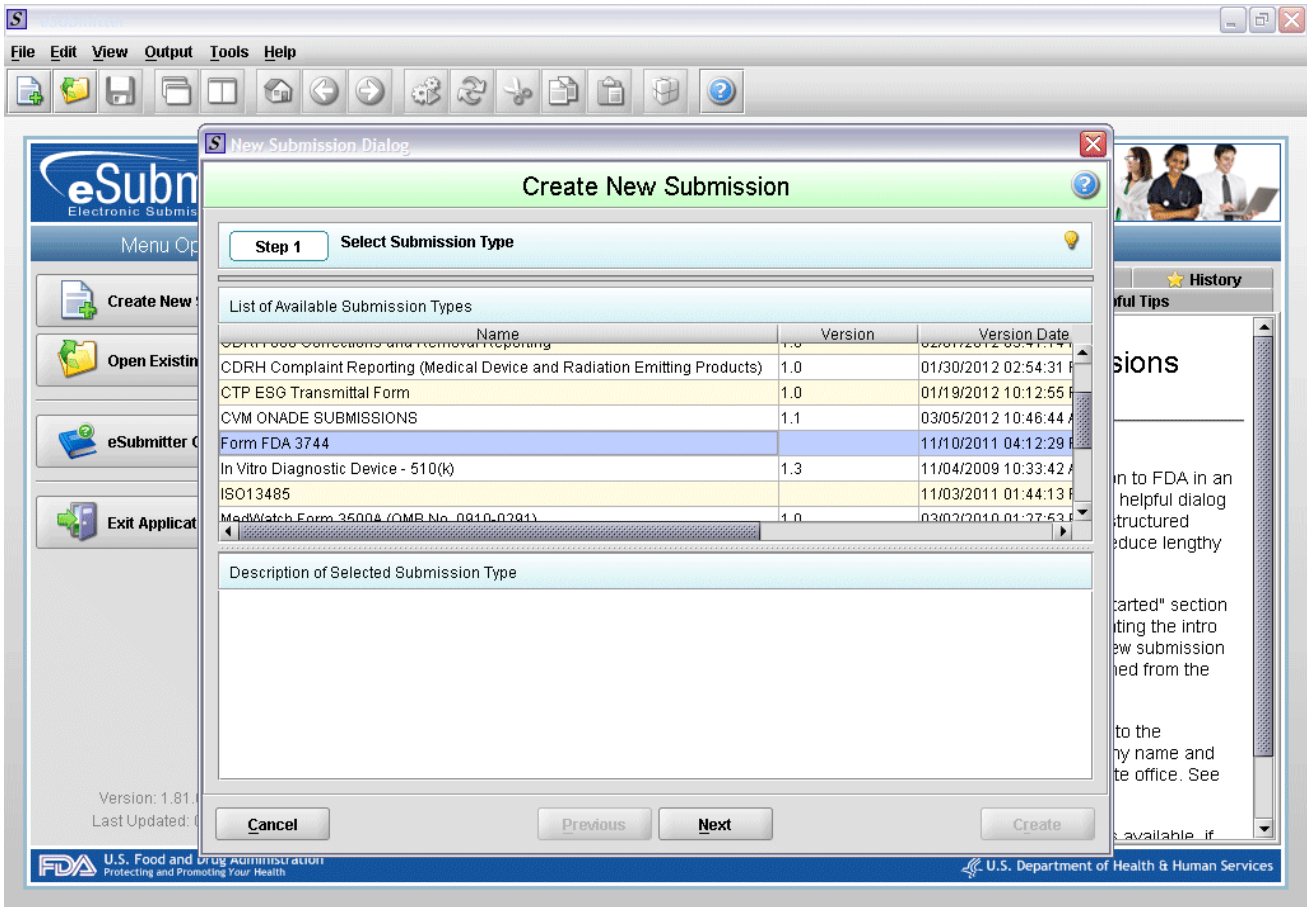
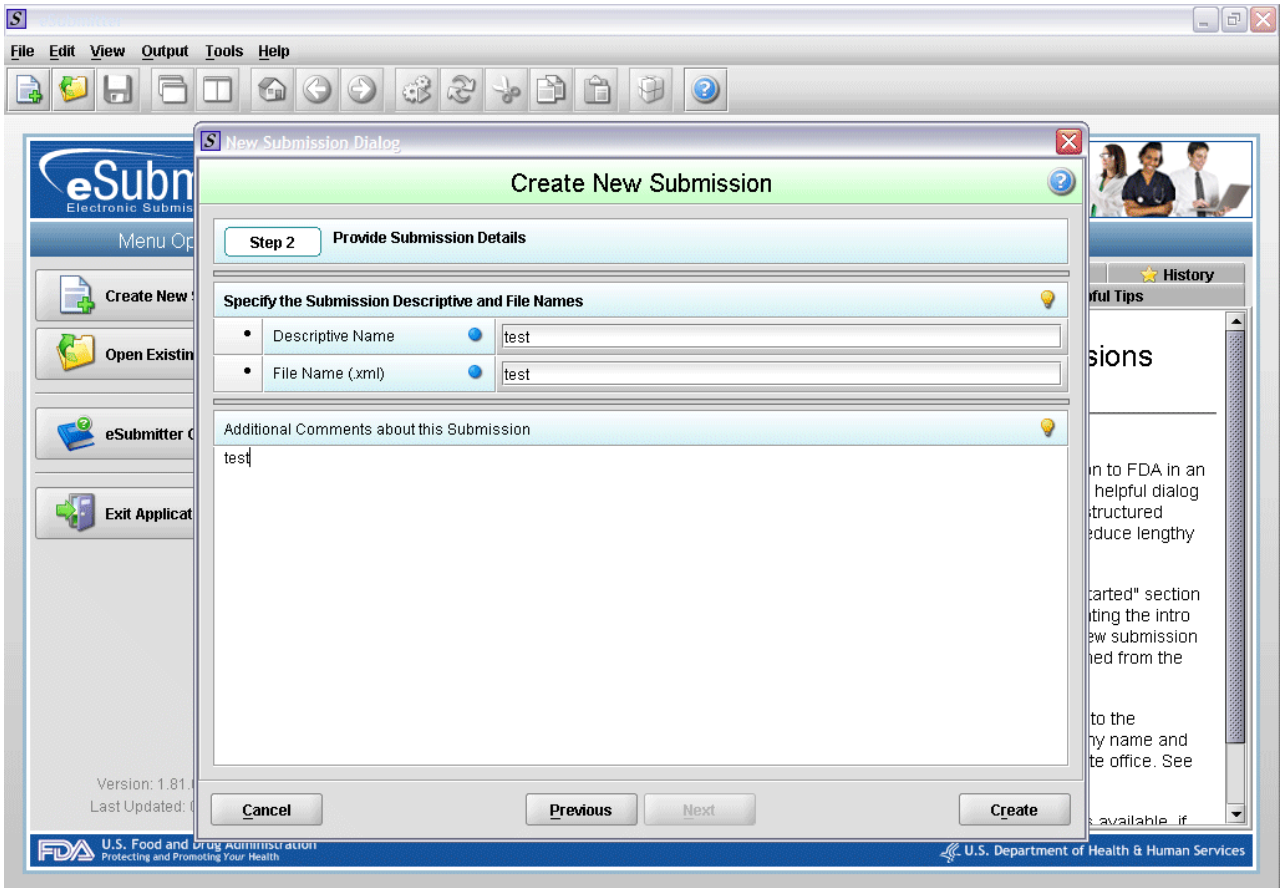


