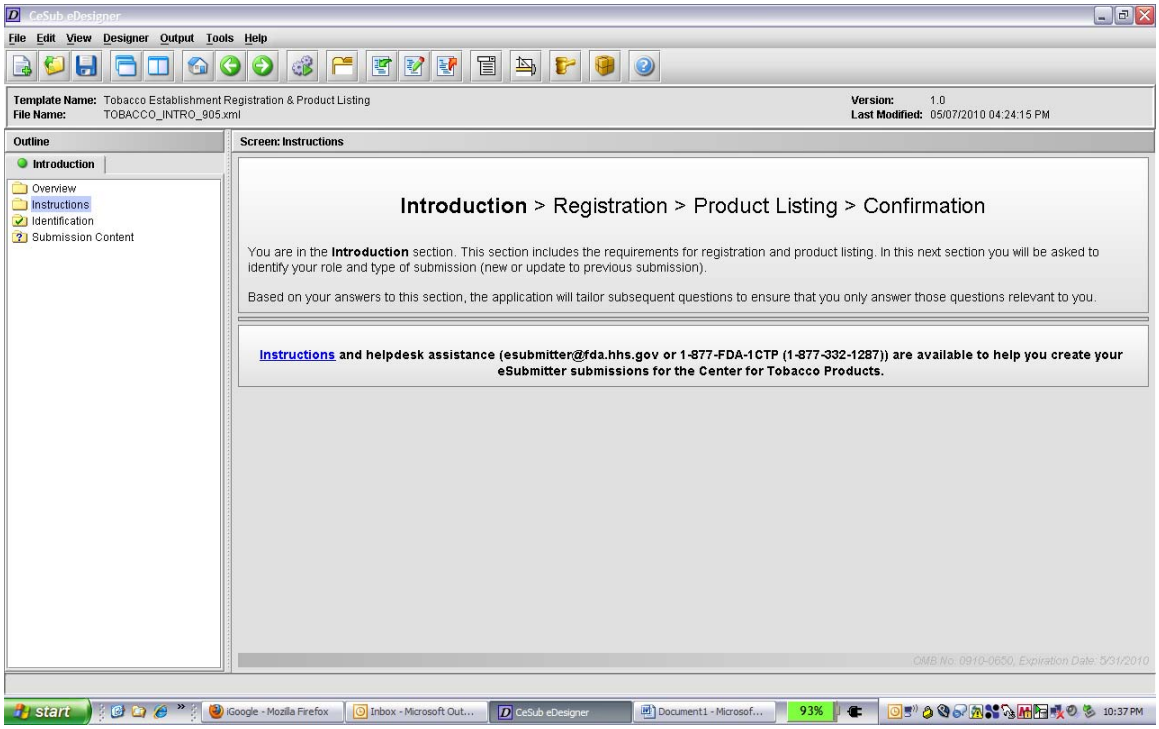
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Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Introduction
Overview
Instructions
Identification
Submission Content
Screen: Instructions
Introduction > Registration > Product Listing > Confirmation
You are in the Introduction section. This section includes the requirements for registration and product listing. In this next 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.
OMB No: 0910-0650, Expiration Date: 5/31/2010
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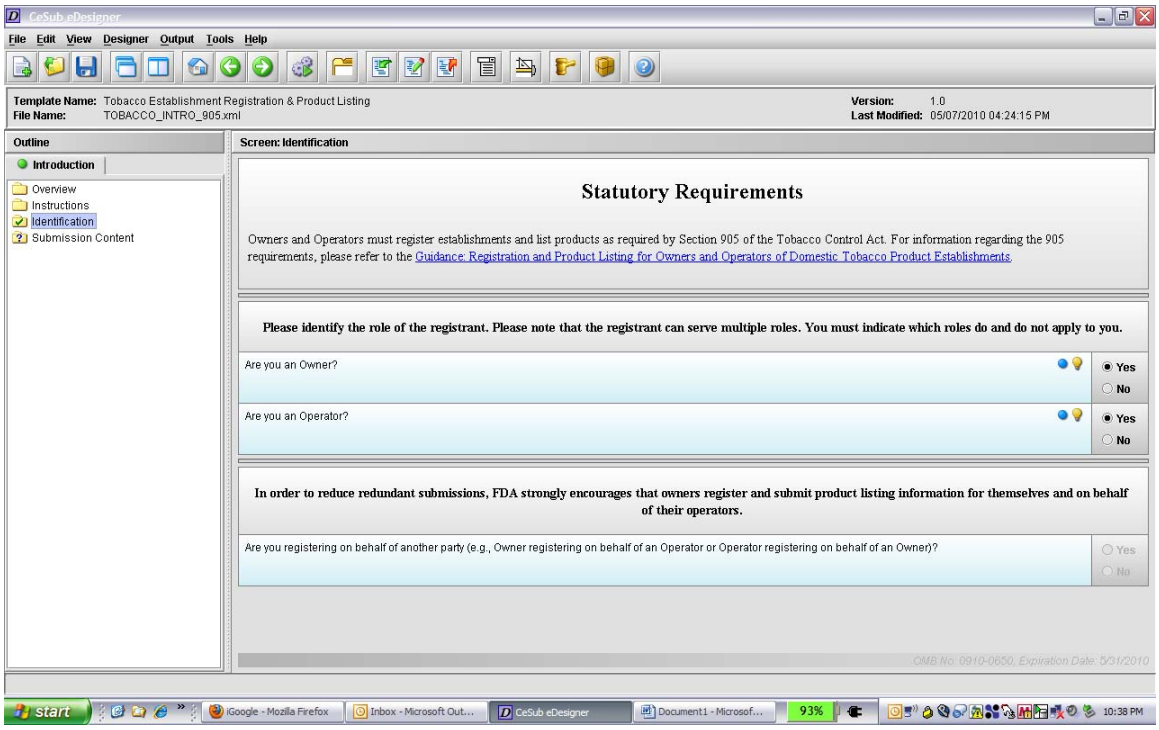
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Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Introduction
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Identification
Submission Content
Screen: Identification
Statutory Requirements
Owners and Operators must register establishments and list products as required by Section 905 of the Tobacco Control Act. For information regarding the 905 requirements, please refer to the Guidance: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.
