

**§ 510.302 [Removed]**

■ 7. Section 510.302 *Reporting forms* is removed.

**PART 514—NEW ANIMAL DRUG APPLICATIONS**

■ 8. The authority citation for 21 CFR part 514 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e, 381.

■ 9. Section 514.3 is added to read as follows:

**§ 514.3 Definitions.**

The definition and interpretation of terms contained in this section apply to those terms as used throughout subchapter E.

*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.

*ANADA* is an abbreviated new animal drug application including all amendments and supplements.

*Applicant* is a person or entity who owns or holds on behalf of the owner the approval for an NADA or an ANADA, and is responsible for

compliance with applicable provisions of the act and regulations.

*Increased frequency of adverse drug experience* is an increased rate of occurrence of a particular serious adverse drug event, expected or unexpected, after appropriate adjustment for drug exposure.

*NADA* is a new animal drug application including all amendments and supplements.

*Nonapplicant* is any person other than the applicant whose name appears on the label and who is engaged in manufacturing, packing, distribution, or labeling of the product.

*Product defect/manufacturing defect* is the deviation of a distributed product from the standards specified in the approved application, or any significant chemical, physical, or other change, or deterioration in the distributed drug product, including any microbial or chemical contamination. A manufacturing defect is a product defect caused or aggravated by a manufacturing or related process. A manufacturing defect may occur from a single event or from deficiencies inherent to the manufacturing process. These defects are generally associated with product contamination, product deterioration, manufacturing error, defective packaging, damage from disaster, or labeling error. For example, a labeling error may include any incident that causes a distributed product to be mistaken for, or its labeling applied to, another product.

*Serious adverse drug experience* is an adverse event that is fatal, or life-threatening, or requires professional intervention, or causes an abortion, or stillbirth, or infertility, or congenital anomaly, or prolonged or permanent disability, or disfigurement.

*Unexpected adverse drug experience* is an adverse event that is not listed in the current labeling for the new animal drug and includes any event that may be symptomatically and pathophysiologically related to an event listed on the labeling, but differs from

the event because of greater severity or specificity. For example, under this definition hepatic necrosis would be unexpected if the labeling referred only to elevated hepatic enzymes or hepatitis.

**§ 514.8 [Amended]**

■ 10. Section 514.8 *Supplemental new animal drug applications* is amended in paragraph (a)(1) by removing “§ 510.300(a) of this chapter” and by adding in its place “§ 514.80”; in paragraph (a)(5) by removing “§ 510.300(b)(4) of this chapter” and by adding in its place “§ 514.80(b)(4)”; in paragraph (a)(5)(ix) by removing “§ 510.300(b)(1) of this chapter” and by adding in its place “§ 514.80(b)(1)”; and by revising paragraph (a)(6) to read as follows:

(a) \* \* \*

(6) Approval of a supplemental new animal drug application will not be required to provide for an additional distributor to distribute a drug which is the subject of an approved new animal drug application if the conditions described in § 514.80(b)(5)(iii) are met before putting such a change into effect.

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**§ 514.11 [Amended]**

■ 11. Section 514.11 *Confidentiality of data and information in a new animal drug application file* is amended in paragraph (a) by removing “510.300” and adding in its place “514.80”.

**§ 514.15 [Amended]**

■ 12. Section 514.15 *Untrue statements in applications* is amended in paragraph (b) by removing “§ 510.300” and adding in its place “§ 514.80”.

■ 13. Section 514.80 is added to subpart B to read as follows:

**§ 514.80 Records and reports concerning experience with approved new animal drugs.**

The following table outlines the purpose for each paragraph of this section:

Purpose	21 CFR Paragraph and Title
What information must be reported concerning approved NADAs or ANADAs?	514.80(a) Applicability.
What authority does FDA have for requesting records and reports? Who is required to establish, maintain, and report required information relating to experiences with a new animal drug? Is information from foreign sources required?	514.80(a)(1).
What records must be established and maintained and what reports filed with FDA?	514.80(a)(2).
What is FDA's purpose for requiring reports?	514.80(a)(3).
Do applicants of Type A medicated articles have to establish, maintain, and report information required under § 514.80?	514.80(a)(4).