**Screenshots for the Electronic Form FDA 3744 -  
Antimicrobial Animal Drug Distribution Report for ADUFA Section 105**



1. Create new submission.



2. Enter description.

Submission Name: test  
Report Type: Form FDA 3744  
Last Modified:  
Date Packaged:

Screen View Antimicrobial Animal Drug Distribution Report: Firm and Application Information

Select the Application Type NADA

Enter the Application Number ###-###-####

Enter the Firm Name test

Enter the calendar year for which the data in this submission are being reported 2012

Outline View

3. Enter identifying information for application.

Submission Name: test  
Report Type: Form FDA 3744  
Last Modified:  
Date Packaged:

Screen View Antimicrobial Animal Drug Distribution Report: Food Animal Dosage Form Information

Select +Add to complete the Food Animal Dosage Form Information section for each dosage form covered by this application.

This screen requires at least one (1) dosage form to be entered.

Once complete, highlight the dosage form in the list to complete Individual Product Information for that item on the next screen.

Use the List and Detail buttons to toggle between screen views.

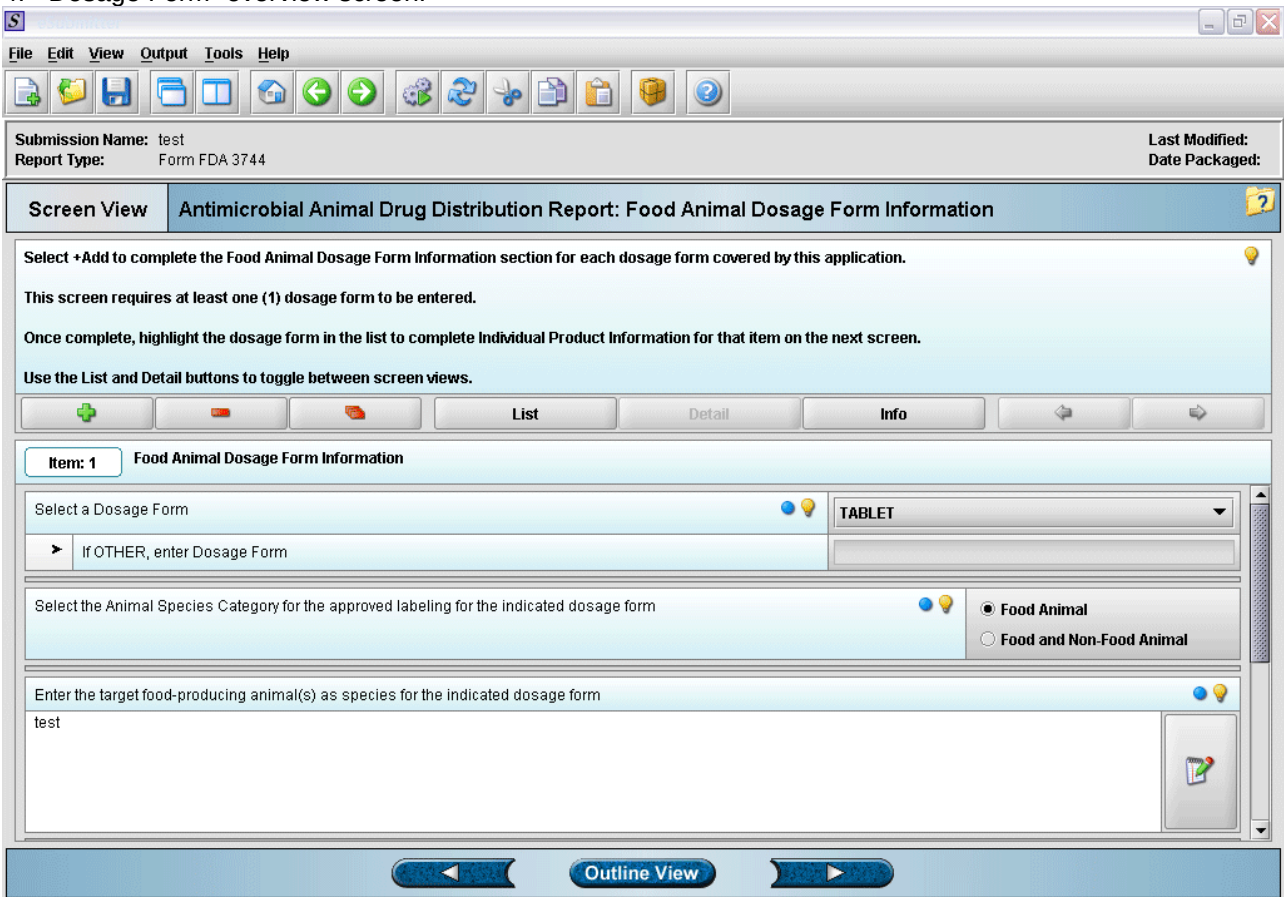
List Detail Info

This screen supports the data input of tabular Dosage Form information.

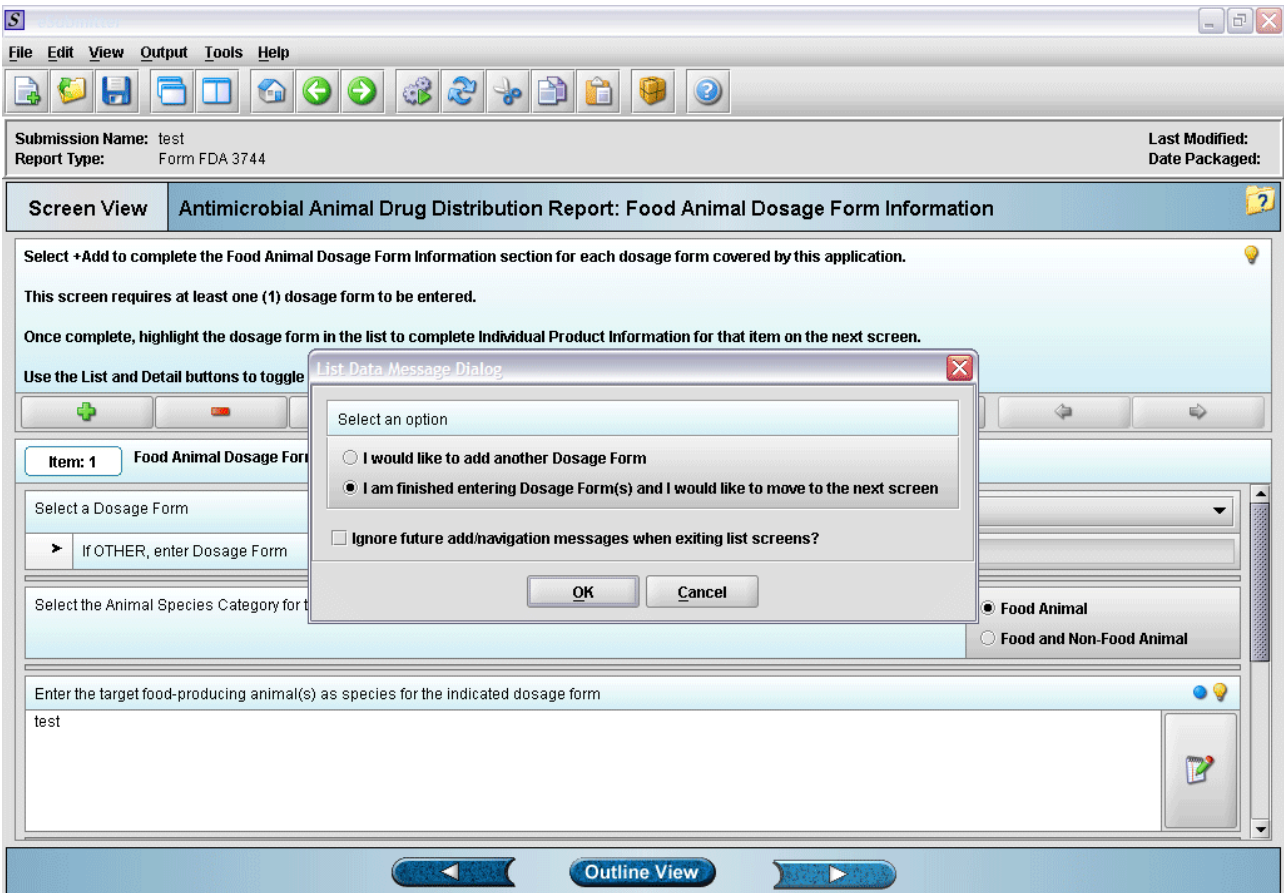
For help on how to use this screen, view the screen instructions available by selecting the 'Hint' option (denoted by a lightbulb) at the top right of the screen.

