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

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eSubmitter (Form FDA 3744 In Vitro Diagnostic Device - 510(k) ISO13485	1.3	11/10/2011 04:12:29 11/10/2019 10:33:42 / 11/04/2009 10:33:42 / 11/03/2011 01:44:13 F	in to FDA in an helpful dialog
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3. Enter identifying information for application.

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This screen sup For help on how screen.	ports the data in	nput of tabular <u>Do</u> een, view the scree	<u>sage Form</u> information. en instructions available	by selecting the 'Hint'	option (denoted by a lig	htbulb) at the top r	ight of the
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. "Dosage Form" overview screen					
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Submission Name: test Report Type: Form FDA 3744					Last Modified: Date Packaged:
Screen View Antimicrobial Animal Drug	g Distribution Report	Food Animal Dosage	Form Informati	on	2
Select +Add to complete the Food Animal Dosage Form I	nformation 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 ca	omplete Individual Product Ir	nformation for that item on th	e next screen.		
Use the List and Detail buffons to focule between screen	views.				
	List	Detail	Info	4	•
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Item: 1 1000 Anima Dosage Form information			1		
Select a Dosage Form		• 💡	TABLET		▼
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Select the Animal Species Calegory for the approved fab	enng for the mulcated dosage	: 101111	• •	Food Animal Eood and Non Eoo	d ûnimal
Enter the target food-producing animal(s) as species for	the indicated dosage form				• 💡
test					
			No. of Concession, Name		

5. Entering dosage form information.

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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 I This screen requires at least one (1) dosa Once complete, highlight the dosage form	Dosage Form Information section for each dosage form covered by this application. ge form to be entered. in the list to complete Individual Product Information for that item on the next screen.	•							
Use the List and Detail buttons to toggle	ist Data Message Dialog 🔀								
•	Select an option								
Item: 1 Food Animal Dosage Form Select a Dosage Form If OTHER, enter Dosage Form	I would like to add another Dosage Form I am finished entering Dosage Form(s) and I would like to move to the next screen Ignore future add/navigation messages when exiting list screens?								
Select the Animal Species Category for t	<u>O</u> K <u>C</u> ancel	Food Animal							
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Enter the target food-producing animal(s) test	as species for the indicated dosage form								
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Submission Name Report Type:	: test Form FDA 3744											La Da	st Modified: te Package
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Outline View

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

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File Edit View Output Tools Help		
Submission Name: test Report Type: Form FDA 3744	Last Modified: Date Packaged:	04/09/2012 09:59:7 AM
Screen View Antimicrobial Animal Drug Distribution Report: Containers		
Select +Add to complete container size information for each dosage form covered by this application. The dosage form to which the info this information box. After you have added all container sizes for the indicated dosage form, navigate back to the Food Animal Dosage Fo another dosage form from the list, and complete this screen again for all container sizes, if applicable. This screen requires at least one (1) container size to be entered for each dosage form.	rmation applies is orm Information so	displayed below 💡 reen, select
Use the List and Detail butte List Data Message Dialog		
Dosage Form TABLET Select an option I would like to add another Container Size and Container Size Unit I would like to move to the next s Item: 1 I am finished entering Container Size and Container Size Unit(s) and I would like to move to the next s Enter the Container Size Ignore future add/navigation messages when exiting list screens? Select the Container Size QK	screen	
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9. Prompt after finishing with container size and unit information entry.