Please identify the role of the registrant. Please note that the registrant can serve multiple roles. You must indicate which roles do and do not apply to you.
Are you an Owner?
Yes
No
Are you an Operator?
Yes
No
In order to reduce redundant submissions, FDA strongly encourages that owners register and submit product listing information for themselves and on behalf of their operators.
Are you registering on behalf of another party (e.g., Owner registering on behalf of an Operator or Operator registering on behalf of an Owner)?
Yes
No
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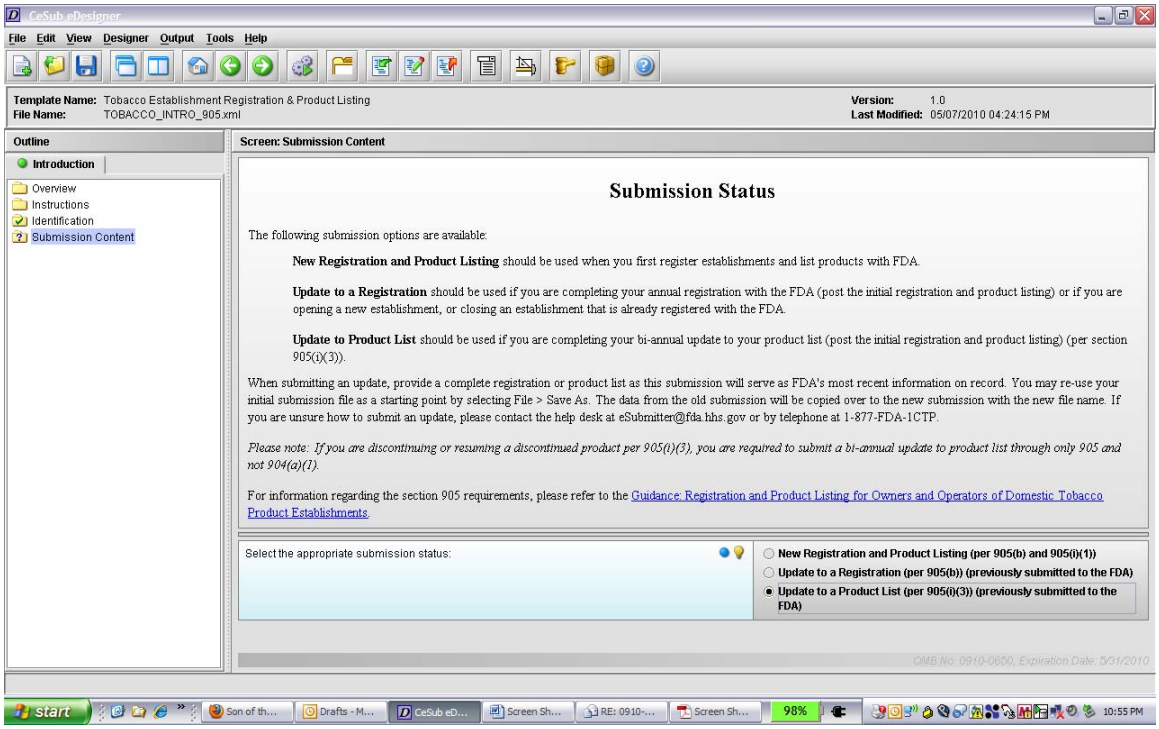
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Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
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Screen: Submission Content
Submission Status
The following submission options are available:
New Registration and Product Listing should be used when you first register establishments and list products with FDA.
Update to a Registration should be used if you are completing your annual registration with the FDA (post the initial registration and product listing) or if you are opening a new establishment, or closing an establishment that is already registered with the FDA.
Update to Product List should be used if you are completing your bi-annual update to your product list (post the initial registration and product listing) (per section 905(i)(3)).