Outline View

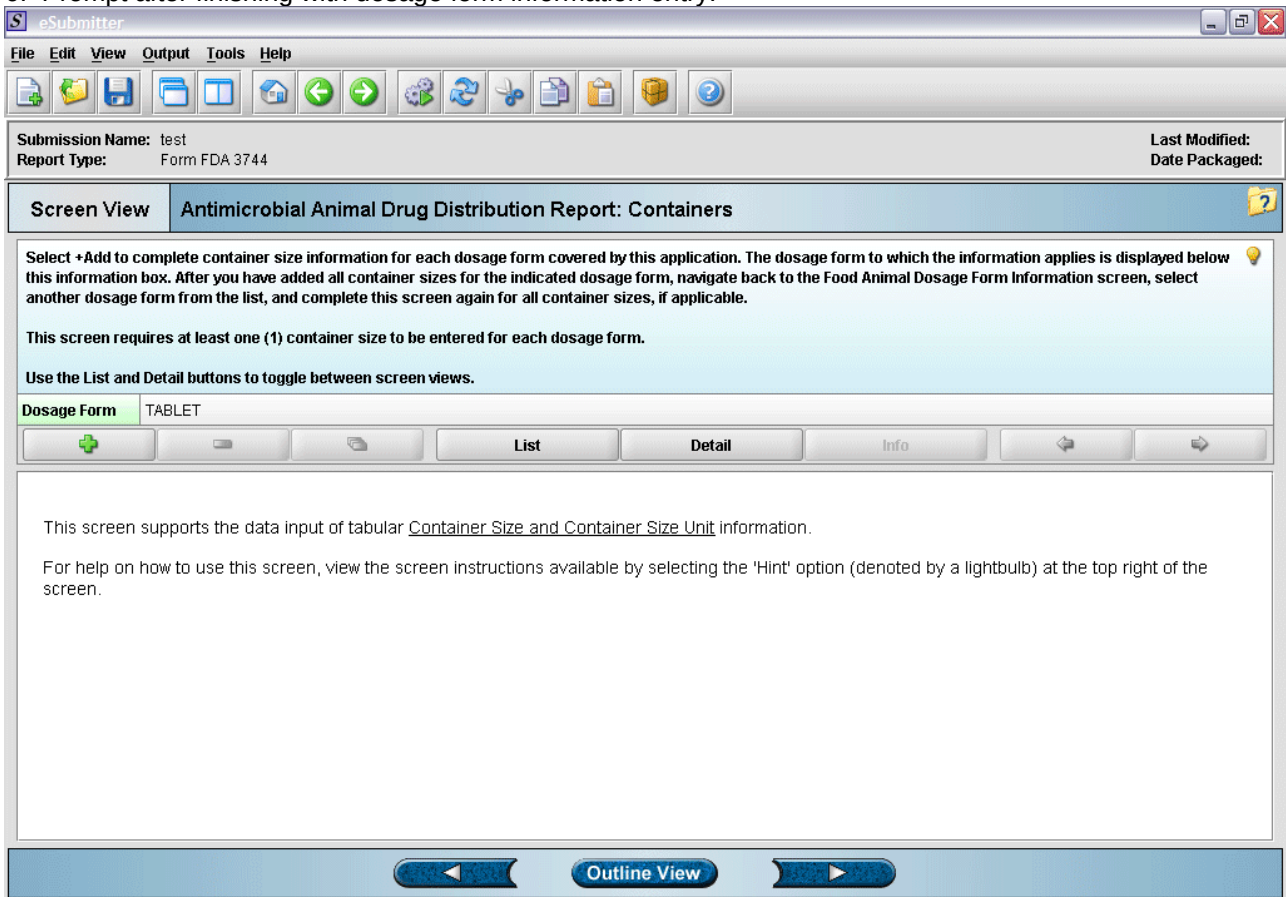
4. "Dosage Form" overview screen.