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With an analysis of the second se	ile Edit <u>V</u> iew <u>O</u> utput <u>T</u> ools <u>H</u> elp					
Submission Name: test Report Type: Form EDA 3744 Last Modified:: 04/09/2012 09:59:7 AM Date Packaged: Screen View Antimicrobial Animal Drug Distribution Report: Active Ingredients Image: 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 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 Dosage Form TABLET Container Size unit 300; GRAM 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.		2 😼 🛍 💼	9			
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 screen views. Dosage Form TABLET Container Size Unit 300; GRAM This screen supports the data input of tabular <u>Active Ingredient</u> 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.	Submission Name: test Report Type: Form FDA 3744				Last Modified: Date Packaged:	04/09/2012 09:59:7 AM
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 hox. 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 It is 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.	Screen View Antimicrobial Animal Drug	Distribution Report	: Active Ingredients			2
Dosage Form TABLET Container Size and Container Size Unit 300; GRAM Itist Detail Info 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.	Select +Add to complete the Active Ingredient section for which the ingredient information applies is displayed belo dosage form, navigate back to the Container screen, selec This screen requires at least one (1) active ingredient and out for each differing active ingredient strength. Use the List and Detail buttons to toggle between screen v	each container size for ea w this information box. Aft xt another container size f its corresponding streng iews.	ch dosage form covered by er you have added all ingre rom the list, and complete h to be entered for each co	y this application. The dos edients for the indicated co this screen again for all a ontainer size for each dos	age form and cont ontainer size for th ctive ingredients, if age form. This scr	ainer size to e indicated f applicable. een must be filled
Container Size and Container Size Unit 300; GRAM List Detail 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.	Dosage Form	TABLET				
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This screen supports the data input of tabular <u>Active Ingredient</u> 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.		List	Detail	Info	4	¢
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10. "Active Ingredient" overview screen.

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Screen View Antimicrobial Animal Drug D	istribution Report:	: Active Ingredients			2		
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Dosage Form	TABLET						
Container Size and Container Size Unit	300; GRAM						
	List	Detail	Info	4	•		
Item: 1 Active Ingredient Information							
Select the Active Ingredient/Preferred Substance Name		• •	PENICILLIN G PROCA	AINE	-		
If OTHER, enter Active Ingredient							
Enter the Active Ingredient Strength - Numerator		۵ 💡	20				
Select the Active Ingredient Strength - Numerator Unit of Mea	Select the Active Ingredient Strength - Numerator Unit of Measure						
Enter the Active Ingredient Strength - Denominator	Enter the Active Ingredient Strength - Denominator						
Select the Active Ingredient Strength - Denominator Unit of M	easure	• 💡	MILLIGRAM		•		
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11. Entering active ingredient information.

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Screen View Antimicrobial Animal Drug Distribution Report: Active Ingredients										2		
Select which t dosage This sc out for Use the	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.											
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12. Entering active ingredient information (continued).

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Screen View Antimicrobial Animal Drug D	istribution Report	Active Ingredients	1				2
Select +Add to complete the Active Ingredient section for ea which the ingredient information applies is displayed below dosage form, navigate back to the Container screen, select This screen requires at least one (1) active ingredient and it out for each differing active ingredient strength.	ich container size for ea this information box. Aft another container size f s corresponding strengt	ch dosage form covered l er you have added all ingr rom the list, and complete h to be entered for each c	ny this applicat edients for the this screen a container size t	ion. The dos: • indicated co gain for all a for each dos:	age form and con ontainer size for t ctive ingredients, age form. This sc	itainer size to he indicated if applicable. creen must be	∂ filled
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Dosage Form	TABLET						
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The Annual Total will be automatically calculated by	eSubmitter based on th	e data values entered for	the months ab	ove.			
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13. Entering active ingredient informa	ation (continue	d).					
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<u>File Edit View Output Tools Help</u>		
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Screen View Antimicrobia	Animal Drug Distribution Report: Active Ingredients	☑
Select +Add to complete the Active Ing which the ingredient information applie dosage form, navigate back to the Com This screen requires at least one (1) at	edient section for each container size for each dosage form covered by this applica s is displayed below this information box. After you have added all ingredients for the ainer screen, select another container size from the list, and complete this screen a tive ingredient and its corresponding strength to be entered for each container size	tion. The dosage form and container size to e indicated container size for the indicated gain for all active ingredients, if applicable. for each dosage form. This screen must be filled
out for each differing active ingredient	List Data Message Dialog	
Use the List and Detail buttons to togg		
Dosage Form	Select an option	
Container Size and Container Size Unit	O I would like to add another Active Ingredient	
	I am finished entering Active Ingredient(s) and I would like to move to the next	t screen
Item: 1 Active Ingredient Inform	□ Ignore future add/navigation messages when exiting list screens?	
July	<u>OK</u> <u>Cancel</u>	
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November	•	123
December	٠	123
The Annual Total will be autom	atically calculated by eSubmitter based on the data values entered for the months al	ove.
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14. Prompt after finishing with active ingredient information entry.