When submitting an update, provide a complete registration or product list as this submission will serve as FDA's most recent information on record. You may re-use your initial submission file as a starting point by selecting File > Save As. The data from the old submission will be copied over to the new submission with the new file name. If you are unsure how to submit an update, please contact the help desk at eSubmitter@fda.hhs.gov or by telephone at 1-877-FDA-1CTP.
Please note: If you are discontinuing or resuming a discontinued product per 905(i)(3), you are required to submit a bi-annual update to product list through only 905 and not 904(a)(1).
For information regarding the section 905 requirements, please refer to the Guidance: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.
Select the appropriate submission status:
New Registration and Product Listing (per 905(b) and 905(i)(1))
Update to a Registration (per 905(b)) (previously submitted to the FDA)
Update to a Product List (per 905(i)(3)) (previously submitted to the FDA)
OMB No. 0910-0650, Expiration Date: 5/31/2010
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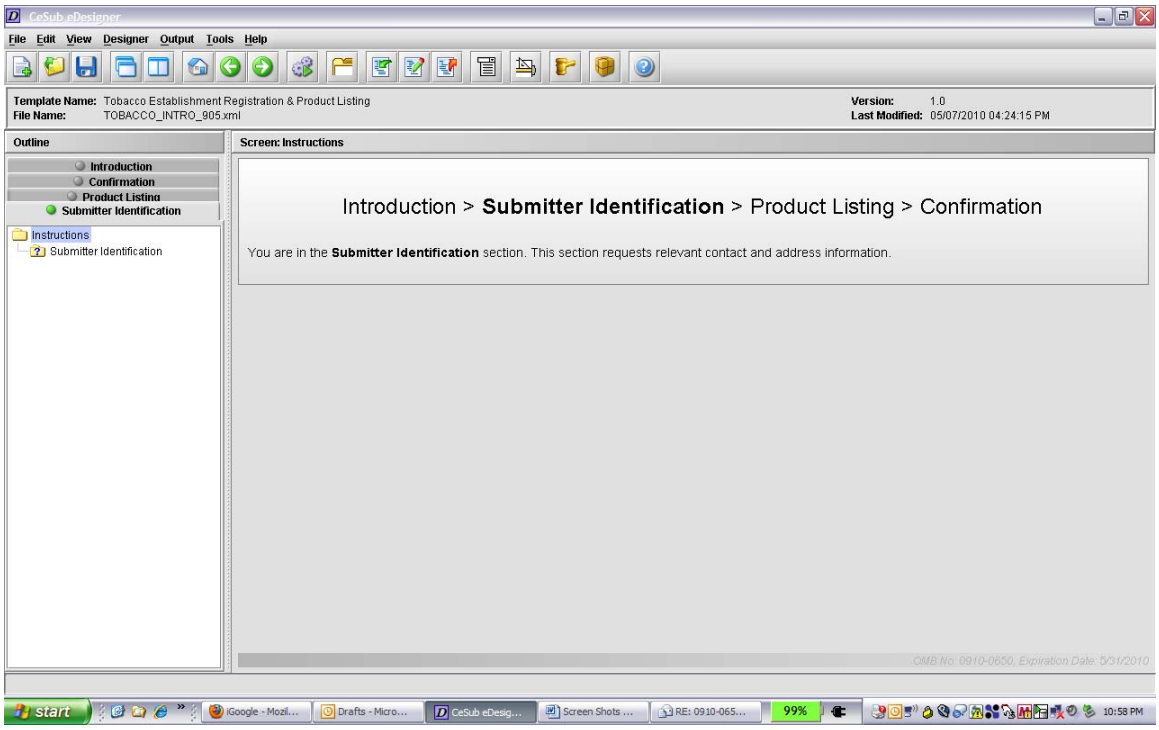
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Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Introduction
Confirmation
Product Listing
Submitter Identification
Instructions
Submitter Identification
Screen: Instructions
Introduction > Submitter Identification > Product Listing > Confirmation
You are in the Submitter Identification section. This section requests relevant contact and address information.
