

§ 516.2 Purpose.

This part establishes standards and procedures for implementing section 573 of the act, including designation of minor use or minor species new animal drugs and associated exclusive marketing rights.

§ 516.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to those terms when used in this part.

(b) The following definitions of terms apply to all subparts of part 516:

Active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the pharmacological action of the drug substance.

Functionally superior means that a drug has been shown to provide a significant therapeutic or physiologic advantage over that provided by a conditionally-approved or approved MUMS drug, that is otherwise the same drug, in one or more of the following ways:

(i) The drug has been shown to be more effective, as assessed by effect on a clinically meaningful endpoint in adequate and well-controlled clinical trials, than a conditionally approved or approved MUMS drug, that is otherwise the same drug. Generally, this would represent the same kind of evidence needed to support a comparative effectiveness claim for two different drugs; in most cases, direct comparative clinical trials will be necessary; or

(ii) The drug has been shown to be safer than a conditionally-approved or approved MUMS drug, that is otherwise the same drug, in a substantial portion of the target population, for example, by the elimination of an ingredient or contaminant that is associated with relatively frequent adverse effects. In some cases, direct comparative clinical trials will be necessary.

Infrequently, as used in the minor use definition, means a disease or condition that is uncommon or that occurs only sporadically on an annualized basis.

Limited geographical areas, as used in the minor use definition, means regions of the United States distinguished by physical, chemical, or biological factors that limit the distribution of a disease or condition.

Major species means cattle, horses, swine, chickens, turkeys, dogs, and cats.

Minor species means animals, other than humans, that are not major species.

Minor use means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

MUMS drug means a new animal drug, as defined in section 201 of the act, intended for a minor use or for use in a minor species.

Same dosage form means the same as one of the dosage forms specified in the following parts of this chapter:

(i) Part 520: Oral dosage form new animal drugs (excluding use in animal feeds as specified in part 558 of this chapter).

(ii) Part 522: Implantation or injectable dosage form new animal drugs.

(iii) Part 524: Ophthalmic and topical dosage form new animal drugs.

(iv) Part 526: Intramammary dosage forms.

(v) Part 529: Certain other dosage form new animal drugs.

(vi) Part 558: New animal drugs for use in animal feeds.

Same drug means a MUMS drug for which designation, indexing, or conditional approval is sought that meets the following criteria:

(i) If it is a MUMS drug composed of small molecules and contains the same active moiety as a prior designated, conditionally-approved, or approved MUMS drug, even if the particular ester or salt (including a salt with hydrogen or coordination bonds) or other noncovalent derivative such as a complex, chelate or clathrate is not the same, it is considered the same drug; except that, if the prior MUMS drug is conditionally approved or approved and the second MUMS drug is shown to be functionally superior to the conditionally approved or approved MUMS

drug for the same intended use, it is not considered the same drug.

(ii) If it is a MUMS drug composed of large molecules (macromolecules) and contains the same principal molecular structural features (but not necessarily all of the same structural features) as a prior designated, conditionally approved, or approved MUMS drug, it is considered the same drug; except that, if the prior MUMS drug is conditionally approved or approved and the second MUMS drug is shown to be functionally superior to the conditionally approved or approved MUMS drug for the same intended use, it is not considered the same drug. This criterion will be applied as follows to different kinds of macromolecules:

(A) Two protein drugs would be considered the same if the only differences in structure between them were due to post-translational events or infidelity of translation or transcription or were minor differences in amino acid sequence; other potentially important differences, such as different glycosylation patterns or different tertiary structures, would not cause the drugs to be considered different unless the subsequent drug is shown to be functionally superior.

(B) Two polysaccharide drugs would be considered the same if they had identical saccharide repeating units, even if the number of units were to vary and even if there were postpolymerization modifications, unless the subsequent drug is shown to be functionally superior.

(C) Two polynucleotide drugs consisting of two or more distinct nucleotides would be considered the same if they had an identical sequence of purine and pyrimidine bases (or their derivatives) bound to an identical sugar backbone (ribose, deoxyribose, or modifications of these sugars), unless the subsequent drug is shown to be functionally superior.

(D) Closely related, complex partly definable drugs with similar pharmacologic intent would be considered the same unless the subsequent drug is shown to be functionally superior.

