

Food and Drug Administration, HHS

§ 516.2

**PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES**

**Subpart A—General Provisions**

Sec.

- 516.1 Scope.
- 516.2 Purpose.
- 516.3 Definitions.

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

- 516.11 Scope of this subpart.
- 516.12 Purpose.
- 516.13 Definitions.
- 516.14 Submission of requests for designation.
- 516.16 Eligibility to request designation.
- 516.20 Content and format of a request for MUMS-drug designation.
- 516.21 Documentation of minor use status.
- 516.22 Permanent-resident U.S. agent for foreign sponsor.
- 516.23 Timing of requests for MUMS-drug designation.
- 516.24 Granting MUMS-drug designation.
- 516.25 Refusal to grant MUMS-drug designation.
- 516.26 Amendment to MUMS-drug designation.
- 516.27 Change in sponsorship.
- 516.28 Publication of MUMS-drug designations.
- 516.29 Termination of MUMS-drug designation.
- 516.30 Annual reports for a MUMS-designated drug.
- 516.31 Scope of MUMS-drug exclusive marketing rights.
- 516.34 FDA recognition of exclusive marketing rights.
- 516.36 Insufficient quantities of MUMS-designated drugs.
- 516.52 Availability for public disclosure of data and information in requests.

**Subpart C—Index of Legally Marketed Unapproved New Animal Drugs for Minor Species**

- 516.111 Scope of this subpart.
- 516.115 Definitions.
- 516.117 Submission of correspondence under this subpart.
- 516.119 Permanent-resident U.S. agent for foreign requestors and holders.
- 516.121 Meetings.
- 516.123 Informal conferences regarding agency administrative actions.
- 516.125 Investigational use of minor species new animal drugs to support indexing.
- 516.129 Content and format of a request for determination of eligibility for indexing.

- 516.131 Refuse to file a request for determination of eligibility for indexing.
- 516.133 Denying a request for determination of eligibility for indexing.
- 516.135 Granting a request for determination of eligibility for indexing.
- 516.137 Notification of decision regarding eligibility for indexing.
- 516.141 Qualified expert panels.
- 516.143 Written report.
- 516.145 Content and format of a request for addition to the index.
- 516.147 Refuse to file a request for addition to the index.
- 516.149 Denying a request for addition to the index.
- 516.151 Granting a request for addition to the index.
- 516.153 Notification of decision regarding index listing.
- 516.155 Labeling of indexed drugs.
- 516.157 Publication of the index and content of an index listing.
- 516.161 Modifications to indexed drugs.
- 516.163 Change in ownership of an index file.
- 516.165 Records and reports.
- 516.167 Removal from the index.
- 516.171 Confidentiality of data and information in an index file.

**Subpart D [Reserved]**

**Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species**

- 516.1215 Florfenicol.
- 516.1318 xMasitinib.

AUTHORITY: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

SOURCE: 72 FR 41017, July 26, 2007, unless otherwise noted.

**Subpart A—General Provisions**

**§ 516.1 Scope.**

- (a) This part implements section 573 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2) and contains the following subparts:
  - (1) Subpart A—General Provisions.
  - (2) Subpart B—Designation of a Minor Use or Minor Species New Animal Drug.
  - (3) Subpart C [Reserved]
  - (4) Subpart D [Reserved]
- (b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

**§ 516.2 Purpose.**

This part establishes standards and procedures for implementing section

### §516.3

### 21 CFR Ch. I (4–1–11 Edition)

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 distin-

guished 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 form categories 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.