OMB No. 0910-0650, Expiration Date: 5/31/2010
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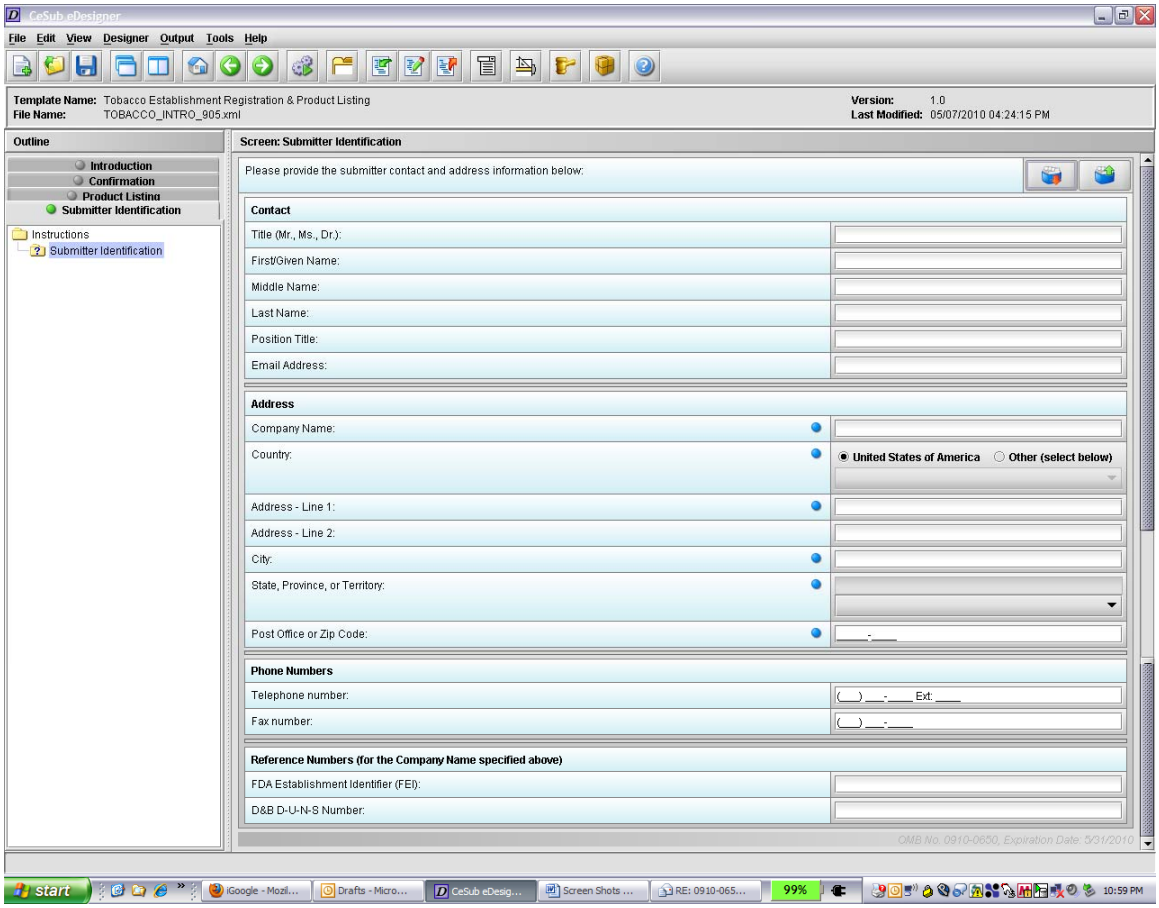
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File Edit View Designer Output Tools Help
Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Introduction
Confirmation
Product Listing
Submitter Identification
Instructions
Submitter Identification
Screen: Submitter Identification
Please provide the submitter contact and address 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)
FDA Establishment Identifier (FEI):
D&B D-U-N-S Number:
OMB No. 0910-0650, Expiration Date: 5/31/2010
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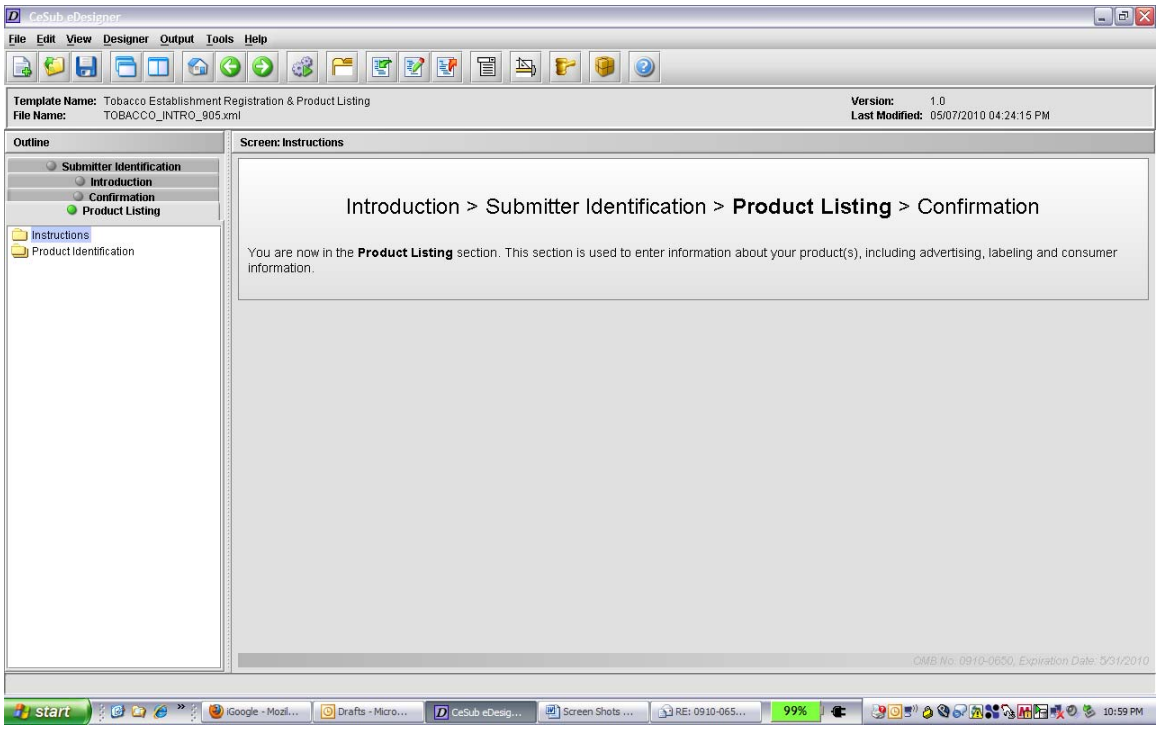
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File Edit View Designer Output Tools Help
Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Submitter Identification
Introduction
Confirmation
Product Listing
Instructions
Product Identification
Screen: Instructions
Introduction > Submitter Identification > Product Listing > Confirmation
You are now in the Product Listing section. This section is used to enter information about your product(s), including advertising, labeling and consumer information.
