DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

ANTIMICROBIAL ANIMAL DRUG DISTRIBUTION REPORT

Form Approved: OMB No. xxxx-xxxx
Expiration Date: xx/xx/20xx
(See Burden Statement below)

Firm and Application Information

Application Type	Application Number

Firm Name	Date Submitted

Food Animal Dosage Form Information

Dosage Form(s)	Production Class(es)

Animal Species Category

☐ Food Animal ☐ Food and Non-Food Animal

Target Food Animal(s)

Indication(s)

Please complete the form and submit it to the address below.

Food and Drug Administration
Center for Veterinary Medicine
7500 Standish Place, HFV-199
Rockville, MD 20855

Public reporting burden for this collection of information is estimated to average 3.0 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the address to the right.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

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.

Total of All Quantities Sold or Distributed *(Domestic and Export)*

1st Active Ingredient

2nd Active Ingredient

3rd Active Ingredient

Domestic Quantities

Domestic Quantities Sold/Distributed by Month – **Unit of Measure for 1st Active Ingredient**	Domestic Quantities Sold/Distributed by Month – **Unit of Measure for 2nd Active Ingredient**	Domestic Quantities Sold/Distributed by Month – **Unit of Measure for 3rd Active Ingredient**

YEAR: _____	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Annual Total**
1st Active Ingredient													
2nd Active Ingredient													
3rd Active Ingredient													

Export Quantities

Export Quantities Sold/Distributed by Month – **Unit of Measure for 1st Active Ingredient**	Export Quantities Sold/Distributed by Month – **Unit of Measure for 2nd Active Ingredient**	Export Quantities Sold/Distributed by Month – **Unit of Measure for 3rd Active Ingredient**

YEAR: _____	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Annual Total**
1st Active Ingredient													
2nd Active Ingredient													
3rd Active Ingredient													

Individual Product Information

Dosage Form	Container Size	Container Size Units

1st Active Ingredient	2nd Active Ingredient	3rd Active Ingredient
1st Active Ingredient Strength – Numerator Number	*2nd Active Ingredient Strength – Numerator Number*	*3rd Active Ingredient Strength – Numerator Number*
1st Active Ingredient Strength – Numerator Unit	*2nd Active Ingredient Strength – Numerator Unit*	*3rd Active Ingredient Strength – Numerator Unit*
1st Active Ingredient Strength – Denominator Number	*2nd Active Ingredient Strength – Denominator Number*	*3rd Active Ingredient Strength – Denominator Number*
1st Active Ingredient Strength – Denominator Unit	*2nd Active Ingredient Strength – Denominator Unit*	*3rd Active Ingredient Strength – Denominator Unit*

Quantities of Individual Product Sold or Distributed *(Domestic and Export)*

Domestic and Export Quantities Sold/Distributed by Month – **Unit of Measure for 1st Active Ingredient**	Domestic and Export Quantities Sold/Distributed by Month – **Unit of Measure for 2nd Active Ingredient**	Domestic and Export Quantities Sold/Distributed by Month – **Unit of Measure for 3rd Active Ingredient**

YEAR: _____	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Annual Total**
1st Active Ingredient													
2nd Active Ingredient													
3rd Active Ingredient													

INSTRUCTIONS FOR COMPLETION OF FORM FDA 3744

General Directions for Use of the Form

This form may be used by sponsors of a new animal drug application (NADA), abbreviated new animal drug application (ANADA), or conditionally approved new animal drug application that contains an antimicrobial active ingredient to submit the antimicrobial animal drug distribution report required by section 512(l)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(l)(3)), as enacted by Title 1, Section 105 of the Animal Drug User Fee Amendments of 2008 (110 P.L. 316; 122 Stat. 3509), For sponsors of more than one such application, use a separate Form FDA 3744 for each application. Where the instructions specify use of structured product labeling (SPL) terminology for dosage form, units, etc., only use such terminology.

FIRM AND APPLICATION INFORMATION

Application Type: Enter ANADA, NADA or Conditional Approval

Application Number: Enter the application number. The application number should include leading zeros.

Firm Name: Enter the name of the application holder. For the purposes of this form, the name is equivalent to applicant or sponsor name.

Date Submitted: Enter date as MM/DD/YYYY

Page Number: The page number block is at the bottom of the page. Enter "1" for the first page, and continue with the page numbering as each page is completed and printed.