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Screen View	Antimicrobi	al Animal Drug	Distribution Report	: Total of All Quantit	ies Sold or Distribute	əd		2
Select +Add to com	plete the Total of <i>i</i>	All Quantities Sold or	Distributed (Domestic and	l Export) for each Active In	gredient.			
The cumulative don (i.e., if an applicatio be reported). Only in	nestic and export n is available in an nclude in this sect	quantities of active a oral suspension, tal ion those quantities (ntimicrobial ingredients sl olet, and capsule form, the of drugs that have been re	nould be reported for all co n the summation of their d ported as sold or distribut	ombinations of dosage form omestic and/or exported qu ed under the Active Ingredic	s, container si Iantities sold o ents section.	zes, and strengths r distributed should	
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15. "Total of	All Quantiti	es Sold or D	istributed" over	view screen.				
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elect +Add to com he cumulative don e., if an applicatio e reported). Only i	plete the Total of A nestic and export o n is available in an nclude in this secti	II Quantities Sold quantities of active oral suspension, on those quantitie	or Distributed (Domestic an e antimicrobial ingredients s tablet, and capsule form, the is of drugs that have been re	d Export) for each Active Ingre hould be reported for all comb en the summation of their dome sported as sold or distributed u	dient. inations o estic and/ inder the /	f dosage form or exported qu Active Ingredia	is, container size lantities sold or ents section.	es, and strengths distributed should
ise the List and De	tail buttons to togg	le between scree	n views.	Detail	In	fo	4	
Select the Active In	ngredient/Preferred :	Substance Name		• 🖓	PENICIL	LIN G PROCAI	NE	•
Fotal Domestic Qu Enter the total nur	uantities neric value of the a	nctive ingredient D	OMESTIC quantity sold or di	stributed by the applicant and (distributor	s by month in	the indicated ca	ılendar year 🛛 🂡
Select the Unit of Measure for the Domestic Quantity Sold or Distributed By Month					۹ 🥹	KILOGRAM		•
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<u>16.</u> Entering total quantity sold information.

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Screen View	Antimicrob	al Animal Dru	g Distribution Repor	t: Total of All Quant	tities Sold o	r Distrib	uted		C
elect +Add to con	nplete the Total of	All Quantities Sold	or Distributed (Domestic an	nd Export) for each Active	Ingredient.				0
he cumulative doi .e., if an applicatio e reported). Only se the List and Do	mestic and export on is available in a include in this sec etail buttons to tog	t quantities of active n oral suspension, i ction those quantitie ggle between scree	e antimicrobial ingredients s tablet, and capsule form, th is of drugs that have been r n views.	should be reported for all en the summation of their eported as sold or distrib	combinations o domestic and/ uted under the /	f dosage fo or exported Active Ingre	rms, container si quantities sold o dients section.	zes, and strengths r distributed should	1
\$			List	Detail	In	ío	4	•	
Tot	al Quantities Sold	or Distributed for A	Active Ingredient	-				*	
	an Quantitico Solu	TOT DISTRIBUCCUTOF P							= -
Total Export Quai	ntities								
Enter the total nu	meric value of the	e active ingredient E	XPORT quantity sold or dist	ributed by the applicant a	nd distributors	by month in	the indicated cal	endar year 🛛 💡	
Select the Unit of	Measure for the Ex	port Quantity Sold o	r Distributed By Month		۹ و	KILOGRA	M	•	
> January					۲	123			j
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. Entering	total quant	tity sold info	ormation (continu	ed).					
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Submission Name: te Report Type: F	est orm FDA 3744		Last Modified: Date Packaged:	04/09/2012 10:09:1	1 AM				
Screen View	Antimicrobial A	Animal Drug Distribution Report: Total of All Quantities Sold or Distribution	uted						
Select +Add to comp	plete the Total of All Q	uantities Sold or Distributed (Domestic and Export) for each Active Ingredient.			9				
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 Deta	ail buttons to toggle b	etween screen views.							
•	<u> </u>	Information		\$					
List of Active Ingredi Item Item PENIC	ients and Total Quant Active Ingred CILLIN G PROCAINE	You have reached the end of the Submission form.	luantity Distributed	- Unit of Measure					
					•				
	1 of 100 items in the list (1 required)								
		Outline View							

18. Form completed.