

Subpart D—Records and Reports**§510.300 Records and reports concerning experience with new animal drugs for which an approved application is in effect.**

(a) On receiving notification that an application submitted pursuant to §514.1 of this chapter for a new animal drug is approved, the applicant shall establish and maintain such records and make such reports as are specified in this section to facilitate a determination as to whether there may be grounds for suspending or withdrawing approval of the application or whether any applicable regulation should be amended or repealed. The applicant shall maintain adequately organized and indexed files containing full reports of information pertinent to the safety or effectiveness of the new animal drug that have not previously been submitted as part of his application for the drug and which are received or otherwise obtained by him from any source, as follows:

(1) Unpublished reports of clinical or other animal experience, studies, investigations, and tests conducted by the applicant or reported to him by any person involving the new animal drug that is the subject of the application or any related drugs. An adequate summary and bibliography of reports in the scientific literature would ordinarily suffice. (The application must identify at the time of each report submission, each drug he considers related to the subject drug.)

(2) Experience, investigations, studies, or tests involving the chemical or physical properties or any other properties of the new animal drug, such as its behavior or properties in relation to microorganisms, including both the effects of the drug on microorganisms and the effect of microorganisms on the drug.

(3) For information required by this section, adequate identification of its source, when known, including the name and post office address of the person who furnishes such information.

(4) Copies of all mailing pieces and other labeling, and, if it is a prescription new animal drug or a veterinary feed directive drug, all advertising other than that contained in the appli-

cation used in promoting the drug, and copies of the currently used package labeling that gives full information for use of the drug whether or not such labeling is contained in the application.

(5) Information concerning the quantity of the new animal drug distributed in a manner and form that facilitates estimates of the incidence of any adverse effects reported to be associated with the use of the drug. This does not require disclosure of financial, pricing, or sales data.

(6) Information concerning any previously unreported changes from the conditions described in an application conforming to the conditions of §514.8(a)(5) of this chapter.

(b) The applicant shall submit to the Food and Drug Administration copies of the records and reports described in paragraph (a) of this section, except routine assay and control records, appropriately identified with the new animal drug application(s) to which they relate, as follows:

(1) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(i) Information concerning a mixup in the new animal drug or its labeling with another article.

(ii) Information concerning any bacteriological or significant physical or other change or deterioration in the new animal drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(2) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records of reports concerning any information of the following kinds:

(i) Information concerning any unexpected side effects, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical use, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as

types of information that may be submitted at other designated intervals. *Unexpected* as used in this subdivision refers to conditions or developments not previously submitted as part of the new animal drug application, or conditions and developments occurring at a rate higher than that shown by information previously submitted as part of the application.

(ii) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activities.

(3) When mailing pieces, any other labeling, and advertising are devised for promotion of the new animal drug, specimens shall be submitted at the time of initial dissemination of such labeling and at the time of initial publication of any advertisement for a prescription drug. Mailing pieces and labeling designed to contain samples of a drug shall be complete except for the omission of the drug.

(4) All the kinds of information described in paragraph (a) of this section, other than that submitted under the provisions of paragraphs (b) (1), (2), and (3) of this section, shall be submitted as follows unless otherwise ordered in a written communication from the Commissioner:

(i) At intervals within 6 months beginning with the date of approval of the new animal drug application during the first year following such date, and at yearly intervals thereafter.

(ii) Whenever an applicant is required to submit reports under the provisions of paragraph (b)(4)(i) of this section with respect to more than one approved application for preparations containing the same new animal drug so that the same item(s) of information is (are) required to be reported for more than one application, he may elect to submit as a part of the report for one such application all the information common to such applications in lieu of reporting separately and repetitively on each. The applicant shall state when this is done and identify all the new animal drug applications for which the reports are submitted.

(iii) The submitted copies of records and reports shall include all the required information that was received

or otherwise obtained by the applicant during the designated intervals.

(5) On written order of the Commissioner, within the time stated in such order or agreed to by the applicant and the Commissioner, any designated records or reports containing the kinds of information described in this section shall be submitted.

(c) The applicant shall, upon request of any properly authorized officer or employee of the Department at reasonable times, permit such officers to have access to and copy and verify any records and reports established and maintained under the provisions of this section.

