ENVIRONMENTAL REVIEW: EVALUATING CLAIMS OF CATEGORICAL EXCLUSION FOR ACTIONS RELATING TO NEW ANIMAL DRUGS

I. PURPOSE

The purposes of this document are to

- describe the basis for the environmental review that we conduct,
- describe when an action pending before us qualifies for a categorical exclusion from the requirement to prepare an environmental assessment (EA),
- describe when extraordinary circumstances would require at least an EA, and
- in some cases, provide standard language for our response.

II. THE REQUIREMENT FOR ENVIRONMENTAL REVIEW

The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies to assess the environmental impact of their actions and to ensure that the interested and affected public is informed of environmental analyses. The Council on Environmental Quality (CEQ) is responsible for overseeing Federal efforts to comply with NEPA. Both CEQ and the Food and Drug Administration (FDA) have issued regulations

governing agency obligations and responsibilities under NEPA. CEQ's regulations implementing the procedural requirements of NEPA can be found at 40 CFR Parts 1500-1508 and FDA's NEPA policies and procedures can be found at 21 CFR Part 25.

Under FDA's regulations, 21 CFR 25.15(a), all applications or petitions requesting agency action require the submission of an environmental assessment (EA) or a claim of categorical exclusion. CEQ and FDA regulations, 40 CFR 1508.4 and 21 CFR 25.5(a)(1), respectively, define "categorical exclusion" to mean a category of actions which have been found by procedures adopted by the Federal agency not to individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an environmental impact statement is required. There may be extraordinary circumstances under which an action that would ordinarily be excluded may have a significant environmental effect. A claim of categorical exclusion must include a citation to the particular categorical exclusion that is claimed, a statement of compliance with the categorical exclusion criteria, and a statement that to the applicant's knowledge, no extraordinary circumstances exist (21 CFR 25.15(a), (d)).

III. ADMINISTRATIVE RESPONSIBILITY FOR ENVIRONMENTAL REVIEW

You, the primary reviewer of the submission, are responsible for making sure that an applicant has submitted an EA or a claim of categorical exclusion. If the applicant does not submit an EA or claim of categorical exclusion, we may refuse to file or approve an application or petition.[1]

If an applicant claims a categorical exclusion, it is your responsibility to determine whether the action the applicant is requesting falls within the categorical exclusion cited by the applicant and, if the action falls within the categorical exclusion, whether the applicant has certified that no extraordinary circumstances exist. If, after consultation with the team leader, you:

- are uncertain whether an action falls within the categorical exclusion cited by the applicant,

[1] See 21 CFR 25.15a.

- find on the face of the submission that there is reason to question whether there are extraordinary circumstances that make it necessary to conduct further environmental review, or

- are aware of extraordinary circumstances, you should consult with the Environmental Assessment Team in person or via email.

You will need to document your consultation with the Environmental Assessment Team for the administrative file, e.g., by incorporation of a memorandum or email in the administrative file, inclusion of a notation of the consultation in the document summary, or other appropriate documentation. If you determine that an action cannot be categorically excluded, the applicant will need to submit an EA to the Environmental Assessment Team for review.

IV. DETERMINING WHETHER AN ACTION QUALIFIES FOR A CATEGORICAL EXCLUSION

The first step in determining whether an action qualifies for a categorical exclusion is to see whether the action falls within a categorical exclusion defined by statute or regulation.[2] If an action falls within a categorical exclusion, you should then confirm that the claim for categorical exclusion is consistent with 21 CFR 25.15(d) and includes a statement that to the applicant's knowledge no extraordinary circumstances exist. If the action qualifies for categorical exclusion under more than one type of action, you should select the single most appropriate categorical exclusion that best fits the action.[3] If there are any questions regarding the best fit, you should contact the Environmental Assessment Team.

Types of animal drug actions that generally qualify for categorical exclusion include:

- Actions on applications that do not increase the use of the drug (21 CFR 25.33(a)). "Increased Use" is defined at 21 CFR 25.5(b)(4).

[2] See 21 CFR 25.33 for the list of categorical exclusions for classes of actions relating to animal drugs.

[3] Guidance for Industry #89 provides further guidance regarding how to determine when actions qualify for categorical exclusion and when extraordinary circumstances may exist.

- Actions on applications for substances that occur naturally in the environment such as electrolytes, peptides, proteins, or vitamins (21 CFR 25.33(c)).

- Actions on applications for drugs intended for use only in non-food animals (21 CFR 25.33(d)(1)).

- Actions on applications for anesthetics, both local and general, that are individually administered to animals (21 CFR 25.33(d)(2)).

- Actions on applications for nonsystemic topical and ophthalmic animal drugs (21 CFR 25.33(d)(3)).

- Actions on applications for new animal drugs intended for use in minor species reared and treated similarly to a major species for which an EA already exists (21 CFR 25.33(d)(4)).

- Actions on applications for new animal drugs intended for use under prescription or veterinarian's order for therapeutic use in terrestrial species (21 CFR 25.33(d)(5)).

V. EXTRAORDINARY CIRCUMSTANCES

We must require at least an EA for any specific action that ordinarily would be categorically excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment.[4] Extraordinary circumstances include, but are not limited to:

- Actions for which available data establish that, at the expected level of exposure, there is potential for serious harm to the environment (21 CFR 25.21(a)).

- Actions that adversely affect endangered or threatened flora or fauna (21 CFR 25.21(b)).

[4] See 21 CFR 25.21.

