

**§ 516.133 Denying a request for determination of eligibility for indexing.**

(a) FDA will deny a request for determination of eligibility for indexing if it determines upon the basis of the request evaluated together with any other information before it with respect to the new animal drug that:

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

(2) There is insufficient information to demonstrate that the new animal drug is intended for use:

(i) In a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals, or

(ii) In a hatchery, tank, pond, or other similar contained man-made structure in (which includes on) an early, non-food life stage of a food-producing minor species, and there is insufficient evidence to demonstrate safety for humans in accordance with the standard of section 512(d) of the act and § 514.111 of this chapter (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance);

(3) The new animal drug is contained in or is a product of a transgenic animal;

(4) There is insufficient information to demonstrate that the requestor has established appropriate specifications for the manufacture and control of the new animal drug and that the requestor has an understanding of current good manufacturing practices;

(5) The requester fails to submit an adequate environmental assessment under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.33 of this chapter;

(6) There is insufficient information to determine that the new animal drug is safe with respect to individuals exposed to the new animal drug through its manufacture or use; or

(7) The request for determination of eligibility for indexing fails to contain any other information required under the provisions of § 516.129.

(b) FDA may deny a request for determination of eligibility for indexing if it contains any untrue statement of a material fact or omits material information.

(c) When a request for determination of eligibility for indexing is denied, FDA will notify the requestor in accordance with § 516.137.

**§ 516.135 Granting a request for determination of eligibility for indexing.**

(a) FDA will grant the request for determination of eligibility for indexing if none of the reasons described in § 516.133 for denying such a request applies.

(b) When a request for determination of eligibility for indexing is granted, FDA will notify the requestor in accordance with § 516.137.

**§ 516.137 Notification of decision regarding eligibility for indexing.**

(a) Within 90 days after the filing of a request for a determination of eligibility for indexing based on § 516.129(c)(7)(i), or 180 days for a request based on § 516.129(c)(7)(ii), FDA shall grant or deny the request, and notify the requestor of FDA's decision in writing.

(b) If FDA denies the request, FDA shall provide due notice and an opportunity for an informal conference as described in § 516.123 regarding its decision. A decision of FDA to deny a request for determination of eligibility for indexing following an informal conference shall constitute final agency action subject to judicial review.

**§ 516.141 Qualified expert panels.**

(a) *Establishment of a qualified expert panel.* Establishing a qualified expert panel is the first step in the process of requesting the addition of a new animal drug to the index. A qualified expert panel may not be established until FDA has determined that the new animal drug is eligible for indexing. The requestor must choose members for the qualified expert panel in accordance with selection criteria listed in paragraph (b) of this section and submit information about these proposed members to FDA. FDA must determine whether the proposed qualified expert panel meets the selection criteria prior

to the panel beginning its work. Qualified expert panels operate external to FDA and are not subject to the Federal Advisory Committee Act, as amended, 5 U.S.C. App.

(b) *Criteria for the selection of a qualified expert panel.* (1) A qualified expert panel member must be an expert qualified by training and experience to evaluate a significant aspect of target animal safety or effectiveness of the new animal drug under consideration.

(2) A qualified expert panel member must certify that he or she has a working knowledge of section 572 of the act (the indexing provisions of the statute) and this subpart, and that he or she has also read and understood a clear written statement provided by the requestor stating his or her duties and responsibilities with respect to reviewing the new animal drug proposed for addition to the index.

(3) A qualified expert panel member may not be an FDA employee.

(4) A qualified expert panel must have at least three members.

(5) A qualified expert panel must have members with a range of expertise such that the panel, as a whole, is qualified by training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration.

(6) Unless FDA makes a determination to allow participation notwithstanding an otherwise disqualifying financial interest, a qualified expert panel member must not have a conflict of interest or the appearance of a conflict of interest, as described in paragraph (g) of this section.

(c) *Requestor responsibilities.* (1) The requestor must:

(i) Choose members for the qualified expert panel in accordance with selection criteria listed in paragraph (b) of this section.

(ii) Provide each potential expert panel member a copy of section 572 of the act (the indexing provisions of the statute) and this subpart and obtain certification that he or she has a working knowledge of the information.

(iii) Provide each potential expert panel member a written statement describing the purpose and scope of his or her participation on the qualified expert panel and obtain certification that

he or she has read and understood the information. The written statement should describe the duties and responsibilities of qualified expert panels and their members established by paragraphs (e) and (f) of this section, including the need to prepare a written report under §516.143.

