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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:

(a) Investigational exemptions for indexing purposes;

(b) Submissions to FDA of requests for determination of eligibility of a new animal drug for indexing;

(c) Establishment and operation of expert panels;

(d) Submissions to FDA of requests for addition of a new animal drug to the index;

(e) Modifications to index listings;

(f) Publication of the index; and

(g) Records and reports.

§ 516.115 Definitions.

(a) The following definitions of terms apply only in the context of subpart C of this part:

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

Holder means the requestor of an index listing after the request is granted and the new animal drug is added to the index.

Index means FDA's list of legally marketed unapproved new animal drugs for minor species.

Intended use has the same meaning as that given in § 516.13 of this chapter.

Qualified expert panel means a panel that is composed of experts qualified by scientific training and experience to evaluate the target animal safety and effectiveness of a new animal drug under consideration for indexing.

Requestor means the person making a request for determination of eligibility for indexing or a request for addition to the index.

Transgenic animal means an animal whose genome contains a nucleotide sequence that has been intentionally modified in vitro, and the progeny of such an animal, provided that the term 'transgenic animal' does not include an animal of which the nucleotide sequence of the genome has been modified solely by selective breeding.

(b) The definitions of the following terms are given in § 514.3 of this chapter:

Adverse drug experience.

Product defect/manufacturing defect.

Serious adverse drug experience.

Unexpected adverse drug experience.

(c) The definitions of the following terms are given in § 516.3 of this chapter:

Same dosage form.

Same drug.

Same intended use.

§ 516.117 Submission of correspondence under this subpart.

Unless directed otherwise by FDA, all correspondence relating to any aspect of the new animal drug indexing process described in this subpart must be addressed to the Director, OMUMS. The initial correspondence for a particular index listing should include the name and address of the authorized contact person. Notifications of changes in such person or changes of address of such person should be provided in a timely manner.

§ 516.119 Permanent-resident U.S. agent for foreign requestors and holders.

Every foreign requestor and holder shall name a permanent resident of the United States as their agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the requestor or holder. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent resident U.S. agent may be an individual, firm, or domestic corporation and may represent any number of requestors or holders. The name and address of the permanent-resident U.S. agent shall be submitted to the Director, OMUMS, and included in the index file.

§ 516.121 Meetings.

(a) A requestor or potential requestor is entitled to one or more meetings to discuss the requirements for indexing a new animal drug.

(b) Requests for such meetings should be in writing, be addressed to the Director, OMUMS, specify the participants attending on behalf of the requestor or potential requestor, and contain a proposed agenda for the meeting.