

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

ANIMAL GENERIC DRUG USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER (Write the Payment Identification Number on your check)

AG2000003-953877

A completed cover sheet must accompany each original application subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/adufa/agdufacoversheet.html>.

1. SPONSOR NAME AND ADDRESS (Include name, street address, city, state, country, and post office code) IVX ANIMAL HEALTH INC 3915 SOUTH 48TH ST TERR ST JOSEPH MO 64503 US	2. CONTACT NAME ROBERT GUNDERSON
	2.1 E-MAIL ADDRESS rob_gunderson@ivax.com
	2.2. TELEPHONE NUMBER (Include Area Code) 816-676-6185
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 431558386	2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 816-676-6873

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/agdufamain.html>)

3.1 Application Type

Original Abbreviated New Animal Drug Application (ANADA) - under provisions of 512(b)(2) of the FDCA

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

The sole purpose of the application is to support conditions of use for minor use or minor species [741(d)]. This waiver request has been approved and the FDA waiver number is

5. USER FEE PAYMENT AMOUNT FOR THIS APPLICATION

\$41,400.00

***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.**

Public Reporting Burden

Public reporting burden for this collection of information is estimated to average 20 minutes per response, including 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer (HFA-710)
5600 Fishers Lane
Rockville, MD 20857

An agency may not conduct or sponsor a collection of information, and a person is not required to respond to a collection of information, unless it displays a currently valid OMB control number.