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 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.