DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TRANSMITTAL OF PERIODIC REPORTS AND PROMOTIONAL MATERIAL FOR NEW ANIMAL DRUGS

(See Instructions on Back)

Form Approved: OMB No. 0910-0284
Exp. Date: 12/31/2014. See PRA statement on pg. 3.

Note: Required by 21 CFR 514.80. Failure to make the reports is a basis for withdrawal of the NADA/ANADA.

1. NADA NO. or ANADA NO.

2. Name of Applicant	3. Date Report Submitted	4. Date Report Due

5. Drug Trade Name	6. Chemical Name

7. Combined Report *(List NADA numbers involved. See Instructions.)*	8. Report Period (MM) (DD) (YYYY) From: (MM) (DD) (YYYY) To:
	9. Type of Report *(Check One)* ☐ 6/12/18/24 Month ☐ Annual ☐ Promo/Ad ☐ Follow Up ☐ Other *(specify)* _____

10. **Information Required – Periodic and Special**
(See CFR 514.80. Check Column A if "None.")

A – None	**B** – None	**C** – Description *(Volume Number(s), Tab(s), Pages of Report)*			
		(1) Total No. of Reports	(2) No. of Product Defects	(3) No. of Complaints Affecting Animals	(4) No. of Animals Reacted
☐	(a) Adverse Drug Experiences				
☐	(b) Clinical Data *(Animal Experience)*				
☐	(c) Mailing Pieces and/or Advertising Material				
☐	(d) Current Package Labeling	*Please Provide on Separate Sheet*			
☐	(e) Quantity Marketed	*Please Provide on Separate Sheet*			

11. **Information Required – Promotional Material Only**

A – Date of Issuance	**B** – Type of Material	**C** – Identification *(Code No., etc.)*

12. Name/Title of Responsible Official/US Agent *(Type of Print)*	15. Return Address of Applicant/Agent
13. Signature of Above Official/Agent	
14. Email Address	16. Telephone & Fax Number of Applicant/Agent

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INSTRUCTIONS FOR COMPLETION OF FORM FDA 2301

Copies of this form may be obtained by writing to:

Department of Health and Human Services
Public Health Service
Food and Drug Administration (HFV-12)
7519 Standish Place, Room 3508
Rockville, MD 20855

1. Enter the NADA number assigned to the drug. If fewer than six digits, add leading zeros.

7. A combined report may be submitted for NADAs or ANADAs [See 514.80 (c)]. Whenever an applicant is required to submit a periodic drug experience report under 514.80(b)(4) with respect to more than one approved NADA or ANADA for preparations containing the same new animal drug so that the same information is required to be reported for more than one application, the applicant may elect to submit as a part of the report for one such application (the primary application) all the information common to such applications in lieu of reporting separately and repetitively on each. If the applicant elects to do this, the applicant must do the following:

   (1) State when a report applies to multiple applications and identify all related applications for which the report is submitted by NADA or ANADA number.

   (2) Ensure that the primary application contains a list of the NADA or ANADA numbers of all related applications.

   (3) Submit a completed Form FDA 2301 to the primary application and each related application with reference to the primary application by NADA/ANADA number and submission date for the complete report of the common information.

   (4) All other information specific to a particular NADA/ANADA must be included in the report for that particular NADA/ANADA.

9. Check this box if report is a follow-up to one previously submitted or is a response to an FDA request. Reports for all NADA/ANADA involved should be submitted on the anniversary date of the earliest approved NADA/ANADA involved (primary application).

10(a). Adverse drug experience is any adverse event associated with the use of a new animal drug, whether or not considered to be drug related, and whether or not the new animal drug was used in accordance with the approved labeling (i.e., used according to label directions or used in an extralabel manner, including but not limited to different route of administration, different species, different indications, or other than labeled dosage). Adverse drug experience includes, but is not limited to:

   (1) An adverse event occurring in animals in the course of the use of an animal drug product by a veterinarian or by a livestock producer or other animal owner or caretaker.

   (2) Failure of a new animal drug to produce its expected pharmacological or clinical effect (lack of expected effectiveness).

   (3) An adverse event occurring in humans from exposure during manufacture, testing, handling, or use of a new animal drug.

10(a)(1). Enter total number of complaints being reported. Each complaint may involve one or more adverse drug reactions. A complaint is defined as a report involving one situation or incident and may involve one or more animals.

10(a)(4). Enter total number of animals experiencing reactions involved in item 10(a)(3).

10(e). Report the quantity marketed in units of highest concentration and the largest marketing package size. In the case of a dosage form product, e.g., tablets which are formulated on body weight range basis, give the quantity marketed of specific strength and package size separately without converting into highest concentration and the largest marketing package size unit.

Submit two copies of the report to:

Department of Health and Human Services
Public Health Service
Food and Drug Administration (HFV-199)
7500 Standish Place, Room N403
Rockville, MD 20855

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 30 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
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 number."