(d) If the Food and Drug Administration finds that the applicant has failed to establish a system for maintaining required records or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with the provisions of this section, or that the applicant has refused to permit access to or copying of, or verification of such records or reports, the Commissioner shall give the applicant notice and opportunity for a hearing on the question of whether to withdraw the approval of the application, as provided in § 514.200 of this chapter.

(e) Upon written request of the applicant stating reasonable grounds therefor, the Commissioner will make available any information in possession of the Food and Drug Administration of the kinds the applicant is required to maintain under the provisions of this section, except information readily available to the applicant from other sources or information which the Commissioner concludes is confidential.

(f) The *applicant* required to establish and maintain records and make reports required by this section includes any person whose name appears on the labeling of the drug as its manufacturer, packer, or distributor under an approval or who is engaged in the manufacturing, processing, packing, or labeling of the drug under an approval of the new animal drug application or any supplement to it; however, to avoid unnecessary duplication in the submission of reports, any such applicant's obligation to submit a report may be met by its submission on his behalf,

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designated as such, by another person responsible for reporting.

[40 FR 13807, Mar. 27, 1975, as amended at 65 FR 76928, Dec. 8, 2000]

EFFECTIVE DATE NOTE: At 68 FR 15364, Mar. 31, 2003, §510.300 was removed, effective June 30, 2003.

§510.301 Records and reports concerning experience with animal feeds bearing or containing new animal drugs for which an approved medicated feed mill license application is in effect.

Records and reports of clinical and other experience with the new animal drug will be maintained and reported, appropriately identified with the new animal drug application(s) to which they relate, to the Center for Veterinary Medicine in duplicate in accordance with the following:

(a) Immediately upon receipt by the applicant, complete records or reports covering information of the following kinds:

(1) Information concerning any mixup in the new animal drug or its labeling with another article.

(2) Information concerning any bacteriological, or any significant chemical, physical, or other change or deterioration in the drug, or any failure of one or more distributed batches of the drug to meet the specifications established for it in the new animal drug application.

(b) As soon as possible, and in any event within 15 working days of its receipt by the applicant, complete records or reports concerning any information of the following kinds:

(1) Information concerning any unexpected side effect, injury, toxicity, or sensitivity reaction or any unexpected incidence or severity thereof associated with clinical uses, studies, investigations, or tests, whether or not determined to be attributable to the new animal drug, except that this requirement shall not apply to the submission of information described in a written communication to the applicant from the Food and Drug Administration as types of information that may be submitted at other designated intervals. *Unexpected* as used in this paragraph refers to conditions or developments not previously submitted as part of the

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new animal drug application or not encountered during clinical trials of the drug, or conditions or developments occurring at a rate higher than shown by information previously submitted as part of the new animal drug application or at a rate higher than encountered during such clinical trials.

(2) Information concerning any unusual failure of the new animal drug to exhibit its expected pharmacological activity.

[40 FR 13807, Mar. 27, 1975, as amended at 54 FR 18280, Apr. 28, 1989]

§510.302 Reporting forms.

(a) The information described in §510.300, except that described in paragraphs (b) (1) and (2) of that section, shall be submitted appropriately identified with the new animal drug application(s) to which they relate in duplicate on Form FD-2301 “Transmittal of Periodic Reports and Promotional Material for New Animal Drugs.”

(b) All adverse experiences with new animal drugs as described in §510.300(b)(2) or §510.301(b) whether or not related to a required periodic report submitted on a Form FD-2301, shall be reported on Form FD-1932 “Adverse Drug Reaction” (except as provided in paragraph (c) of this section). Reports of adverse drug experiences may be submitted initially in the form of a written communication, but any such communication shall be followed promptly (but not necessarily within the prescribed 15 working days) by a completed Form FD-1932. A separate “Adverse Drug Reaction” form should be submitted for each patient where feasible.

(c) In lieu of Form FD-1932 the holder of an approved new animal drug application may submit:

(1) A computerized report if the information contained therein and the sequence in which it is presented are equivalent to that required by Form FD-1932 and the report is submitted in duplicate. Such reports will require initial approval by the Food and Drug Administration prior to use; and

(2) Copies of reports of reactions appearing in the published scientific literature may be submitted.