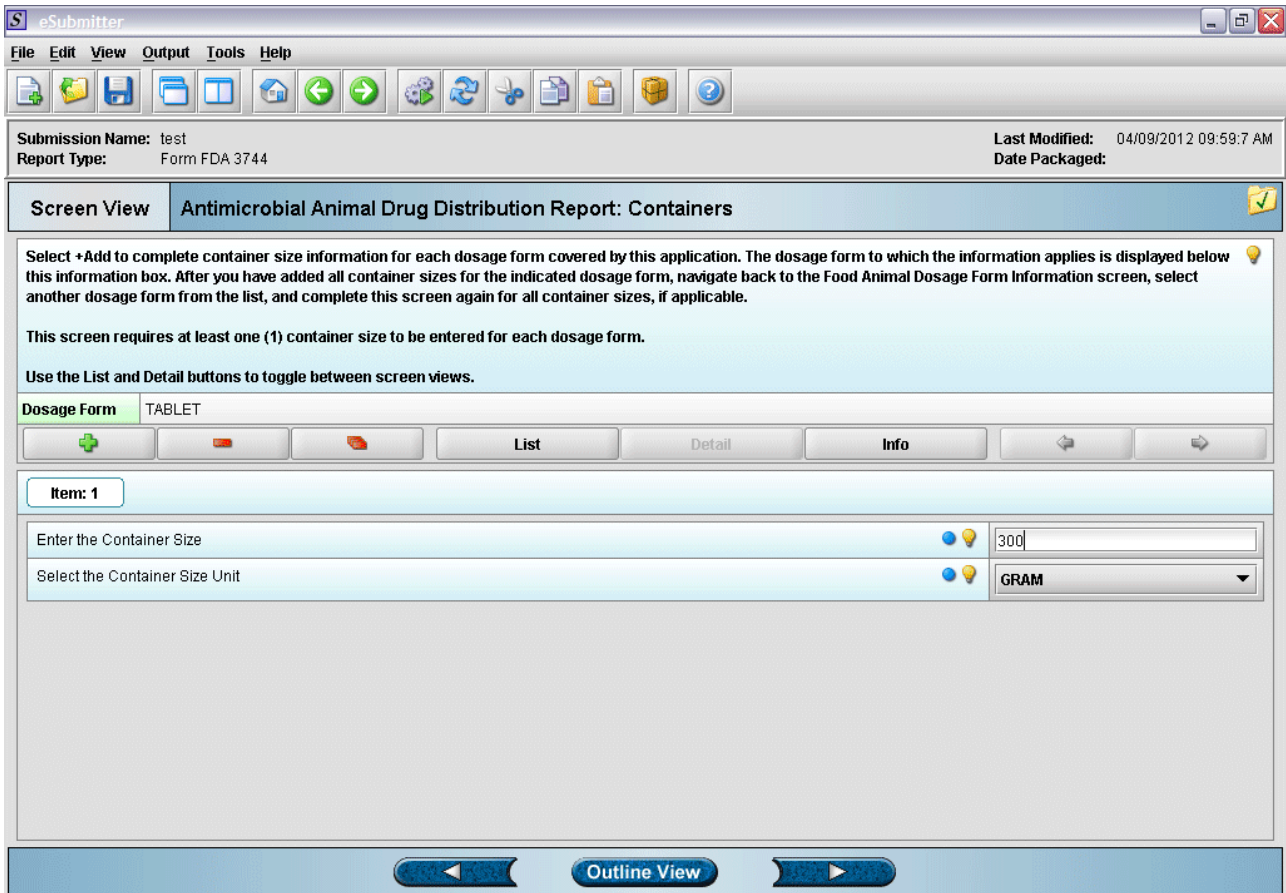
5. Entering dosage form information.



6. Prompt after finishing with dosage form information entry.



7. Container size and unit overview screen.



8. Entering container size and unit information (click green plus to add a container).

The screenshot shows the 'Antimicrobial Animal Drug Distribution Report: Containers' screen. At the top, the submission name is 'test' and the report type is 'Form FDA 3744'. The screen title is 'Antimicrobial Animal Drug Distribution Report: Containers'. Below the title, there is a light blue instruction box: 'Select +Add to complete container size information for each dosage form covered by this application. The dosage form to which the information applies is displayed below this information box. After you have added all container sizes for the indicated dosage form, navigate back to the Food Animal Dosage Form Information screen, select another dosage form from the list, and complete this screen again for all container sizes, if applicable.' Below this, it says 'This screen requires at least one (1) container size to be entered for each dosage form.' There are buttons for 'List' and 'Detail'. A 'List Data Message Dialog' is open, with the following options: 'I would like to add another Container Size and Container Size Unit' (unselected), 'I am finished entering Container Size and Container Size Unit(s) and I would like to move to the next screen' (selected), and 'Ignore future add/navigation messages when exiting list screens?' (unselected). The dialog has 'OK' and 'Cancel' buttons. At the bottom of the screen, there is an 'Outline View' button.

9. Prompt after finishing with container size and unit information entry.

The screenshot shows the 'Antimicrobial Animal Drug Distribution Report: Active Ingredients' screen. At the top, the submission name is 'test' and the report type is 'Form FDA 3744'. The screen title is 'Antimicrobial Animal Drug Distribution Report: Active Ingredients'. Below the title, there is a light blue instruction box: 'Select +Add to complete the Active Ingredient section for each container size for each dosage form covered by this application. The dosage form and container size to which the ingredient information applies is displayed below this information box. After you have added all ingredients for the indicated container size for the indicated dosage form, navigate back to the Container screen, select another container size from the list, and complete this screen again for all active ingredients, if applicable.' Below this, it says 'This screen requires at least one (1) active ingredient and its corresponding strength to be entered for each container size for each dosage form. This screen must be filled out for each differing active ingredient strength.' There are buttons for 'List' and 'Detail'. The 'Container Size and Container Size Unit' is set to '300; GRAM'. Below the buttons, there is a light blue instruction box: 'This screen supports the data input of tabular Active Ingredient information. For help on how to use this screen, view the screen instructions available by selecting the 'Hint' option (denoted by a lightbulb) at the top right of the screen.' At the bottom of the screen, there is an 'Outline View' button.

