§ 516.165 Records and reports.

(a) *Scope and purpose.* (1) The recordkeeping and reporting requirements of this section apply to all holders of indexed drugs, including indexed drugs intended for use in medicated feeds.

(2) A holder is not required to report information under this section if the holder has reported the same information under § 514.80 of this chapter.

(3) The records and reports referred to in this section are in addition to those required by the current good manufacturing practice regulations in parts 211, 225, and 226 of this chapter.

(4) FDA will review the records and reports required in this section to determine, or facilitate a determination, whether there may be grounds for removing a drug from the index under section 572(f) of the act.

(b) *Recordkeeping requirements.* (1) Each holder of an indexed drug must establish and maintain complete files containing full records of all information pertinent to the safety or effectiveness of the indexed drug. Such records must include information from foreign and domestic sources.

(2) The holder must, upon request from any authorized FDA officer or employee, at all reasonable times, permit such officer or employee to have access to copy and to verify all such records.

(c) *Reporting requirements.* (1) *Three-day indexed drug field alert report.* The holder must inform the appropriate FDA District Office or local FDA resident post of any product or manufacturing defects that may result in serious adverse drug events within 3 working days of first becoming aware that such a defect may exist. The holder may initially provide this information by telephone or other electronic communication means, with prompt written followup. The mailing cover must be plainly marked "3–Day Indexed Drug Field Alert Report."

(2) *Fifteen-day indexed drug alert report.* The holder must submit a report on each serious, unexpected adverse drug event, regardless of the source of the information. The holder must submit the report within 15 working days of first receiving the information. The mailing cover must be plainly marked "15–Day Indexed Drug Alert Report."

(3) *Annual indexed drug experience report.* The holder must submit this report every year on the anniversary date of the letter granting the request for addition of the new animal drug to the index, or within 60 days thereafter. The report must contain data and information for the full reporting period. Any previously submitted information contained in the report must be identified as such. The holder may ask FDA to change the date of submission and, after approval of such request, file such reports by the new filing date. The report must contain the following:

(i) The number of distributed units of each size, strength, or potency (e.g., 100,000 bottles of 100 5-milligram tablets; 50,000 10-milliliter vials of 5- percent solution) distributed during the reporting period. This information must be presented in two categories: Quantities distributed domestically and quantities exported. This information must include any distributor-labeled product.

(ii) If the labeling has changed since the last report, include a summary of those changes and the holder's and distributor's current package labeling, including any package inserts. For large-size package labeling or large shipping cartons, submit a representative copy (e.g., a photocopy of pertinent areas of large feed bags). If the labeling has not 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