OMB No: 0910-0650, Expiration Date: 5/31/2010
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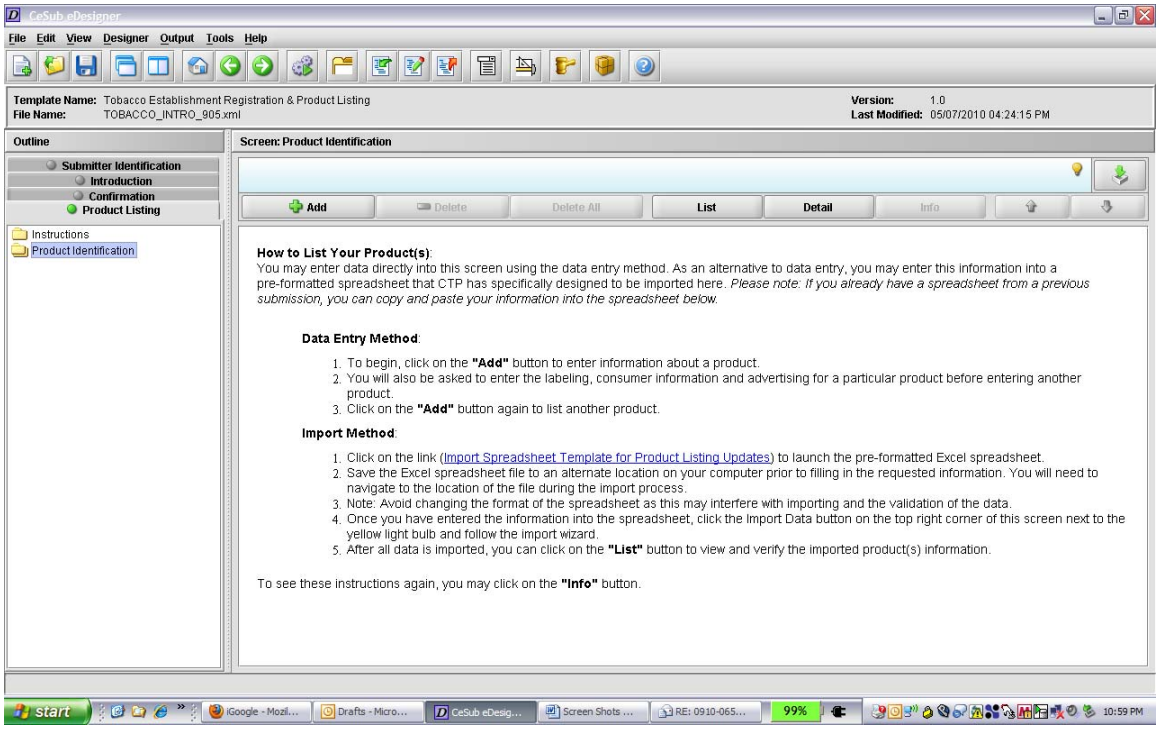
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Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Submitter Identification
Introduction
Confirmation
Product Listing
Instructions
Product Identification
Screen: Product Identification
Add
Delete
Delete All
List
Detail
Info
How to List Your Product(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. Please note: If you already have a spreadsheet from a previous submission, you can copy and paste your information into the spreadsheet below.
Data Entry Method:
1. To begin, click on the "Add" button to enter information about a product.
2. You will also be asked to enter the labeling, consumer information and advertising for a particular product before entering another product.
3. Click on the "Add" button again to list another product.
Import Method:
1. Click on the link (Import Spreadsheet Template for Product Listing Updates) 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. 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.
5. After all data is imported, you can click on the "List" button to view and verify the imported product(s) information.