10. "Active Ingredient" overview screen.

Submission Name: test  
Report Type: Form FDA 3744

Last Modified: 04/09/2012 09:59:7 AM  
Date Packaged:

Screen View: Antimicrobial Animal Drug Distribution Report: Active Ingredients

Select +Add to complete the Active Ingredient section for each container size for each dosage form covered by this application. The dosage form and container size to which the ingredient information applies is displayed below this information box. After you have added all ingredients for the indicated container size for the indicated dosage form, navigate back to the Container screen, select another container size from the list, and complete this screen again for all active ingredients, if applicable.

This screen requires at least one (1) active ingredient and its corresponding strength to be entered for each container size for each dosage form. This screen must be filled out for each differing active ingredient strength.

Use the List and Detail buttons to toggle between screen views.

Dosage Form: TABLET  
Container Size and Container Size Unit: 300; GRAM

Item: 1 Active Ingredient Information

Select the Active Ingredient/Preferred Substance Name: PENICILLIN G PROCAINE  
If OTHER, enter Active Ingredient:

Enter the Active Ingredient Strength - Numerator: 20  
Select the Active Ingredient Strength - Numerator Unit of Measure: MILLIGRAM

Enter the Active Ingredient Strength - Denominator: 30  
Select the Active Ingredient Strength - Denominator Unit of Measure: MILLIGRAM

Outline View

11. Entering active ingredient information.

Submission Name: test  
Report Type: Form FDA 3744

Last Modified: 04/09/2012 09:59:7 AM  
Date Packaged:

Screen View: Antimicrobial Animal Drug Distribution Report: Active Ingredients

Select +Add to complete the Active Ingredient section for each container size for each dosage form covered by this application. The dosage form and container size to which the ingredient information applies is displayed below this information box. After you have added all ingredients for the indicated container size for the indicated dosage form, navigate back to the Container screen, select another container size from the list, and complete this screen again for all active ingredients, if applicable.

This screen requires at least one (1) active ingredient and its corresponding strength to be entered for each container size for each dosage form. This screen must be filled out for each differing active ingredient strength.

Use the List and Detail buttons to toggle between screen views.

Dosage Form: TABLET  
Container Size and Container Size Unit: 300; GRAM

Item: 1 Active Ingredient Information

Quantities of Individual Product Sold or Distributed

Enter the numeric value of the active ingredient domestic and export quantities sold or distributed by the applicant and distributors by month in the indicated calendar year for the indicated container size

Select the Unit of Measure for the Domestic and Export Quantities Sold or Distributed by Month: KILOGRAM

January	123
February	123
March	123
April	123

Outline View

12. Entering active ingredient information (continued).

Submission Name: test  
Report Type: Form FDA 3744  
Last Modified: 04/09/2012 09:59:7 AM  
Date Packaged:

Screen View: Antimicrobial Animal Drug Distribution Report: Active Ingredients

Select +Add to complete the Active Ingredient section for each container size for each dosage form covered by this application. The dosage form and container size to which the ingredient information applies is displayed below this information box. After you have added all ingredients for the indicated container size for the indicated dosage form, navigate back to the Container screen, select another container size from the list, and complete this screen again for all active ingredients, if applicable.

This screen requires at least one (1) active ingredient and its corresponding strength to be entered for each container size for each dosage form. This screen must be filled out for each differing active ingredient strength.

Use the List and Detail buttons to toggle between screen views.

Dosage Form: TABLET  
Container Size and Container Size Unit: 300, GRAM

Buttons: +, -, List, Detail, Info, <, >

Item: 1 Active Ingredient Information

> July	123
> August	123
> September	123
> October	123
> November	123
> December	123
The Annual Total will be automatically calculated by eSubmitter based on the data values entered for the months above.	

Buttons: <, Outline View, >

13. Entering active ingredient information (continued).

Submission Name: test  
Report Type: Form FDA 3744  
Last Modified: 04/09/2012 09:59:7 AM  
Date Packaged:

Screen View: Antimicrobial Animal Drug Distribution Report: Active Ingredients

Select +Add to complete the Active Ingredient section for each container size for each dosage form covered by this application. The dosage form and container size to which the ingredient information applies is displayed below this information box. After you have added all ingredients for the indicated container size for the indicated dosage form, navigate back to the Container screen, select another container size from the list, and complete this screen again for all active ingredients, if applicable.

This screen requires at least one (1) active ingredient and its corresponding strength to be entered for each container size for each dosage form. This screen must be filled out for each differing active ingredient strength.

Use the List and Detail buttons to toggle between screen views.