Same intended use means an intended use of a MUMS drug, for which designation, indexing, or conditional approval is sought, that is determined to be the

same as (or not different from) a previously designated, conditionally approved, or approved intended use of a MUMS drug. Same intended use is established by comparing two intended uses and not by simply comparing the specific language by means of which the intent is established in labeling in accordance with the following criteria:

(i) Two intended uses are considered the same if one of the intended uses falls completely within the scope of the other.

(ii) For intended uses associated with diseases or conditions with multiple causative organisms, two intended uses are not considered the same when they involve different causative organisms or different subsets of causative organisms of that disease or condition when the causative organisms involved can reliably be shown to be clinically significant causes of the disease or condition.

(iii) Two intended uses of a drug are not considered the same if they involve different intended species or different definable subpopulations (including "production classes") of a species.

Small number of animals means equal to or less than 50,000 horses; 70,000 dogs; 120,000 cats; 310,000 cattle; 1,450,000 pigs; 14,000,000 turkeys; and 72,000,000 chickens.

Sponsor means the person requesting designation for a MUMS drug who must be the real party in interest of the development and the intended or actual production and sales of such drug (in this context, the sponsor may be an individual, partnership, organization, or association). Sponsor also means the person responsible for an investigation of a new animal drug (in this context, the sponsor may be an individual, partnership, corporation, or Government agency or may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new animal drugs). Sponsor also means the person submitting or receiving approval for a new animal drug application (in this context, the sponsor may be an individual, partnership, organization, or association). In all contexts,

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the sponsor is responsible for compliance with applicable provisions of the act and regulations.

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Subpart B—Designation of a Minor Use or Minor Species New Animal Drug

§516.11 Scope of this subpart.

This subpart implements section 573 of the act. Specifically, this subpart sets forth the procedures and requirements for submissions to FDA of requests for designation of a new animal drug for a minor use or a minor species.

§516.12 Purpose.

This subpart establishes standards and procedures for determining eligibility for designation and the associated incentives and benefits described in section 573 of the act, including a 7-year period of exclusive marketing rights.

§516.13 Definitions.

The following definitions of terms apply only in the context of subpart B of this part:

Director means the Director of the Office of Minor Use and Minor Species Animal Drug Development of the FDA Center for Veterinary Medicine.

Intended use means the intended treatment, control or prevention of a disease or condition, or the intention to affect the structure or function of the body of animals within an identified species, subpopulation of a species, or collection of species.

MUMS-designated drug means a new animal drug, as defined in section 201 of the act, intended for a minor use or for use in a minor species that has been designated under section 573 of the act.

MUMS-drug exclusive marketing rights or *exclusive marketing rights* means that, effective on the date of FDA conditional approval or approval as stated in the approval letter of an application for a MUMS-designated drug, no conditional approval or approval will be given to a subsequent application for the same drug, in the same dosage form, for the same intended use for 7

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years, except as otherwise provided by law or in this subpart.

§516.14 Submission of requests for designation.

All correspondence relating to a request for designation of a MUMS drug must be addressed to the Director of the Office of Minor Use and Minor Species Animal Drug Development. Submissions not including all elements specified in §516.20 will be returned to the sponsor without review.

§516.16 Eligibility to request designation.

The person requesting designation must be the sponsor and the real party in interest of the development and the intended or actual production and sales of the drug or the permanent-resident U.S. agent for such a sponsor.

§516.20 Content and format of a request for MUMS-drug designation.

(a) A sponsor that submits a request for designation of a new animal drug intended for a minor use or minor species must submit each request in the form and containing the information required in paragraph (b) of this section. While a request for designation may involve multiple intended uses, each request for designation must constitute a separate submission. A sponsor may request MUMS-drug designation of a previously unapproved drug, or a new intended use or dosage form for an already conditionally approved or approved drug. Only one sponsor may receive MUMS-drug designation of the same drug, in the same dosage form, for the same intended use.

(b) A sponsor must submit two copies of a completed, dated, and signed request for designation that contains the following information:

(1) A request for designation of a new animal drug for a minor use or use in a minor species, which must be specific.

(2) The name and address of the sponsor; the name of the sponsor's primary contact person and/or permanent-resident U.S. agent including title, address, and telephone number; the generic and trade name, if any, of the drug; and the name and address of the source of the drug.