or grants, unless categorically excluded in \( \S 25.30 \) (e) or (f).

(f) Establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in \( \S \S 25.30 \) (k) or 25.31 (a), (b), (c), (h), (l), or (j), or 25.32 (a) or (p).

(g) Issuance, amendment, and enforcement of FDA regulations, or an exemption or variance from FDA regulations, unless categorically excluded in \( \S \S 25.30 \) (k) or 25.31 (a), (b), (c), (h), (l), or (j), or 25.32 (a) or (p).

(h) Withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in \( \S \S 25.31 \) (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 exemption from regulation as a food additive, the granting of requests for exemption from regulation as a food additive under \( \S 170.39 \) of this chapter, and allowing notifications submitted under 21 U.S.C. 340(b) to become effective, unless categorically excluded in \( \S 25.33 \) (b), (c), (d), (g), (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) Affirmation of a food substance as GRAS for humans or animals, on FDA’s initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in \( \S \S 170.3 \) (l) and 181.5(a) of this chapter, unless categorically excluded in \( \S 25.33 \) (f), (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 \( \S 25.31 \) (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 \( \S 25.33 \) (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 \( \S 25.34 \).


\( \S 25.21 \) 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.

\( \S 25.22 \) 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 responsible agency official that a proposed action may significantly affect the quality of the human environment.

\( \text{Subpart C—Categorical Exclusions} \)

\( \S 25.30 \) General.

The classes of actions listed in this section and \( \S \S 25.31 \) through 25.34 are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:
§ 25.31 Human drugs and biologics.

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 NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

(b) Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.