

delays later in the process, and to avoid potential conflicts.

(c) For actions initiated by the agency, the NEPA process will begin when the agency action under consideration is first identified. For actions initiated by applicants or petitioners, NEPA planning begins when FDA receives from an applicant or petitioner an EA or a claim that a categorical exclusion applies, or when FDA personnel consult with applicants or petitioners on the NEPA-related aspects of their requested actions. FDA may issue a public call for environmental data or otherwise consult with affected individuals or groups when a contemplated action in which it is or may be involved poses potential significant environmental effects.

(d) Environmental documents shall concentrate on timely and significant issues, not amass needless detail.

(e) If a proposed action for which an EIS will be prepared involves possible environmental effects that are required to be considered under statutes or Executive Orders other than those referred to under “Authority” in this part, these effects shall be considered in the NEPA review, consistent with 40 CFR 1502.25 and the HHS General Administration Manual, part 30: Environmental Protection.

### Subpart B—Agency Actions Requiring Environmental Consideration

#### § 25.15 General procedures.

(a) All applications or petitions requesting agency action require the submission of an EA or a claim of categorical exclusion. A claim of categorical exclusion shall include a statement of compliance with the categorical exclusion criteria and shall state that to the applicant’s knowledge, no extraordinary circumstances exist. Failure to submit an adequate EA for an application or petition requesting action by the agency of a type specified in § 25.20, unless the agency can determine that the action qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34, is sufficient grounds for FDA to refuse to file or approve the application or petition. An EA adequate for filing is one that addresses the relevant environ-

mental issues. An EA adequate for approval is one that contains sufficient information to enable the agency to determine whether the proposed action may significantly affect the quality of the human environment.

(b) The responsible agency officials will evaluate the information contained in the EA to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS will be prepared. If significant effects requiring the preparation of an EIS are identified, FDA will prepare an EIS for the action in accordance with the procedures in subparts D and E of this part. If significant effects requiring the preparation of an EIS are not identified, resulting in a decision not to prepare an EIS, the responsible agency official will prepare a FONSI in accordance with § 25.41.

(c) Classes of actions that individually or cumulatively do not significantly affect the quality of the human environment ordinarily are excluded from the requirement to prepare an EA or an EIS. The classes of actions that qualify as categorical exclusions are set forth in §§ 25.30, 25.31, 25.32, 25.33, or 25.34.

(d) A person submitting an application or petition of a type subject to categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34, or proposing to dispose of an article as provided in § 25.30(d) or 25.32(h), is not required to submit an EA if the person states that the action requested qualifies for a categorical exclusion, citing the particular categorical exclusion that is claimed, and states that to the applicant’s knowledge, no extraordinary circumstances exist.

#### § 25.16 Public health and safety emergencies.

There are certain regulatory actions that, because of their immediate importance to the public health or safety, may make full adherence to the procedural provisions of NEPA and CEQ’s regulations impossible. For such actions, the responsible agency official shall consult with CEQ about alternative arrangements before the action is taken, or after the action is taken, if

## § 25.20

time does not permit prior consultation with CEQ.

### § 25.20 Actions requiring preparation of an environmental assessment.

Any proposed action of a type specified in this section ordinarily requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, or 25.34:

(a) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(b) Destruction or other disposition of articles condemned after seizure or whose distribution or use has been enjoined, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(c) Destruction or other disposition of articles following detention or recall at agency request, unless categorically excluded in §§ 25.30(d) or 25.32(h).

(d) Disposition of FDA laboratory waste materials, unless categorically excluded in § 25.30(m).

(e) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants, unless categorically excluded in § 25.30 (e) or (f).

(f) Establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in §§ 25.30(k) or 25.31 (a), (b), (c), (h), (i), 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 § 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).

## 21 CFR Ch. I (4–1–01 Edition)

(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 §§ 170.3(l) and 181.5(a) of this chapter, unless categorically excluded in § 25.32 (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 § 25.31 (a), (b), (c), (e), or (l).

(m) Approval of NADA's, abbreviated applications, supplements, and actions on INAD's, 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.

[62 FR 40592, July 29, 1997, as amended at 65 FR 30355, May 11, 2000]

### § 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