in § 25.30 (h), (i), or (j), or § 25.32 (e), (g), (n), or (p).

(h) Withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in §§ 25.31 (d) or (k), 25.32(m), or 25.33 (g) or (h).

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under § 170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in § 25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

(j) Establishment of a tolerance for unavoidable poisonous or deleterious substances in food or in packaging materials to be used for food.

(k) Establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, or establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, unless categorically excluded in § 25.32(f), (i), (j), (k), or (r).

(l) Approval of NDA's, abbreviated applications, applications for marketing approval of a biologic product, supplements to such applications, and actions on IND's, unless categorically excluded in § 25.31 (a), (b), (c), (e), or (l).

(m) Approval of NADA's, abbreviated applications, supplements, actions on INAD's, and granting of requests for determination of eligibility for indexing, unless categorically excluded under § 25.33 (a), (c), (d), or (e).

(n) Approval of PMA's for medical devices, notices of completion of PDP's for medical devices, authorizations to commence clinical investigation under an approved PDP, or applications for an IDE, unless categorically excluded in § 25.34.

(o) Issuance of an order finding a tobacco product substantially equivalent under the Federal Food, Drug, and Cosmetic Act, or granting of a request for an exemption under 21 CFR part 1107 from the requirement of demonstrating substantial equivalence, unless categorically excluded under § 25.35.

(p) Issuance of an order authorizing marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act or an order authorizing marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act, unless categorically excluded under § 25.35.

(q) Establishment, amendment, or revocation of an import tolerance in accordance with subpart C of part 510 of this chapter.

[62 FR 40592, July 29, 1997, as amended at 65 FR 30355, May 11, 2000; 72 FR 69118, Dec. 6, 2007; 80 FR 57535, Sept. 24, 2015; 81 FR 55047, Aug. 17, 2016; 86 FR 52410, Sept. 21, 2021]

§ 25.21 Extraordinary circumstances.

As required under 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (see 40 CFR 1508.27 for examples of significant impacts). Examples of such extraordinary circumstances include:

(a) Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment; and

(b) Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.

§ 25.22 Actions requiring the preparation of an environmental impact statement.

(a) There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS.

(b) EIS's are prepared for agency actions when evaluation of data or information in an EA or otherwise available to the agency leads to a finding by the