

§ 516.24

§ 516.24 Granting MUMS-drug designation.

(a) FDA may grant the request for MUMS-drug designation if none of the reasons described in § 516.25 for refusal to grant such a request apply.

(b) When a request for MUMS-drug designation is granted, FDA will notify the sponsor in writing and will give public notice of the MUMS-drug designation in accordance with § 516.28.

§ 516.25 Refusal to grant MUMS-drug designation.

(a) FDA will refuse to grant a request for MUMS-drug designation if any of the following reasons apply:

(1) The drug is not intended for use in a minor species or FDA determines that there is insufficient evidence to demonstrate that the drug is intended for a minor use in a major species.

(2) The drug is the same drug in the same dosage form for the same intended use as one that already has a MUMS-drug designation but has not yet been conditionally approved or approved.

(3) The drug is the same drug in the same dosage form for the same intended use as one that is already conditionally approved or approved. A drug that FDA has found to be functionally superior is not considered the same drug as an already conditionally approved or approved drug even if it is otherwise the same drug in the same dosage form for the same intended use.

(4) The sponsor has failed to provide:

(i) A credible scientific rationale in support of the intended use,

(ii) Sufficient information about the product development plan for the drug, its dosage form, and its intended use to establish that adherence to the plan can lead to successful drug development in a timely manner, and

(iii) Any other information required under § 516.20.

(b) FDA may refuse to grant a request for MUMS-drug designation if the request for designation contains an untrue statement of material fact or omits material information.

§ 516.26 Amendment to MUMS-drug designation.

(a) At any time prior to conditional approval or approval of an application

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for a MUMS-designated drug, the sponsor may apply for an amendment to the designated intended use if the proposed change is due to new and unexpected findings in research on the drug, information arising from FDA recommendations, or other unforeseen developments.

(b) FDA will grant the amendment if it finds:

(1) That the initial designation request was made in good faith;

(2) That the amendment is intended to make the MUMS-drug designated intended use conform to the results of new and unexpected findings in research on the drug, information arising from FDA recommendations, or other unforeseen developments; and

(3) In the case of a minor use, that as of the date of the submission of the amendment request, the amendment would not result in the intended use of the drug no longer being considered a minor use.

§ 516.27 Change in sponsorship.

(a) A sponsor may transfer sponsorship of a MUMS-designated drug to another person. A change of sponsorship will also transfer the designation status of the drug which will remain in effect for the new sponsor subject to the same conditions applicable to the former sponsor provided that at the time of a potential transfer, the new and former sponsors submit the following information in writing and obtain permission from FDA:

(1) The former sponsor shall submit a letter to FDA that documents the transfer of sponsorship of the MUMS-designated drug. This letter shall specify the date of the transfer. The former sponsor shall also certify in writing to FDA that a complete copy of the request for MUMS-drug designation, including any amendments to the request, and correspondence relevant to the MUMS-drug designation, has been provided to the new sponsor.

(2) The new sponsor shall submit a letter or other document containing the following information:

(i) A statement accepting the MUMS-drug designated file or application;

(ii) The date that the change in sponsorship is intended to be effective;

(iii) A statement that the new sponsor has a complete copy of the request for MUMS-drug designation, including any amendments to the request and any correspondence relevant to the MUMS-drug designation;

(iv) A statement that the new sponsor understands and accepts the responsibilities of a sponsor of a MUMS-designated drug established elsewhere in this subpart;

(v) The name and address of a new primary contact person or permanent resident U.S. agent; and

(vi) Evidence that the new sponsor is capable of actively pursuing approval with due diligence.

(b) No sponsor may relieve itself of responsibilities under the act or under this subpart by assigning rights to another person without:

(1) Assuring that the new sponsor will carry out such responsibilities; and

(2) Obtaining prior permission from FDA.

§ 516.28 Publication of MUMS-drug designations.

FDA will periodically update a publicly available list of MUMS-designated drugs. This list will be placed on file at the FDA Division of Dockets Management, and will contain the following information for each MUMS-designated drug:

(a) The name and address of the sponsor;

(b) The established name and trade name, if any, of the drug;

(c) The dosage form of the drug;

(d) The species and the proposed intended use for which MUMS-drug designation was granted; and

(e) The date designation was granted.

§ 516.29 Termination of MUMS-drug designation.

(a) The sponsor of a MUMS-designated drug must notify FDA of any decision to discontinue active pursuit of conditional approval or approval of such MUMS drug. FDA must terminate the designation upon such notification.

(b) A conditionally-approved or approved MUMS-designated drug sponsor must notify FDA at least 1 year before it intends to discontinue the manufacture of such MUMS drug. FDA must

terminate designation upon such notification.

(c) MUMS designation shall terminate upon the expiration of any applicable period of exclusive marketing rights under this subpart.

(d) FDA may terminate designation if it independently determines that the sponsor is not actively pursuing conditional approval or approval with due diligence. At a minimum, due diligence must be demonstrated by:

(1) Submission of annual progress reports in a timely manner in accordance with § 516.30 that demonstrate that the sponsor is progressing in accordance with the drug development plan submitted to the agency under § 516.20 and

(2) Compliance with all applicable requirements of part 511 of this chapter.

(e) Designation of a conditionally approved or approved MUMS-designated drug and the associated exclusive marketing rights may be terminated if the sponsor is unable to provide sufficient quantities of the drug to meet the needs for which it is designated.

(f) FDA may also terminate MUMS-drug designation for any drug if the agency finds that:

(1) The request for designation contained an untrue statement of material fact; or

(2) The request for designation omitted material information required by this subpart; or

(3) FDA subsequently finds that the drug in fact had not been eligible for MUMS-drug designation at the time of submission of the request;

(4) The same drug, in the same dosage form, for the same intended use becomes conditionally approved or approved for another sponsor; or

(5) FDA withdraws the conditional approval or approval of the application for the new animal drug.

(g) For a conditionally approved or approved drug, termination of MUMS-drug designation also terminates the sponsor's exclusive marketing rights for the drug but does not withdraw the conditional approval or approval of the drug's application.

(h) Where a drug has been MUMS-designated for a minor use in a major species, its designation will not be terminated on the grounds that the number