allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance registered by the Environmental Protection Agency under FIFRA for the same use requested in the petition, request for exemption, or notification.

(r) Approval of a food additive petition, color additive, GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance that occurs 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.


§ 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) Action on an INAD.

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

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


§ 25.34 Devices and electronic products.

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 a device premarket notification submission under subpart E of part 807 of this chapter.

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.