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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.

[62 FR 40592, July 29, 1997, as amended at 71 FR 74782, Dec. 13, 2006; 72 FR 69119, Dec. 6, 2007; 85 FR 72907, Nov. 16, 2020]

§ 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.

(c) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance

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of exemptions or variances from such a standard.

(d) Approval of a PMA or a notice of completion of a PDP or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device.

(e) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(f) Issuance of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(g) Action on an application for an IDE or an authorization to commence a clinical investigation under an approved PDP.

(h) Issuance of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

(i) Approval of humanitarian device exemption under subpart H of part 814 of this chapter.

[62 FR 40592, July 29, 1997, as amended at 70 FR 69277, Nov. 15, 2005]

§ 25.35 Tobacco product applications.

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

(a) Issuance of an order finding a tobacco product substantially equivalent under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act;

(b) Issuance of an order finding a tobacco product not substantially equivalent under section 910(a) of the Federal Food, Drug, and Cosmetic Act, denial of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence, issuance of an order under section 910(c) of the Federal Food, Drug, and Cosmetic Act that a new tobacco product may not be introduced or delivered for introduction into interstate commerce, or issuance of an order under section 911 of the Federal Food, Drug, and Cosmetic Act that a modified risk tobacco product may not