

## §514.11

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- (A) A completed Form FDA 356V;
- (B) A detailed description of the proposed change;
- (C) The drug(s) involved;
- (D) The data derived from studies in support of the change; and
- (E) Any other information as directed by FDA.

(3) *Labeling changes to be placed into effect prior to receipt of a written notice of approval of a supplemental application.*

(i) Labeling changes of the following kinds that increase the assurance of drug safety proposed in supplemental applications must be placed into effect immediately:

(A) The addition to package labeling, promotional labeling, or prescription drug advertising of additional warning, contraindication, adverse reaction, and precaution information;

(B) The deletion from package labeling, promotional labeling, or drug advertising of false, misleading, or unsupported intended uses or claims for effectiveness; and

(C) Any other changes as directed by FDA.

(ii) Labeling changes (for example, design and style) that do not decrease safety of drug use proposed in supplemental applications may be placed into effect prior to written notice of approval from FDA of a supplemental application.

(iii) A supplement submitted under paragraph (c)(3) of this section must include the following information:

(A) A full explanation of the basis for the changes, the date on which such changes are being effected, and plainly marked on the mailing cover and on the supplement, “Supplement—Labeling Changes Being Effected”;

(B) Two sets of printed copies of any revised labeling to be placed in use, identified with the new animal drug application number; and

(C) A statement by the applicant that all promotional labeling and all drug advertising will promptly be revised consistent with the changes made in the labeling on or within the new animal drug package no later than upon approval of the supplemental application.

(iv) If the supplemental application is not approved and the drug is being distributed with the proposed labeling,

FDA may initiate an enforcement action because the drug is misbranded under section 502 of the act and/or adulterated under section 501 of the act. In addition, under section 512(e) of the act, FDA may, after due notice and opportunity for a hearing, issue an order withdrawing approval of the application.

(4) *Changes providing for additional distributors to be reported under Records and reports concerning experience with approved new animal drugs (§514.80).* Supplemental applications as described under paragraph (c)(2) of this section will not be required for an additional distributor to distribute a drug that is the subject of an approved new animal drug application or abbreviated new animal drug application if the conditions described under §514.80(b)(5)(iii) are met.

(d) *Patent information.* The applicant must comply with the patent information requirements under section 512(c)(3) of the act.

(e) *Claimed exclusivity.* If an applicant claims exclusivity under section 512(c)(2)(F) of the act upon approval of a supplemental application for a change in its previously approved drug, the applicant must include such a statement.

(f) *Good laboratory practice for nonclinical laboratory studies.* A supplemental application that contains nonclinical laboratory studies must include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

[71 FR 74782, Dec. 13, 2006]

### **§514.11 Confidentiality of data and information in a new animal drug application file.**

(a) For purposes of this section the *NADA file* includes all data and information submitted with or incorporated by reference in the NADA, INAD's incorporated into the NADA, supplemental NADA's, reports under §§514.80 and 510.301 of this chapter, master files, and other related submissions. The availability for public disclosure of any

record in the NADA file shall be handled in accordance with the provisions of this section.

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before the application has been approved, unless it has been previously disclosed or acknowledged.

(c) If the existence of an NADA file has not been publicly disclosed or acknowledged, no data or information in the NADA file is available for public disclosure.

(d) If the existence of an NADA file has been publicly disclosed or acknowledged before the application has been approved, no data or information contained in the file is available for public disclosure, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, i.e., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an application has been approved, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information previously disclosed to the public, as defined in § 20.81 of this chapter.

(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the NADA file. Such summaries do not constitute the full reports of investigations under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)) on which the safety or effectiveness of the drug may be approved. Such summaries shall consist of the following:

(i) For an NADA approved prior to July 1, 1975, internal agency records that describe such data and information, e.g., a summary of basis for approval or internal reviews of the data and information, after deletion of:

(a) Names and any information that would identify the investigators.

(b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an NADA approved after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the application is approved.

(a) The Center for Veterinary Medicine may at an appropriate time prior to approval of the NADA require the applicant to prepare a summary of such data and information, which will be reviewed and, where appropriate, revised by the Center.

(b) The Center for Veterinary Medicine may prepare its own summary of such data and information.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 20.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 20.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 20.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of part 20 of this chapter.

(f) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time any one of the following events occurs unless extraordinary circumstances are known:

(1) The NADA has been abandoned and no further work is being undertaken with respect to it.

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(2) A final determination is made that the NADA is not approvable, and all legal appeals have been exhausted.

(3) Approval of the NADA is withdrawn, and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

(5) A final determination has been made that the animal drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NADA file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 20.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

[40 FR 13825, Mar. 27, 1975, as amended at 42 FR 3109, Jan. 14, 1977; 42 FR 15675, Mar. 22, 1977; 54 FR 18280, Apr. 28, 1989; 68 FR 15365, Mar. 31, 2003; 79 FR 14611, Mar. 17, 2014]

### **§ 514.12 Confidentiality of data and information in an investigational new animal drug notice.**

(a) The existence of an INAD notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

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(b) The availability for public disclosure of all data and information in an INAD file shall be handled in accordance with provisions established in § 514.11.

### **§ 514.15 Untrue statements in applications.**

Among the reasons why an application for a new animal drug or animal feed bearing or containing a new animal drug may contain an untrue statement of a material fact are:

(a) Differences in:

(1) Conditions of use prescribed, recommended, or suggested by the applicant for the product from the conditions of such use stated in the application;

(2) Articles used as components of the product from those listed in the application;

(3) Composition of the product from that stated in the application;

(4) Methods used in or the facilities and controls used for the manufacture, processing, or packing of the product from such methods, facilities, and controls described in the application;

(5) Labeling from the specimens contained in the application; or

(b) The unexplained omission in whole or in part from an application or from an amendment or supplement to an application or from any record or report required under the provisions of section 512 of the act and § 514.80 or § 510.301 of this chapter of any information obtained from:

(1) Investigations as to the safety, effectiveness, identity, strength, quality, or purity of the drug, made by the applicant on the drug, or

(2) Investigations or experience with the product that is the subject of the application, or any related product, available to the applicant from any source if such information is pertinent to an evaluation of the safety, effectiveness, identity, strength, quality, or purity of the drug, when such omission would bias an evaluation of the safety or effectiveness of the product.

(c) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, and the application fails to include a brief