

§516.36 Insufficient quantities of MUMS-designated drugs.

(a) Under section 573 of the act, whenever FDA has reason to believe that sufficient quantities of a conditionally-approved or approved, MUMS-designated drug to meet the needs for which the drug was designated cannot be assured by the sponsor, FDA will so notify the sponsor of this possible insufficiency and will offer the sponsor the following options, one of which must be exercised by a time that FDA specifies:

(1) Provide FDA information and data regarding how the sponsor can assure the availability of sufficient quantities of the MUMS-designated drug within a reasonable time to meet the needs for which the drug was designated; or

(2) Provide FDA in writing the sponsor's consent for the conditional approval or approval of other applications for the same drug before the expiration of the 7-year period of exclusive marketing rights.

(b) If, within the time that FDA specifies, the sponsor fails to consent to the conditional approval or approval of other applications and if FDA finds that the sponsor has not shown that it can assure the availability of sufficient quantities of the MUMS-designated drug to meet the needs for which the drug was designated, FDA will issue a written order terminating designation of the MUMS drug and the associated exclusive marketing rights. This order will state FDA's findings and conclusions and will constitute final agency action. An order terminating designation and associated exclusive marketing rights may issue whether or not there are other sponsors that can assure the availability of alternative sources of supply. Such an order will not withdraw the conditional approval or approval of an application. Once terminated under this section, neither designation, nor exclusive marketing rights may be reinstated.

§516.52 Availability for public disclosure of data and information in requests.

(a) FDA will not publicly disclose the existence of a request for MUMS-drug designation under section 573 of the act

prior to final FDA action on the request unless the existence of the request has been previously publicly disclosed or acknowledged.

(b) Whether or not the existence of a pending request for designation has been publicly disclosed or acknowledged, no data or information in the request are available for public disclosure prior to final FDA action on the request.

(c) Except as provided in paragraph (d) of this section, upon final FDA action on a request for designation, the public availability of data and information in the request will be determined in accordance with part 20 of this chapter and other applicable statutes and regulations.

(d) In accordance with §516.28, FDA will make a cumulative list of all MUMS-drug designations available to the public and update such list periodically. In accordance with §516.29, FDA will give public notice of the termination of all MUMS-drug designations.

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

SOURCE: 72 FR 69121, Dec. 6, 2007, unless otherwise noted.

§516.111 Scope of this subpart.

This subpart implements section 572 of the act and provides standards and procedures to establish an index of legally marketed unapproved new animal drugs. This subpart applies only to minor species and not to minor use in major species. This index is only available for new animal drugs intended for use 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 and for new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, nonfood life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) of the act (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance). The index shall not include a new animal drug that is