To see these instructions again, you may click on the "Info" button.
start
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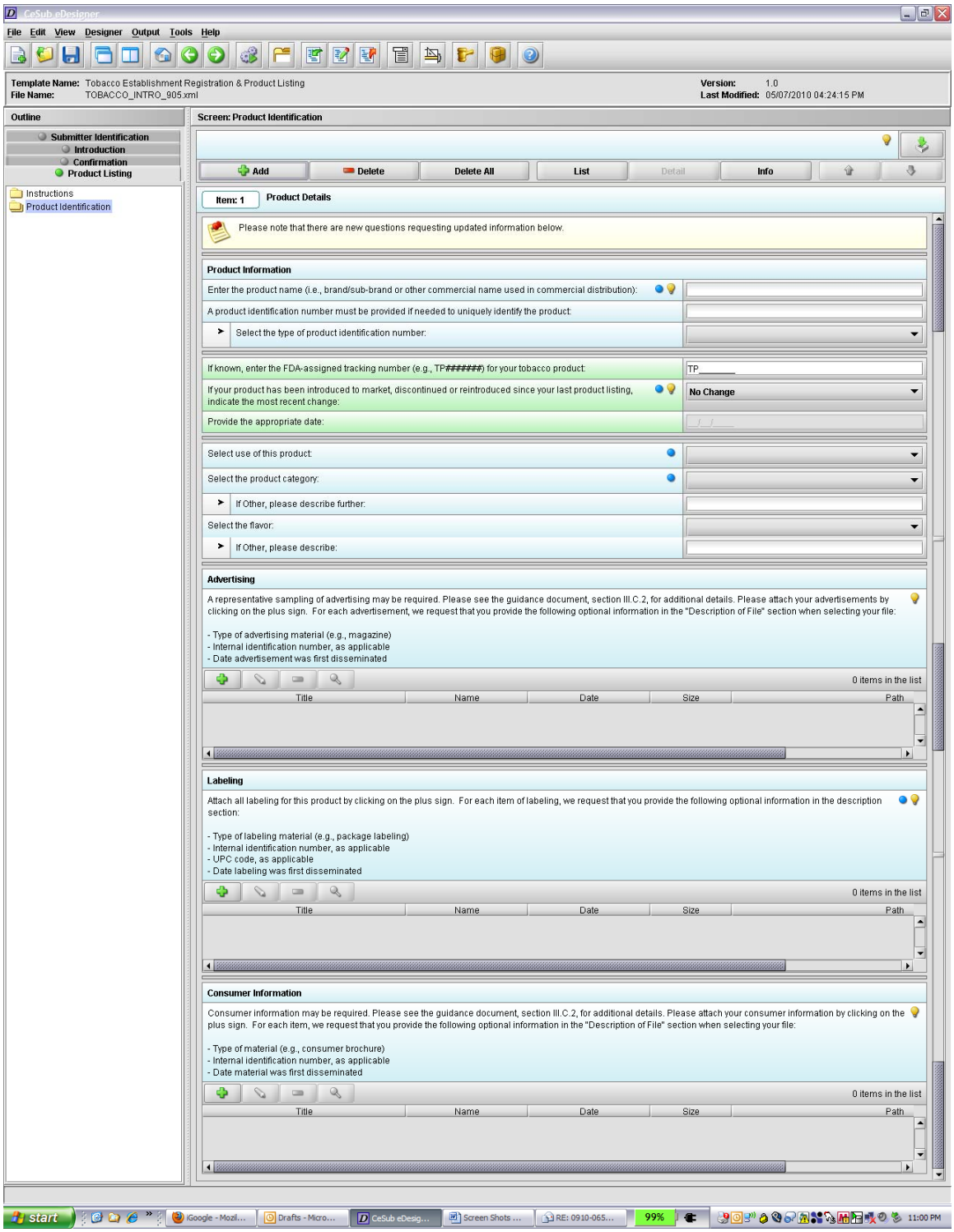
CeSub eDesigner
File Edit View Designer Output Tools Help
Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Submitter Identification
Introduction
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Instructions
Product Identification
Screen: Product Identification
Add
Delete
Delete All
List
Detail
Info
Item: 1
Product Details
Please note that there are new questions requesting updated information below.