(iv) Obtain information from each potential expert panel member demonstrating that he or she is qualified by training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration. This information can be obtained from a comprehensive curriculum vitae or similar document.

(v) Notify each potential expert panel member that he or she must submit information relating to potential conflict of interest directly to FDA in a timely manner, as required in paragraph (e)(6) of this section.

(2) The requestor must submit, in writing, the names and addresses of the proposed qualified expert panel members and sufficient information about each proposed member for FDA to determine whether the panel meets the selection criteria listed in paragraphs (b)(1) through (b)(5) of this section.

(3) After FDA has determined that the qualified expert panel meets the selection criteria, the requestor must provide to the panel all information known by the requestor that is relevant to a determination of the target animal safety and the effectiveness of the new animal drug at issue. In addition, the requestor must notify FDA of the name of the qualified expert panel leader.

(4) The requestor must immediately notify FDA if it believes a qualified expert panel member no longer meets the selection criteria listed in paragraph (b) of this section or is otherwise not in compliance with the requirements of this section.

(5) If a qualified expert panel member cannot complete the review for which he or she was selected, the requestor must either choose a replacement or justify the continued work of the panel in the absence of the lost panelist. In either case, the requestor must submit sufficient information for FDA to determine whether the proposed revised

qualified expert panel meets the selection criteria listed in paragraphs (b)(1) through (b)(5) of this section.

(6) The requestor must keep copies of all information provided to, or received from, qualified expert panel members, including the written report, for 2 years after the completion of the report, or the product is added to the index, whichever occurs later, and make them available to a duly authorized employee of the agency at all reasonable times.

(d) *FDA responsibilities.* (1) FDA will determine whether the requestor's proposed qualified expert panel meets the selection criteria listed in paragraph (b) of this section. FDA will expeditiously inform the requestor, in writing, of its determination. If FDA determines that the qualified expert panel does not meet the selection criteria, FDA will provide due notice and an opportunity for an informal conference as described in §516.123. A determination by FDA that a proposed qualified expert panel does not meet the selection criteria following an informal conference shall constitute final agency action subject to judicial review.

(2) If FDA determines that a qualified expert panel no longer meets the selection criteria listed in paragraph (b) of this section or that the panel or its members are not in compliance with the requirements of this section, the agency will expeditiously inform the requestor, in writing, of this determination and provide due notice and an opportunity for an informal conference as described in §516.123. A determination by FDA, following an informal conference, that a qualified expert panel no longer meets the selection criteria listed in paragraph (b) of this section or that the panel or its members are not in compliance with the requirements of this section shall constitute final agency action subject to judicial review.

(e) *Responsibilities of a qualified expert panel member.* A qualified expert panel member must do the following:

(1) Continue to meet all selection criteria described in paragraph (b) of this section.

(2) Act in accordance with generally accepted professional and ethical business practices.

(3) Review all information relevant to a determination of the target animal safety and effectiveness of the new animal drug provided by the requestor. The panel should also consider all relevant information otherwise known by the panel members, including anecdotal information.

(4) Participate in the preparation of the written report of the findings of the qualified expert panel, described in §516.143.

(5) Sign, or otherwise approve in writing, the written report. Such signature or other written approval will serve as certification that the written report meets the requirements of the written report in §516.143.

(6) Provide the information relating to potential conflict of interest described in paragraph (g) of this section to FDA for its consideration. Such information should be submitted directly to the Director, OMUMS, when notified by the requestor.

(7) Immediately notify the requestor and FDA of any change in conflict of interest status.

(8) Certify at the time of submission of the written report that there has been no change in conflict of interest status, or identify and document to FDA any such change.

(f) *Additional responsibilities of a qualified expert panel leader.* (1) The qualified expert panel leader must ensure that the activities of the panel are performed efficiently and in accordance with generally accepted professional and ethical business practices.

(2) The qualified expert panel leader serves as the principal point of contact between representatives of the agency and the panel.

(3) The qualified expert panel leader is responsible for submitting the written report and all notes or minutes relating to panel deliberations to the requestor.

(4) The qualified expert panel leader must maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted. Such records must be made available to a duly authorized employee of the agency for inspection at all reasonable times.

(g) *Prevention of conflicts of interest.*

(1) For the purposes of this subpart, FDA will consider a conflict of interest to be any financial or other interest that could impair a person's objectivity in serving on the qualified expert panel or could create an unfair competitive advantage for a person or organization.