Dosage Form: TABLET  
Container Size and Container Size Unit: 300, GRAM

Buttons: +, -, List, Detail, Info, <, >

Item: 1 Active Ingredient Information

> July	123
> August	123
> September	123
> October	123
> November	123
> December	123
The Annual Total will be automatically calculated by eSubmitter based on the data values entered for the months above.	

Buttons: <, Outline View, >

List Data Message Dialog

Select an option

I would like to add another Active Ingredient

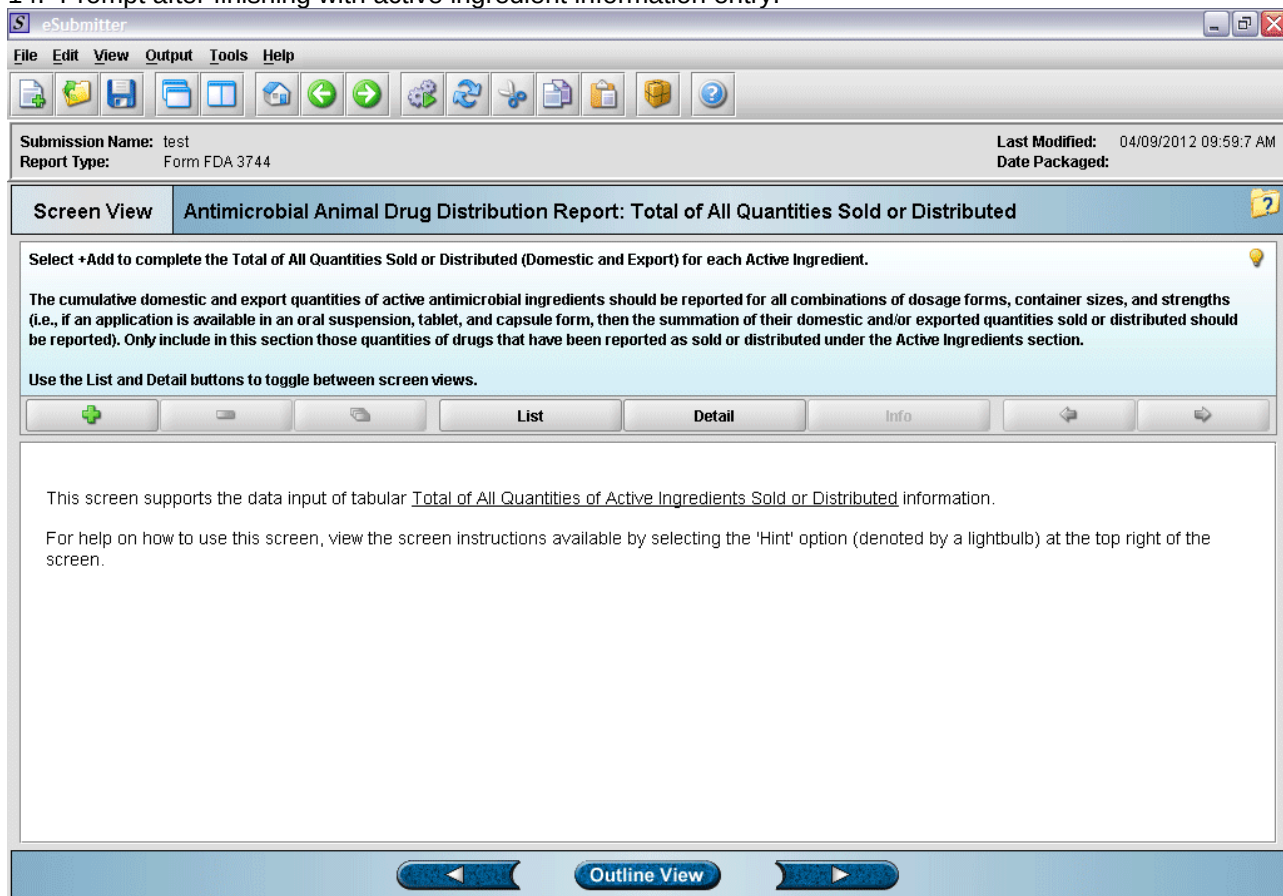
I am finished entering Active Ingredient(s) and I would like to move to the next screen

Ignore future add/navigation messages when exiting list screens?

