(e) Be signed, or otherwise approved in writing, by all panel members, in accordance with §516.141; and

(f) If the panel unanimously concludes that the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm being caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question, the written report shall:

(1) Provide draft labeling that includes all conditions of use and limitations of use of the new animal drug deemed necessary by the panel to assure that the benefits of use of the new animal drug outweigh the risks, or provide narrative information from which such labeling can be written by the requestor; and

(2) Include a recommendation regarding whether the new animal drug should be limited to use under the professional supervision of a licensed veterinarian.

§516.145 Content and format of a request for addition to the index.

(a) A requestor may request addition of a new animal drug to the index only after the new animal drug has been granted eligibility for indexing.

(b) A requestor shall submit two copies of a dated request signed by the authorized contact for addition of a new animal drug to the index that contains the following:

(1) A copy of FDA's determination of eligibility issued under §516.137;

(2) A copy of FDA's written determination that the proposed qualified expert panel meets the selection criteria provided for in §516.141(b);

(3) A written report that meets the requirements of §516.143;

(4) A proposed index entry that contains the information described in §516.157;

(5) Proposed labeling, including representative labeling proposed to be used for Type B and Type C medicated feeds if the drug is intended for use in the manufacture of medicated feeds;

(6) Anticipated annual distribution of the new animal drug, in terms of the total quantity of active ingredient, after indexing;

(7) A written commitment to manufacture the new animal drug and animal feeds bearing or containing such new animal drug according to current good manufacturing practices;

(8) A written commitment to label, distribute, and promote the new animal drug only in accordance with the index entry;

(9) The name and address of the contact person or permanent-resident U.S. agent; and

(10) A draft Freedom of Information summary which includes the following information:

(i) A general information section that contains the name and address of the requestor and a description of the drug, route of administration, indications, and recommended dosage.

(ii) A list of the names and affiliations of the members of the qualified expert panel, not including their addresses or other contact information.

(iii) A summary of the findings of the qualified expert panel concerning the target animal safety and effectiveness of the drug.

(iv) Citations of all publicly-available literature considered by the qualified expert panel.

(v) For an early life stage of a food-producing minor species animal, a human food safety summary.

(c) Upon specific request by FDA, the requestor shall submit the information described in §516.141 that it submitted to the qualified expert panel. Any such information not in English should be accompanied by an English translation.

§516.147 Refuse to file a request for addition to the index.

(a) If a request for addition to the index contains all of the information required by §516.145(b), FDA shall file it, and the filing date shall be the date FDA receives the request.

(b) If a request for addition to the index lacks any of the information required by §516.145, FDA will not file it, but will inform the requestor in writing within 30 days of receiving the request as to what information is lacking.