FOOD ANIMAL DOSAGE FORM INFORMATION

General Directions for Completing This Section

Complete this section for each dosage form covered by an application such that the target food-producing animals, production classes, and indications on the approved label for each dosage form are reported. If the approved labeling for a dosage form is indicated for non food-producing animals only, the dosage form does not need to be reported; however, if the labeling for the dosage form includes indications for food-producing animals or for both food-producing and non food- producing animals, report the dosage form). If an application has more than one dosage form and the approved labeling for these dosage forms is not identical with respect to target food-producing animals, production classes, and indications, use a separate Form FDA 3744 for each dosage form and the corresponding target food-producing animal(s), production classes, and indications information. If an application has more than one dosage form and the approved labeling for these dosage forms is identical with respect to target food-producing animals, production classes, and indications, then the information may be presented on a single Form FDA 3744 (i.e., simply list all of the dosage forms in the "Dosage Form(s)" field, followed by the target food-producing animal(s), production classes, and indications applicable to these dosage forms).

Dosage Form: Enter the dosage form using the terminology on the FDA website for Structured Product Labeling (go to: *www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm* and click the link for Dosage Forms.)

Animal Species Category: Check the "Food Animal" box if the approved labeling for the dosage form includes only indications for food-producing animal species. Check the "Food and Non-Food Animal" box if the approved labeling for the dosage form includes indications for both non food-producing animal species and food-producing animal species.

Target Food Animal: Enter all the target food-producing animals as species for the first dosage form. Examples include cattle, fish, turkey, chicken, etc.

Production Class: Enter all the production classes for that target food-producing animal, if applicable. Examples include breeding swine; cattle, calves, excluding veal calves; chicken, not laying eggs for human consumption.

Indications: Enter all the indications for species/production classes.

TOTAL OF ALL QUANTITIES SOLD OR DISTRIBUTED (DOMESTIC AND EXPORT)

General Directions for Completing This Section

Complete this section for each application. This section only needs to be completed once for each application (i.e., if multiple Form FDA 3744s are used to report an application because of multiple dosage forms, container sizes, or strengths, this section only needs to be completed once, on the first Form FDA 3744). The cumulative domestic quantities of active antimicrobial ingredients and cumulative exported quantities of active antimicrobial ingredients should be reported for all combinations of dosage forms, container sizes,

and strengths for all antimicrobial active ingredients (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 "Individual Product Information" section, below. If the approved labeling for a particular product (i.e., dosage form, strength, and/or container size) is indicated for non food-producing animals only, that amount is not to be reported under the "Individual Product Information" section (see directions for that section, below) and should not be included in the total quantity of antimicrobial active ingredients reported in this section.

1st Active Ingredient: Enter the first antimicrobial active ingredient, e.g., lincomycin hydrochloride" using the "Preferred Substance Name" from the list on the FDA SPL website (go to: *www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm* and click the link for Unique Ingredient Identifiers (UNII), Preferred Substance Names, and their Identified Synonyms).

2nd and 3rd Active Ingredient: Enter the second antimicrobial active ingredient, if applicable. If there are more than three antimicrobial active ingredients, use a separate Form FDA 3744 to include the information about the additional active ingredient(s). In this case, complete all sections of page one of this form template except the Food Animal Dosage Form Information.

Domestic Quantities

Domestic Quantities Sold/Distributed by – Unit of Measure for 1st Active Ingredient: Enter the appropriate unit of measure for the amounts of all antimicrobial active ingredient quantity sold or distributed.

For example if 500 cases of 100 mL bottles @ 200 mg lincomycin hydrochloride/1 mL, each case containing 6 bottles, were distributed, enter "g" since the calculated quantity would amount to 60,000 grams.

Year: Enter the calendar year for which the data are being reported. For example, enter "2009".

1st Active Ingredient: Enter the numeric value of the amount for the first antimicrobial active ingredient sold or distributed domestically for the application by month and annual total. Each monthly total is the sum of all domestic sales and distribution (i.e., by the sponsor and all distributors, for all dosage forms, container sizes, and strengths).

For example if 500 cases of 100 mL bottles @ 200 mg lincomycin hydrochloride/1 mL, each case containing 6 bottles, were distributed/sold during the month of January, enter "60,000" since the calculated quantity would amount to 60,000 grams. Ensure that there are five significant figures (i.e. Instead of entering "60" for "60 kg", enter "60,000" for 60,000 g).

If 1250 bottles of 1000 tablet bottles @ 25 mg/1 tablet were distributed, enter "31,250" since the calculated quantity would amount to 31,250 grams.

