

index, the benefits of using the new animal drug for the indexed use do not outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question;

(4) Any of the conditions in §516.133(a)(2), (5), or (6) are present;

(5) The manufacture of the new animal drug is not in accordance with current good manufacturing practices;

(6) The labeling, distribution, or promotion of the new animal drug is not in accordance with the index listing;

(7) The conditions and limitations of use associated with the index listing have not been followed; or

(8) Any information used to support the request for addition to the index contains any untrue statement of material fact.

(b) The agency may partially remove an indexing listing if, in the opinion of the agency, such partial removal would satisfactorily resolve a safety or effectiveness issue otherwise warranting removal of the listing under section 572(f)(1)(B) of the act.

(c) FDA may immediately suspend a new animal drug from the index if FDA determines that there is a reasonable probability that the use of the drug would present a risk to the health of humans or other animals. The agency will subsequently provide due notice and an opportunity for an informal conference as described in §516.123.

(d) A decision of FDA to remove a new animal drug from the index following an informal conference, if any, shall constitute final agency action subject to judicial review.

§516.171 Confidentiality of data and information in an index file.

(a) For purposes of this section, the index file includes all data and information submitted to or incorporated by reference into the index file, such as data and information related to investigational use exemptions under §516.125, requests for determination of eligibility for indexing, requests for addition to the index, modifications to indexed drugs, changes in ownership, reports submitted under §516.165, and master files. The availability for public disclosure of any record in the index

file shall be handled in accordance with the provisions of this section.

(b) The existence of an index file will not be disclosed by FDA before an index listing has been made public by FDA, unless it has previously been publicly disclosed or acknowledged by the requestor.

(c) If the existence of an index file has not been publicly disclosed or acknowledged, no data or information in the index file are available for public disclosure.

(d) If the existence of an index file has been publicly disclosed or acknowledged before an index listing has been made public by FDA, no data or information contained in the file will be available for public disclosure before such index listing is made public, but the agency may, at its discretion, disclose a brief summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After FDA sends a written notice to the requestor granting a request for addition to the index, the following data and information in the index file are available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information previously disclosed to the public, as defined in §20.81 of this chapter.

(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the index file. Such summaries do not constitute the full information described under section 572(c) and (d) of the act on which the safety or effectiveness of the drug may be determined. Such summaries will be based on the draft Freedom of Information summary submitted under §516.145, which will be reviewed and, where appropriate, revised by FDA.

(3) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in §20.61 of this chapter.

(4) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of the following:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a veterinarian.

(5) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in §20.81 of this chapter.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in §20.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the index file, in accordance with the provisions of part 20 of this chapter.

(f) The following data and information in an index file are not available for public disclosure unless they have been previously disclosed to the public as defined in §20.81 of this chapter, or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in §20.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(g) Subject to the disclosure provisions of this section, the agency shall regard the contents of an index file as confidential information unless specifically notified in writing by the holder of the right to disclose, to reference, or otherwise utilize such information on behalf of another named person.

(h) For purposes of this regulation, safety and effectiveness data include all studies and tests of an animal drug on animals and all studies and tests on the animal drug for identity, stability, purity, potency, and bioavailability.

(i) Safety and effectiveness data and information that have not been previously disclosed to the public are available for public disclosure at the time any of the following events occurs unless extraordinary circumstances are shown:

(1) No work is being or will be undertaken to have the drug indexed in accordance with the request.

(2) A final determination is made that the drug cannot be indexed and all legal appeals have been exhausted.

(3) The drug has been removed from the index and all legal appeals have been exhausted.

(4) A final determination has been made that the animal drug is not a new animal drug.

Subpart D [Reserved]

Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species

SOURCE: 72 FR 57200, Oct. 9, 2007, unless otherwise noted.

§516.1318 Masitinib.

(a) *Specifications.* Each tablet contains 50 or 150 milligrams (mg) masitinib mesylate.

(b) *Sponsor.* See No. 052913 in §510.600(c) of this chapter.

(c) *Conditions of use in dogs* (1) *Amount.* 12.5 mg/kilograms (5.7 mg/lb) of body weight daily.

(2) *Indications for use.* For the treatment of nonresectable Grade II or III cutaneous mast cell tumors in dogs that have not previously received radiotherapy and/or chemotherapy except corticosteroids.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

[76 FR 6327, Feb. 4, 2011, as amended at 77 FR 35837, June 15, 2012]