§ 25.33 Animal drugs.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NADA, abbreviated application, request for determination of eligibility for indexing, a supplement to such applications, or a modification of an index listing, if the action does not increase the use of the drug. Actions to which this categorical exclusion applies may include:

(1) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;
(2) A combination of previously approved animal drugs;
(3) A new premix or other formulation of a previously approved animal drug;
(4) Changes specified in § 514.8(b)(3), (b)(4), or (c)(3) of this chapter;
(5) A change of sponsor;
(6) A previously approved animal drug to be contained in medicated feed blocks under § 510.455 of this chapter or as a liquid feed supplement under § 558.5 of this chapter; or
(7) Approval of a drug for use in animal feeds if such drug has been approved under § 514.2 or 514.9 of this chapter for other uses.

(b) [Reserved]

(c) Action on an NADA, abbreviated application, request for determination of eligibility for indexing, a supplement to such applications, or a modification of an index listing, in the case of substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Action on an NADA, abbreviated application, request for determination of eligibility for indexing, a supplement to such applications, or a modification of an index listing, for:

(1) Drugs intended for use in nonfood animals;
(2) Anesthetics, both local and general, that are individually administered;
(3) Nonsystemic topical and ophthalmic animal drugs;
(4) Drugs for minor species, including wildlife and endangered species, when the drug has been previously approved for use in another or the same species where similar animal management practices are used; and
(5) Drugs intended for use under prescription or veterinarian’s order for therapeutic use in terrestrial species.

(e) Action on an INAD.

(f) Action on an application submitted under section 512(m) of the act.

(g) Withdrawal of approval of an NADA or an abbreviated NADA or removal of a new animal drug from the index.

(h) Withdrawal of approval of a food additive petition that reduces or eliminates animal feed uses of a food additive.