Continue entering monthly distribution amounts for February through December of the calendar year. Enter the total amount distributed in that year.

Returned Products: When product is sold or distributed and returned, subtract the returned amount from the monthly total (in whole container sizes).

2nd and 3rd Active Ingredient: Enter the numeric value of the amount(s) of the second and third antimicrobial active ingredients that are sold or distributed domestically for the application or conditional approval in the same manner and on the same form as the 1st active ingredient. If there are more than 3 active ingredients, use a separate Form FDA 3744 to include the information about the additional active ingredient(s). The unit of measure for 2nd and 3rd active ingredients does not have to be identical to the 1st Active Ingredient Unit.

Export Quantities

Export Quantities Sold/Distributed by – Unit of Measure for 1st Active Ingredient: Enter the appropriate unit of measure for the amounts of all antimicrobial active ingredient quantity sold or distributed. The unit of measure does not have to be identical to the "1st Active Ingredient Unit" entered under "Domestic Quantities".

For example if 300 cases of 100 mL bottles @ 200 mg lincomycin hydrochloride/1 mL, each case containing 6 bottles, were distributed during the month of January, enter "g" since the calculated quantity would amount to 36,000 grams.

Year: Enter the calendar year for which the data are being reported. For example, enter "2009".

1st Active Ingredient: Enter the numeric value of the amount for the first antimicrobial active ingredient sold or distributed for export for the application by month and annual total. Each monthly total is the sum of all exported sales and distribution (i.e., by the sponsor and all distributors, for all dosage forms, container sizes, and strengths).

For example if 300 cases of 100 mL bottles @ 200 mg lincomycin hydrochloride/1 mL, each case containing 6 bottles, were distributed, enter "36,000" in the box for January since the calculated quantity would amount to 36,000 grams.

If 1250 bottles of 1000 tablet bottles @ 25 mg/1 tablet were distributed, enter "31,250" since the calculated quantity would amount to 31,250 grams.

Continue entering monthly distribution amounts for February through December of the calendar year. Enter the total amount distributed in that year.

Returned Products: When product is sold or distributed and returned, subtract the returned amount from the monthly total (in whole container sizes).

2nd and 3rd Active Ingredient: Enter the numeric value of the amount(s) of the second and third antimicrobial active ingredients that are sold or distributed for export for the application or conditional approval in the same manner and on the same form as the 1st active ingredient. If there are more than 3 active ingredients, use a separate Form FDA 3744 to include the information about the additional active ingredient(s). The unit(s) of measure does not have to be identical to the unit of measure used for the 1st Active Ingredient.

INDIVIDUAL PRODUCT INFORMATION

General Directions for Completing This Section

Complete this section for each combination of dosage form, container size, and strength of product marketed. For example, if a particular dosage form has 3 strengths, complete this section on a separate Form FDA 3744 for each combination of dosage form and strength, such that a total of 3 separate forms are used. If multiple container sizes are available in a given dosage form and strength, use a separate Form FDA 3744 for each combination of dosage form, container size, and strength. Using the example of a dosage form with three strengths, if each strength is marketed in 3 different container sizes, use a separate page for each combination of dosage form, strength, and container size, such that a total of 9 separate forms are used. If there are multiple dosage forms, container sizes, and/or strengths requiring the use of more than one form, the information in the "Firm and Application," "Food Animal Dosage Form Information," "Total of All Quantities Sold or Distributed (Domestic and Export)," "Domestic Quantities," and "Export Quantities" sections of the form do not need to be filled out again on the additional forms used.

Quantities of Antimicrobial Active Ingredients to be Reported

If the approved labeling for a particular product(s) (i.e., dosage form, strength, and/or container size) includes indications for only food-producing animals, report all quantities sold or distributed. If the approved labeling includes indications for both food-producing and non food-producing animal species, report all quantities sold or distributed. If the approved labeling for a particular product is indicated for non food-producing animals only, do not report the quantity sold or distributed for that product.

Dosage Form: Enter the dosage form for the first new animal drug using the terminology on the FDA website for Structured Product Labeling (go to: *www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm* and click the link for Dosage Forms.)

Container Size: Enter the container size without units for the Product; e.g., if the product is manufactured in 100 mL vials, enter "100."

