

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
ANIMAL DRUG USER FEE COVER SHEET**

PAYMENT IDENTIFICATION NUMBER:
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit this completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail payment and printed copy of this Cover Sheet to the Food and Drug Administration, P.O. Box 953877, St. Louis, MO, 63195-3877. *(Note: In no case should payment be submitted with the application.)*
4. If you prefer to send payment by a courier, the courier may deliver the payment and a printed copy of this Cover Sheet to: US Bank, Attn: Government Lockbox 953877, 1005 Convention Plaza, St. Louis, MO 63101. *(Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)*
5. Include a copy of this completed Cover Sheet in volume one of the application when submitting to the Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV-199), 7500 Standish Place, Rockville, MD 20855

1. SPONSOR NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)	2. CONTACT NAME
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.1 E-MAIL ADDRESS
	2.2. TELEPHONE NUMBER (Include Area Code)
	2.3 FACSIMILE (FAX) NUMBER (Include Area Code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following website: <http://www.fda.gov/oc/adufa>)

3.1 <u>Select Application Type</u>	3.2 <u>Select one of the types below:</u>
<input type="checkbox"/> New Animal Drug Application	<input type="checkbox"/> Original Application
<input type="checkbox"/> Abbreviated New Animal Drug Application	<input type="checkbox"/> Supplemental Application

(under provisions of 512(b)(1) of the FDCA)

4. IS THIS NEW APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE WAIVERS? IF SO, CHECK THE APPLICABLE SECTION.*

- The assessment of the fee would present a significant barrier to innovation [740(d)(1)(A)] This waiver request has been approved and the FDA Decision number is
- The application is intended solely for use in Type B medicated feed intended for use in Type C free-choice medicated feed or a Type C free choice medicated feed [740(d)(1)(C)] This waiver request has been approved and the FDA Decision number is
- The sole purpose of the application is to support conditions of use for minor use and/or minor species [740(d)(1)(D)] This waiver request has been approved and the FDA Decision number is
- This application is the first application submitted by a qualified small business, including any affiliates, parents, and partner firms [740(d)(1)(E)] This waiver request has been approved and the FDA Decision number is

Use the box below to indicate the waiver is still under consideration:

WAIVER REQUEST SUBMISSION DATE:

Waiver under consideration

***Note to section 4 above: Unless a waiver or reduction has been previously granted by the Agency for this application, payment is expected pending the outcome of the waiver or reduction decision.**

5. USER FEE PAYMENT AMOUNT FOR THIS APPLICATION