§ 516.125 Investigational use of minor species new animal drugs to support indexing.

(a) The investigational use of a new animal drug or animal feed bearing or containing a new animal drug intended solely for investigational use in minor species shall meet the requirements of part 511 of this chapter if the investigational use is for the purpose of:

(1) Demonstrating human food safety under section 572(a)(1)(B) of the act;

(2) Demonstrating safety with respect to individuals exposed to the new animal drug through its manufacture and use under section 572(c)(1)(F) of the act;

(3) Conducting an environmental assessment under section 572(c)(1)(E) of the act; or

(4) Obtaining approval of a new animal drug application or abbreviated new animal drug application under section 512(b) of the act.

(b) Correspondence and information associated with investigations described in paragraph (a) of this section shall not be sent to the Director, OMUMS, but shall be submitted to FDA in accordance with the provisions of part 511 of this chapter.

(c) The investigational use of a new animal drug or animal feed bearing or containing a new animal drug intended solely for investigational use in minor species, other than for an investigational use described in paragraph (a) of this section, shall meet the requirements of this section. For such investigations, all provisions of part 511 of this chapter apply with the following modifications:

(1) Under §511.1(a)(1) of this chapter, the label statement is as follows:

"Caution. Contains a new animal drug for investigational use only in laboratory animals or for tests in vitro in support of index listing. Not for use in humans."

(2) Under §511.1(b)(1) of this chapter, the label statement is as follows:

"Caution. Contains a new animal drug for use only in investigational animals in clinical trials in support of index listing. Not for use in humans."
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§ 516.129 Content and format of a request for determination of eligibility for indexing.

(a) Each request for determination of eligibility:

(1) May involve only one drug (or one combination of drugs) in one dosage form;
(2) May not involve a new animal drug that is contained in or a product of a transgenic animal;
(3) May not involve the same drug in the same dosage form for the same intended use as a drug that is already approved or conditionally approved; and
(4) Must be submitted separately.

(b) A request for determination of eligibility for indexing may involve multiple intended uses and/or multiple minor species. However, if a request for determination of eligibility for indexing that contains multiple intended uses and/or multiple minor species cannot be granted in any part, the entire request will be denied.

(c) A requestor must submit two copies of a dated request signed by the authorized contact person for determination of eligibility for indexing that contains the following:

(1) Identification of the minor species or groups of minor species for which the new animal drug is intended;
(2) Information regarding drug components and composition;
(3) A statement of the intended use(s) of the new animal drug in the identified minor species or groups of minor species;
(4) A statement of the proposed conditions of use associated with the stated intended use(s) of the new animal drug, including the proposed dosage, route of administration, contraindications, warnings, and any other significant limitations associated with the intended use(s) of the new animal drug;
(5) A brief discussion of the need for the new animal drug for the intended use(s);
(6) An estimate of the anticipated annual distribution of the new animal drug, in terms of the total quantity of active ingredient, after indexing;
(7) Information to establish that the new animal drug is intended for use:

(i) In a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; or
(ii) In a hatchery, tank, pond, or other similar contained man-made structure in which includes on an