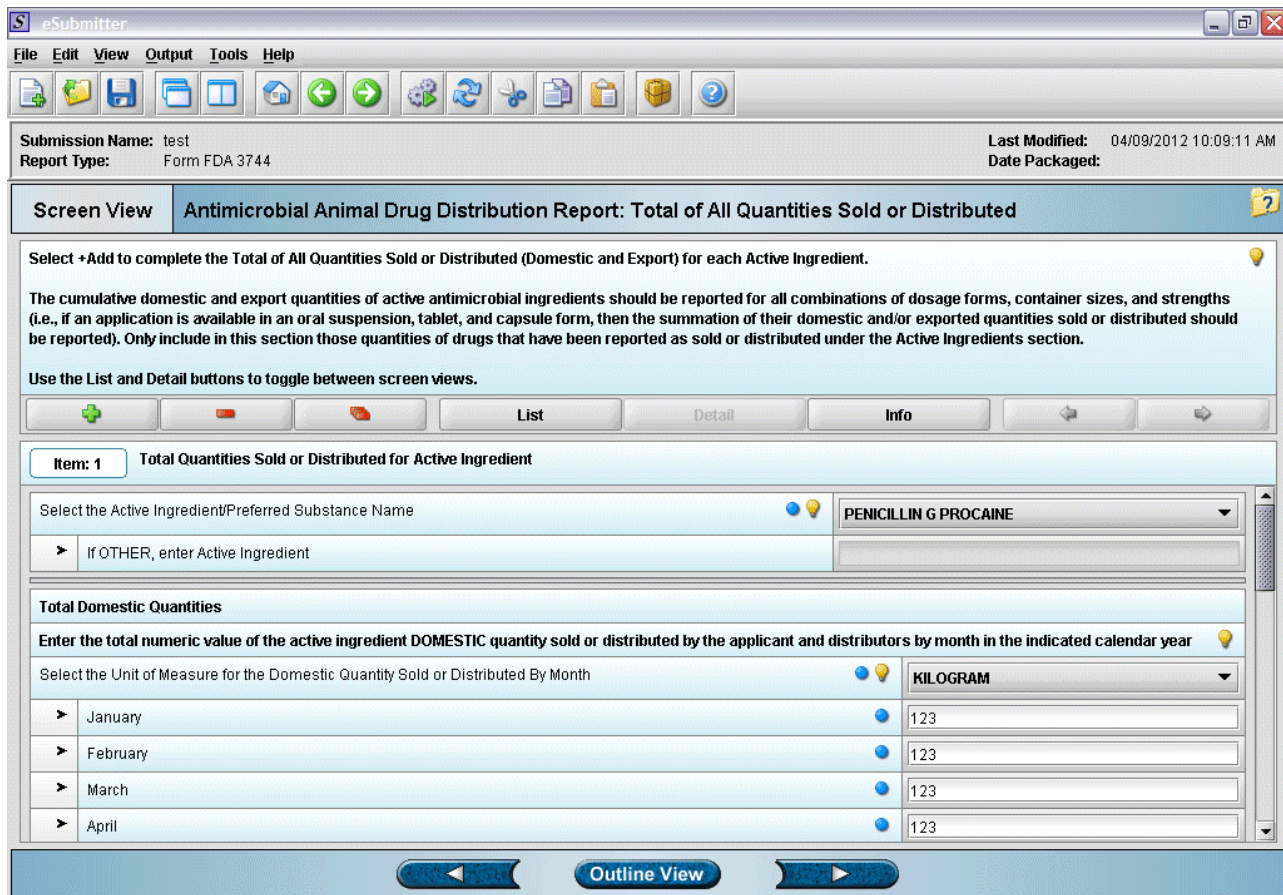
Buttons: OK, Cancel



14. Prompt after finishing with active ingredient information entry.



15. "Total of All Quantities Sold or Distributed" overview screen.



16. Entering total quantity sold information.

Submission Name: test  
Report Type: Form FDA 3744  
Last Modified: 04/09/2012 10:09:11 AM  
Date Packaged:

Screen View: Antimicrobial Animal Drug Distribution Report: Total of All Quantities Sold or Distributed

Select +Add to complete the Total of All Quantities Sold or Distributed (Domestic and Export) for each Active Ingredient.

The cumulative domestic and export quantities of active antimicrobial ingredients should be reported for all combinations of dosage forms, container sizes, and strengths (i.e., if an application is available in an oral suspension, tablet, and capsule form, then the summation of their domestic and/or exported quantities sold or distributed should be reported). Only include in this section those quantities of drugs that have been reported as sold or distributed under the Active Ingredients section.

Use the List and Detail buttons to toggle between screen views.

Item: 1 Total Quantities Sold or Distributed for Active Ingredient

Total Export Quantities

Enter the total numeric value of the active ingredient EXPORT quantity sold or distributed by the applicant and distributors by month in the indicated calendar year

Select the Unit of Measure for the Export Quantity Sold or Distributed By Month: **KILOGRAM**

Month	Quantity
January	123
February	123
March	123
April	123
May	123
June	123
July	123

Outline View

17. Entering total quantity sold information (continued).

Submission Name: test  
Report Type: Form FDA 3744  
Last Modified: 04/09/2012 10:09:11 AM  
Date Packaged:

Screen View: Antimicrobial Animal Drug Distribution Report: Total of All Quantities Sold or Distributed

Select +Add to complete the Total of All Quantities Sold or Distributed (Domestic and Export) for each Active Ingredient.

The cumulative domestic and export quantities of active antimicrobial ingredients should be reported for all combinations of dosage forms, container sizes, and strengths (i.e., if an application is available in an oral suspension, tablet, and capsule form, then the summation of their domestic and/or exported quantities sold or distributed should be reported). Only include in this section those quantities of drugs that have been reported as sold or distributed under the Active Ingredients section.

Use the List and Detail buttons to toggle between screen views.

Information: You have reached the end of the Submission form.

Close

List of Active Ingredients and Total Quantities Sold or Distributed

Item	Active Ingredient	Quantity Sold or Distributed - Unit of Measure
1	PENICILLIN G PROCAINE	

1 of 100 items in the list (1 required)

Outline View

18. Form completed.