(2) Factors relevant to whether there is a conflict of interest or the appearance of a conflict of interest include whether the qualified expert panel member, their spouse, their minor children, their general partners, or any organizations in which they serve as an officer, director, trustee, general partner or employee:

(i) Is currently receiving or seeking funding from the requestor through a contract or research grant (either directly or indirectly through another entity, such as a university).

(ii) Has any employment, contractual, or other financial arrangement with the requestor other than receiving a reasonable fee for serving as a member of the qualified expert panel.

(iii) Has any ownership or financial interest in any drug, drug manufacturer, or drug distributor which will benefit from either a favorable or unfavorable evaluation or opinion.

(iv) Has any ownership or financial interest in the new animal drug being reviewed by the qualified expert panel.

(v) Has participated in the design, manufacture, or distribution of any drug that will benefit from either a favorable or unfavorable opinion of the qualified expert panel.

(vi) Has provided within 1 year any consultative services regarding the new animal drug being reviewed by the qualified expert panel.

(vii) Has entered into an agreement in which fees charged or accepted are contingent upon the panel member making a favorable evaluation or opinion.

(viii) Receives payment for services related to preparing information the requestor presents to the qualified expert panel, other than for services related to the written report described in §516.143.

(3) To permit FDA to make a decision regarding potential conflict of interest, a potential qualified expert panel mem-

ber must submit to the Director, OMUMS, the following information relating to themselves, their spouse, their minor children, their general partners, or any organizations in which they serve as an officer, director, trustee, general partner or employee, regarding the following issues to the extent that they are, in any way, relevant to the subject of the review of the qualified expert panel:

(i) Investments (for example, stocks, bonds, retirement plans, trusts, partnerships, sector funds, etc.), including for each the following: Name of the firm, type of investment, owner (self, spouse, etc.), number of shares / current value.

(ii) Employment (full or part time, current or under negotiation), including for each the following: Name of the firm, relationship (self, spouse, etc.), position in firm, date employment or negotiation began.

(iii) Consultant/advisor (current or under negotiation), including for each the following: Name of the firm, topic/issue, amount received, date initiated.

(iv) Contracts, grants, Cooperation Research and Development Agreement (CRADAs) (current or under negotiation), including for each the following: Type of agreement, product under study and indications, amount of remuneration (institution/self), time period, sponsor (government, firm, institution, individual), role of the person (site investigator, principal investigator, coinvestigator, partner, no involvement, other), awardee.

(v) Patents/royalties/trademarks, including for each the following: Description, name of firm involved, income received.

(vi) Expert witness (last 12 months or under negotiation), including for each the following: For or against, name of firm, issue, amount received.

(vii) Speaking/writing (last 12 months or under negotiation), including for each the following: Firm, topic/issue, amount received (honorarium/travel), date.

(viii) Whether the potential qualified expert panel member, their spouse, their minor children, their general partners or any organizations in which they serve as an officer, director, trustee, general partner or employee, have

had, at any time in the past, involvement of the kind noted in paragraph (g)(3)(i) through (g)(3)(vii) of this section with respect to the animal drug that is the subject of the qualified expert panel review.

(ix) Whether there are any other involvements (other kinds of relationships) that would give the appearance of a conflict of interest which have not been described in paragraph (g)(3)(i) through (g)(3)(viii) of this section.

(x) In all cases, a response of “no,” “none,” or “not applicable” is satisfactory when there is no relevant information to submit.

(xi) A certification statement signed by the potential qualified expert panel member to the effect that all information submitted is true and complete to the best of their knowledge, that they have read and understood their obligations as an expert panel member, and that they will notify FDA and the requestor of any change in their conflict of interest status.

(4) The fact that a qualified expert panel member receives a reasonable fee for services as a member of the qualified expert panel, provided that the fee is no more than commensurate with the value of the time that the member devotes to the review process, does not constitute a conflict of interest or the appearance of a conflict of interest.

#### § 516.143 Written report.

The written report required in § 516.145(b)(3) shall:

(a) Be written in English by a qualified expert panel meeting the requirements of § 516.141;

(b) Describe the panel’s evaluation of all available target animal safety and effectiveness information relevant to the proposed use of the new animal drug, including anecdotal information;

(c) For all information considered, including anecdotal information, include either a citation to published literature or a summary of the information;

(d) State the panel’s opinion regarding whether 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-ap-

proved new animal drug for the minor species in question;

(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