Product Information
Enter the product name (i.e., brand/sub-brand or other commercial name used in commercial distribution):
A product identification number must be provided if needed to uniquely identify the product:
Select the type of product identification number:
If known, enter the FDA-assigned tracking number (e.g., TP######) for your tobacco product:
TP_____
If your product has been introduced to market, discontinued or reintroduced since your last product listing, indicate the most recent change:
No Change
Provide the appropriate date:
__/__/____
Select use of this product:
Select the product category:
If Other, please describe further:
Select the flavor:
If Other, please describe:
Advertising
A representative sampling of advertising may be required. Please see the guidance document, section III.C.2, for additional details. Please attach your advertisements by clicking on the plus sign. For each advertisement, we request that you provide the following optional information in the "Description of File" section when selecting your file:
- Type of advertising material (e.g., magazine)
- Internal identification number, as applicable
- Date advertisement was first disseminated
0 items in the list
Title
Name
Date
Size
Path
Labeling
Attach all labeling for this product by clicking on the plus sign. For each item of labeling, we request that you provide the following optional information in the description section:
- Type of labeling material (e.g., package labeling)
- Internal identification number, as applicable
- UPC code, as applicable
- Date labeling was first disseminated
0 items in the list
Title
Name
Date
Size
Path
Consumer Information
Consumer information may be required. Please see the guidance document, section III.C.2, for additional details. Please attach your consumer information by clicking on the plus sign. For each item, we request that you provide the following optional information in the "Description of File" section when selecting your file:
- Type of material (e.g., consumer brochure)
- Internal identification number, as applicable
- Date material was first disseminated
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Title
Name
Date
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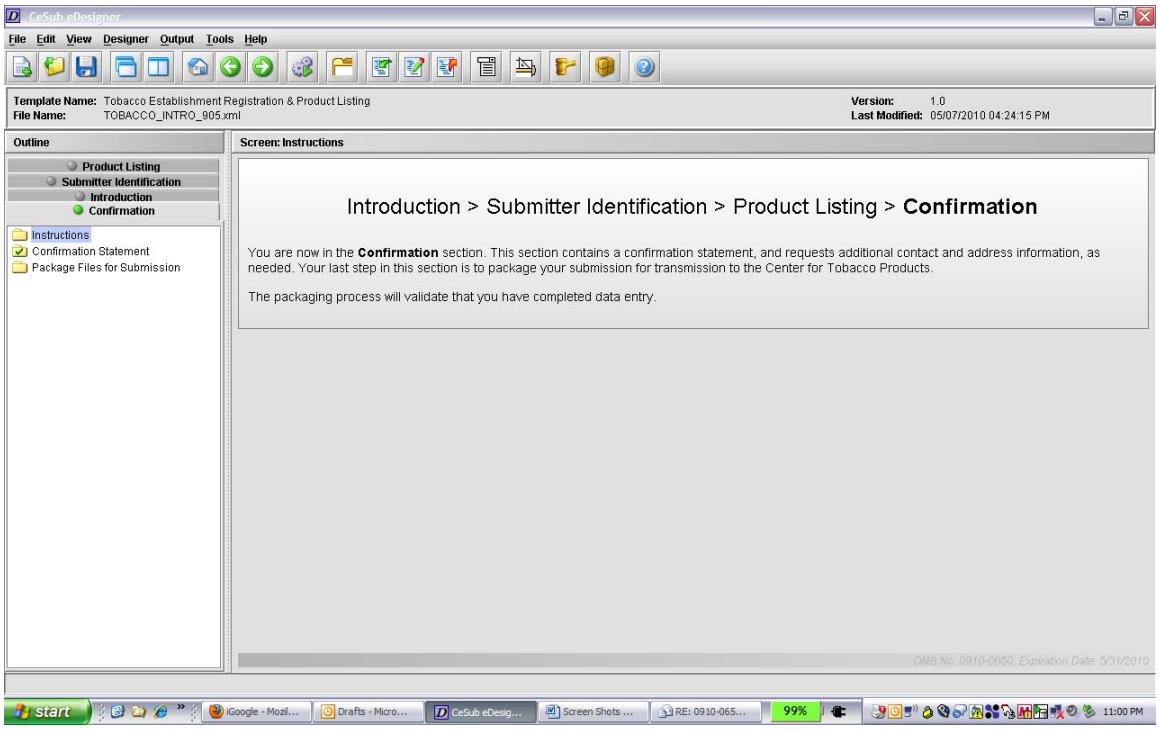
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File Edit View Designer Output Tools Help
Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Product Listing
Submitter Identification
Introduction
Confirmation
Instructions
Confirmation Statement
Package Files for Submission
Screen: Instructions
Introduction > Submitter Identification > Product Listing > 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. 0910-0650, Expiration Date: 5/31/2010
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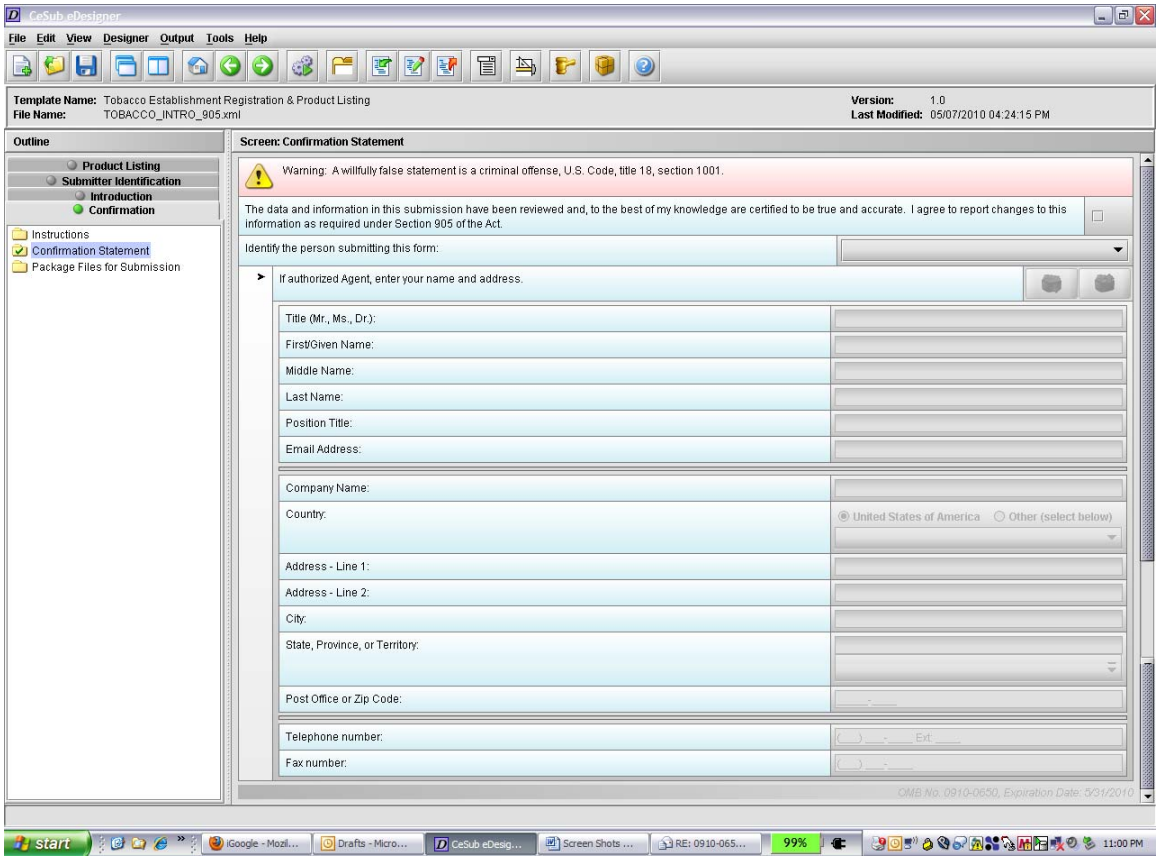
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File Edit View Designer Output Tools Help
Template Name: Tobacco Establishment Registration & Product Listing
File Name: TOBACCO_INTRO_905.xml
Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Product Listing
Submitter Identification
Introduction
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 905 of the Act.
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:
Ext
Fax number:
OMB No. 0910-0650, Expiration Date: 5/31/2010
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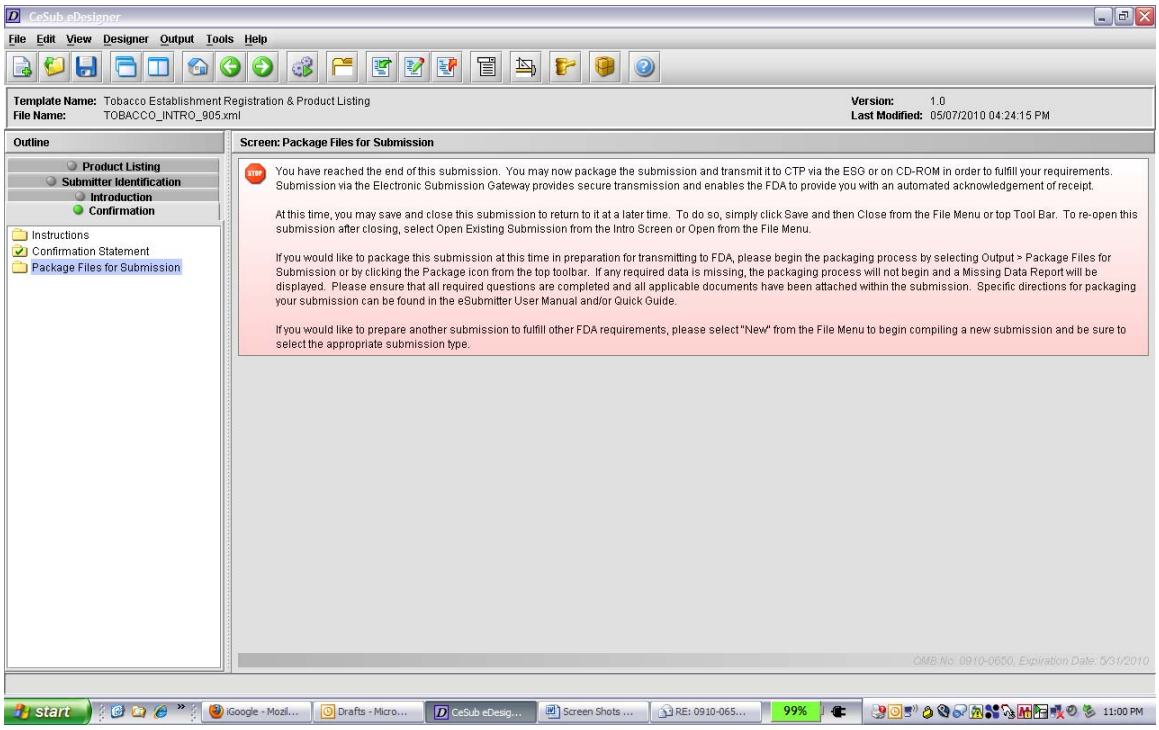
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Version: 1.0
Last Modified: 05/07/2010 04:24:15 PM
Outline
Product Listing
Submitter Identification
Introduction
Confirmation
Instructions
Confirmation Statement
Package Files for Submission
Screen: Package Files for Submission
You have reached the end of this submission. You may now package the submission and transmit it to CTP via the 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. 0910-0650, Expiration Date: 5/31/2010
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