

changed since the last report, include a statement of such fact.

(iii) A summary of any changes made during the reporting period in the methods used in, and facilities and controls used for, manufacture, processing, and packing. This information must be presented in the same level of detail that it was presented in the request for determination of eligibility for indexing. Do not include changes that have already been submitted under §516.161.

(iv) Nonclinical laboratory studies and clinical data not previously reported under this section.

(v) Adverse drug experiences not previously reported under this section.

(vi) Any other information pertinent to safety or effectiveness of the indexed drug not previously reported under this section.

(4) *Distributor's statement.* At the time of initial distribution of an indexed drug by a distributor, the holder must submit a report containing the following:

(i) The distributor's current product labeling. This must be identical to that in the index listing except for a different and suitable proprietary name (if used) and the name and address of the distributor. The name and address of the distributor must be preceded by an appropriate qualifying phrase such as "manufactured for" or "distributed by."

(ii) A signed statement by the distributor stating:

(A) The category of the distributor's operations (e.g., wholesale or retail);

(B) That the distributor will distribute the drug only under the indexed drug labeling;

(C) That the distributor will promote the indexed drug only for use under the conditions stated in the index listing; and

(D) If the indexed drug is a prescription new animal drug, that the distributor is regularly and lawfully engaged in the distribution or dispensing of prescription products.

(5) *Other reporting.* FDA may by order require that a holder submit information in addition to that required by this section or that the holder submit the same information but at different times or reporting periods.

#### § 516.167 Removal from the index.

(a) After due notice to the holder of the index listing and an opportunity for an informal conference as described in §516.123, FDA shall remove a new animal drug from the index if FDA finds that:

(1) The same drug in the same dosage form for the same intended use has been approved or conditionally approved;

(2) The expert panel failed to meet the requirements in §516.141;

(3) On the basis of new information before FDA, evaluated together with the evidence available to FDA when the new animal drug was listed in the 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.