Container Size Units: Enter the units for the container size, choosing the SPL Units of Measure or Units of Presentation from those listed on the FDA SPL website (go to: *www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm* and click either the link for Units of Measure or the link for Units of Presentation). If the unit is based on the standards of the metric system/International System of Weights and Measures, refer to the SPL Units of Measure list; if the unit is not present on this list, refer to the SPL Units of Presentation list. For example, if the product is manufactured in 100 mL vials, since, "mL" is a metric system unit, refer to the SPL Units of Measure list; or if the product is manufactured in 100 tablet bottles, enter "tablet" from the Units of Presentation SPL list since tablet is not a Unit of Measure.

1st Active Ingredient: Enter the first antimicrobial active ingredient, e.g., "lincomycin hydrochloride" using the "Preferred Substance Name" from the list on the FDA SPL website (go to: *www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm* and click the link for Unique Ingredient Identifiers (UNII), Preferred Substance Names, and their Identified Synonyms).

1st Active Ingredient Strength – Numerator Number: Enter the strength without units for the first antimicrobial active ingredient; e.g., if the product is manufactured at 200 mg/1 mL, enter “200."

1st Active Ingredient Strength – Numerator Unit: Enter the numerator unit of the numerator strength for the first antimicrobial active ingredient, choosing from the SPL Units of Measure list. For the 200 mg/1 mL example, enter the numerator unit in the box, e.g., “mg.”

1st Active Ingredient Strength – Denominator Number: Enter the denominator without units for the first antimicrobial active ingredient; e.g., if the product is manufactured as 200 mg/1 mL, enter “1”.

1st Active Ingredient Strength – Denominator Unit: Enter the unit for the first antimicrobial active ingredient, choosing from the SPL Units of Measure list or the SPL Units of Presentation list. For the 200 mg/1 mL example, the denominator unit is “mL”. For the 25 mg/1 tablet example, the denominator unit is “tablet”.

2nd and 3rd Active Ingredients: For dosage forms with more than one antimicrobial active ingredient, enter the antimicrobial active ingredient name and strength information for the second and third antimicrobial active ingredients in the same manner and on the same form as the first antimicrobial active ingredient. If there are more than three antimicrobial active ingredients, this section will have to be filled out to include the additional ingredients. The first page of this form does not need to be filled out again. Number the additional pages in sequence.

QUANTITIES OF INDIVIDUAL PRODUCT SOLD OR DISTRIBUTED (DOMESTIC AND EXPORT)

General Directions for Completing this Section

Complete this section for all Form FDA 3744s created under the “Individual Product Information” directions, above, such that the sale or distribution information is reported for all combinations of dosage forms, container size and units, and strengths for all antimicrobial active ingredients. Domestic and exported quantities are reported together.

Domestic and Export Quantities Distributed by – Unit of Measure for 1st Active Ingredient: Enter the appropriate unit of measure for the amounts of all antimicrobial active ingredient quantity sold or distributed. The unit of measure does not have to be identical to the unit used for the “1st Active Ingredient Numerator Unit” in the “Total of All Quantities Sold or Distributed (Domestic and Export)” section.

For example if 500 cases of 100 mL bottles @ 200 mg lincomycin hydrochloride/1 mL, each case containing 6 bottles, were distributed, enter “g” since the calculated quantity would amount to 60,000 grams.

Year: Enter the calendar year for which the data are being reported. For example, enter 2009.

1st Active Ingredient: Enter the numeric value of the amount of the first antimicrobial active ingredient sold or distributed by month. Include all domestic and exported product sold or distributed by the applicant and distributors. Enter the numeric value for the total amount sold or distributed for the year in the annual total.

For example, if 500 cases of 100 mL bottles @200 mg lincomycin hydrochloride/1 mL, each case containing 6 bottles, were distributed domestically and 200 cases exported, enter “84,000” since the calculated quantity would amount to 84,000 grams.

Returned Products: When product is sold or distributed and returned, subtract the returned amount from the monthly total (in whole container sizes).

Continue entering monthly distribution amounts for February through December of the calendar year. Enter the total amount distributed in that year.

2nd and 3rd Active Ingredient: Enter the numeric value of the amount(s) of the second and third antimicrobial active ingredients that are sold or distributed domestically and for export for the application or conditional approval in the same manner and on the same form as the 1st active ingredient. If there are more than three active ingredients, use a separate Form FDA 3744 to include the information about the additional active ingredient(s).

SUBMISSION OF FORM(S)

Submit the completed form to the Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Place, HFV-199, Rockville, MD 20855. Please attach the form to a signed cover letter.