

**TRANSMITTAL OF PERIODIC REPORTS
AND PROMOTIONAL MATERIAL
FOR NEW ANIMAL DRUGS**
(See Instructions on Back)

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:

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)			
<input type="checkbox"/>	(a) Adverse Drug Experiences	(1) Total No. of Reports	(2) No. of Product Defects	(3) No. of Complaints Affecting Animals	(4) No. of Animals Reacted
<input type="checkbox"/>	(b) Clinical Data (Animal Experience)				
<input type="checkbox"/>	(c) Mailing Pieces and/or Advertising Material				
<input type="checkbox"/>	(d) Current Package Labeling	Please Provide on Separate Sheet			
<input type="checkbox"/>	(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

INSTRUCTIONS FOR COMPLETION OF FORM FDA 2301

Copies of this form may be obtained by writing to:

Food and Drug Administration
Center for Veterinary Medicine (HFV-212)
7519 Standish Place
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). Enter the numeric value of the amount of total packages sold or distributed domestically or for export for the reporting time period. Include all the domestic and export 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/sold during the reporting time period, enter "3,000" since the calculated number of packages (100 mL bottles @ 200 mg/1 mL) would amount to 3,000 bottles. If 1250 bottles of 1000 tablet bottles @ 25mg/1 tablet were distributed, enter "1250" since the calculated quantity would amount to 1250 bottles. Returned Products: When product is sold or distributed and returned, subtract the returned amount from the monthly total (in packages).

Submit two copies of the report to:

Food and Drug Administration
Center for Veterinary Medicine
Document Control Unit, HFV-199
MPN 2, E150
12225 Wilkins Avenue
Rockville, MD 20852

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

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

The burden time for this collection of information is estimated to average 1 hour 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 Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“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.”