

## §516.131

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 early, non-food life stage of a food-producing minor species, and information to demonstrate food safety in accordance with the standards of section 512(d) of the act and §514.111 of this chapter (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance);

(8) A description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of the new animal drug sufficient to demonstrate that the requestor has established appropriate specifications for the manufacture and control of the new animal drug and that the requestor has an understanding of current good manufacturing practices;

(9) Either a claim for categorical exclusion under §25.30 or §25.33 of this chapter or an environmental assessment under §25.40 of this chapter;

(10) Information sufficient to support the conclusion that the new animal drug is safe under section 512(d) of the act with respect to individuals exposed to the new animal drug through its manufacture and use; and

(11) The name and address of the contact person or permanent-resident U.S. agent.

### **§516.131 Refuse to file a request for determination of eligibility for indexing.**

(a) If a request for determination of eligibility for indexing contains all of

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the information required by §516.129, FDA shall file it, and the filing date shall be the date FDA receives the request.

(b) If a request for a determination of eligibility lacks any of the information required by §516.129, FDA will not file it, but will inform the requestor in writing within 30 days of receiving the request as to what information is lacking.

### **§516.133 Denying a request for determination of eligibility for indexing.**

(a) FDA will deny a request for determination of eligibility for indexing if it determines upon the basis of the request evaluated together with any other information before it with respect to the new animal drug that:

(1) The same drug in the same dosage form for the same intended use is already approved or conditionally approved;

(2) There is insufficient information to demonstrate 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 early, non-food life stage of a food-producing minor species, and there is insufficient evidence to demonstrate safety for humans in accordance with the standard of section 512(d) of the act and §514.111 of this chapter (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance);

(3) The new animal drug is contained in or is a product of a transgenic animal;

(4) There is insufficient information to demonstrate that the requestor has established appropriate specifications for the manufacture and control of the new animal drug and that the requestor has an understanding of current good manufacturing practices;

(5) The requester fails to submit an adequate environmental assessment under §25.40 of this chapter or fails to