- Actions relating to new animal drugs intended for use in food animals in a terrestrial environment if the predicted environmental concentration in soil (with or without mitigation) is equal to or greater than 100 micrograms per kilogram.

- Actions relating to new animal drugs that are intended for use in food animals if they are new endo- and/or ectoparasiticides.

You can find a description of when an effect is "significant" at 40 CFR 1508.27. It also provides further examples of extraordinary circumstances under which an environmental assessment may be required for an action that would ordinarily be categorically excluded.

VI. CATEGORICAL EXCLUSION OF INVESTIGATIONS UNDER AN INAD

Actions relating to investigations conducted after an investigational new animal drug file (INAD) is established are generally categorically excluded under 21 CFR 25.33(e). It is likely, however, that the Environmental Assessment Team will need to review INADs for aquatic species and investigations with recombinant gene technology. Categorical exclusions ordinarily cover all investigations under the INAD and are not just for individual investigations under the INAD. Once we have categorically excluded an INAD, we do not ordinarily need any further documentation from the sponsor. However, if at any time during the INAD, you believe extraordinary circumstances exist which call into question the categorical exclusion for the INAD, you should consult with the Environmental Assessment Team. If the sponsor did not claim an exclusion for investigations under an INAD, you should contact the sponsor by phone or letter and request that they make a claim for categorical exclusion using the standard language below:

> Your submission did not claim a categorical exclusion from the requirement to prepare an environmental assessment (EA) or include an EA as required by 21 CFR 25.15(a). If you feel that a categorical exclusion is appropriate, please claim an exclusion under 21 CFR 25.33(e). According to 21 CFR 25.15(a), if you make such a claim, you must be able to state that to your knowledge no extraordinary circumstances, exist which may significantly affect the human environment. You will find further information about extraordinary circumstances in 21 CFR 25.21.

If you do not feel a claim for a categorical exclusion is supportable, please prepare an EA and forward it to us for review.

If the sponsor does not claim a categorical exclusion, or submit an EA, then we may suspend further action (e.g., issuing an authorization letter) on that INAD.

If you find that we can categorically exclude investigations under an INAD, the letter to the sponsor should include the following language:

> We find your claim for the investigational use of <*drug*> for <*proposed intended uses if not stated in a prior paragraph*> falls within the categorical exclusion in 21 CFR 25.33(e). Your submission states that, to your knowledge, no extraordinary circumstances exist which may significantly affect the human environment. Therefore, neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. This categorical exclusion from the preparation of an EA and an EIS does not relieve you of the responsibility for determining and meeting all Federal, State, and local environmental and occupational laws and regulations that apply to the manufacturing, use, and disposal of the investigational drugs.

VII. CATEGORICAL EXCLUSION OF AN APPROVAL OF A NEW ANIMAL DRUG

Because 21 CFR 25.15 requires that each application requesting agency action include the submission of a claim for categorical exclusion or an EA, any original or supplemental (including one for manufacturing changes) new animal drug application (NADA), or original or supplemental abbreviated NADA must include a claim for categorical exclusion or an EA. An applicant may submit this information for review under the phased review process or as part of an NADA.

If, upon review of a claim for categorical exclusion submitted under the phased review process, you find that the approval of the new animal drug for the proposed uses and conditions of use falls within the claimed categorical exclusion, you should prepare a technical section complete (TSC) letter (to be filed under the INAD). Please reference P&P 1243.4080 for the TSC letter language for the TSC letters based on our concurrence with the applicant's claim for categorical exclusion.

If the applicant submits a claim for categorical exclusion under the phased review process or as part of the NADA and you find that the claim is inappropriate, you should prepare an incomplete letter and include the following language:

> We have reviewed your claim for categorical exclusion and find that it is inappropriate because <*the proposed action does not fall within the claimed categorical exclusion*> or <*there are extraordinary circumstances*>. <*You will need to supply specific reason(s) for denying the categorical exclusion and the letter should specify what environmental information is being requested by the Environmental Assessment Team or direct the applicant to meet with the Environmental Assessment Team*>.

You should encourage applicant to submit a claim for categorical exclusion during phased review. If the applicant submits a claim for categorical exclusion initially as part of the NADA and an EA is then required, significant delays in approval may occur. If you find that, the approval of the new animal drug for the proposed uses and conditions of use falls within the claimed categorical exclusion, the approval package and the approval regulation should cite the categorical exclusion and state that we have found that the action qualified for categorical exclusion and no extraordinary circumstances exist.[5]

The FEDERAL REGISTER notice announcing the approval of a new animal drug that qualifies for categorical exclusion should include the following statements:

> The agency has determined under 21 CFR 25.33(d)<(*insert number of applicable exclusion)*> that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. CATEGORICAL EXCLUSION OF SUITABILITY PETITIONS

Actions relating to suitability petitions are generally categorically excluded under 21 CFR 25.30(h).

[5] One purpose of NEPA is to insure that environmental information is available to public officials and citizens. If environmental information is not included in the approval regulation, FDA should use some other mechanism such as the FOI summary to make the information available to the public.

IX. REFERENCES

CVM Guidance for Industry

89, Environmental impact assessment impact (EIA) for veterinary medicinal products (VMPs) – phase I

Program Policy and Procedures Manual

1243.4080, Technical section complete letters

X. VERSION HISTORY

November 16, 2001

Original version

January 26, 2006

Deleted TSC letter boilerplate language for letters based on our concurrence with the applicant's claim for categorical exclusion (language now incorporated into P&P 1243.4080) and minor formatting and other plain language edits.