

§ 516.30

of animals to which the drug could potentially be administered on an annual basis for the treatment, control, or prevention of the disease or condition for which the drug is being developed, including animals administered the drug as part of herd or flock treatment, subsequently increases.

(i) When a MUMS-drug designation is terminated, FDA will notify the sponsor in writing and will give public notice of the termination of the MUMS-drug designation.

§ 516.30 Annual reports for a MUMS-designated drug.

Within 14 months after the date on which a MUMS drug is granted designation and annually thereafter until approval, the sponsor of a MUMS-designated drug shall submit a brief progress report on the drug to the investigational new animal drug file addressed to the Director of the Office of Minor Use and Minor Species Animal Drug Development that includes the following information:

(a) A short account of the progress of drug development including a description of studies initiated, ongoing, and completed, and a short summary of the status or results of such studies;

(b) A description of the investigational plan for the coming year, as well as any anticipated difficulties in development, testing, and marketing; and

(c) A brief discussion of any changes that may affect the MUMS-designated drug status of the product. For example, situations in which testing data demonstrate that the proposed intended use is inappropriate due to unexpected issues of safety or effectiveness.

§ 516.31 Scope of MUMS-drug exclusive marketing rights.

(a) After conditional approval or approval of an application for a MUMS-designated drug in the dosage form and for the intended use for which MUMS-drug designation has been granted, FDA will not conditionally approve or approve another application or abbreviated application for the same drug in the same dosage form for the same intended use before the expiration of 7 years after the date of conditional approval or approval as stated in the ap-

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proval letter from FDA, except that such an application can be conditionally approved or approved sooner if, and at such time as, any of the following occurs:

(1) FDA terminates the MUMS-drug designation and associated exclusive marketing rights under § 516.29; or

(2) FDA withdraws the conditional approval or approval of the application for the drug for any reason; or

(3) The sponsor with exclusive marketing rights provides written consent to FDA to conditionally approve or approve another application before the expiration of 7 years; or

(4) The sponsor fails to assure a sufficient quantity of the drug in accordance with section 573 of the act and § 516.36.

(b) If an application for a MUMS drug cannot be approved until the expiration of the period of exclusive marketing of a MUMS-designated drug, FDA will so notify the sponsor in writing.

§ 516.34 FDA recognition of exclusive marketing rights.

(a) FDA will send the sponsor (or the permanent-resident U.S. agent, if applicable) timely written notice recognizing exclusive marketing rights when an application for a MUMS-designated drug has been conditionally approved or approved. The written notice will inform the sponsor of the requirements for maintaining MUMS-designated drug exclusive marketing rights for the full 7-year term. This notice will generally be contained in the letter conditionally approving or approving the application.

(b) When an application is conditionally approved or approved for a MUMS-designated drug that qualifies for exclusive marketing rights, FDA will publish this information in the FEDERAL REGISTER at the time of the conditional approval or approval. This notice will generally be contained in the notice of conditional approval or approval of the application.

§ 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 contained in, or a product of, a transgenic animal. Among its topics, this subpart sets forth the standards and procedures for: