

## § 25.10

- (5) Environmental assessment (EA) (40 CFR 1508.9).
  - (6) Environmental document (40 CFR 1508.10).
  - (7) Environmental impact statement (EIS) (40 CFR 1508.11).
  - (8) Federal agency (40 CFR 1508.12).
  - (9) Finding of no significant impact (40 CFR 1508.13).
  - (10) Human environment (40 CFR 1508.14).
  - (11) Lead agency (40 CFR 1508.16).
  - (12) Legislation (40 CFR 1508.17).
  - (13) Major Federal action (40 CFR 1508.18).
  - (14) Mitigation (40 CFR 1508.20).
  - (15) NEPA process (40 CFR 1508.21).
  - (16) Notice of intent (40 CFR 1508.22).
  - (17) Proposal (40 CFR 1508.23).
  - (18) Scope (40 CFR 1508.25).
  - (19) Significantly (40 CFR 1508.27).
- (b) The following terms are defined solely for the purpose of implementing the supplemental procedures provided by this part and are not necessarily applicable to any other statutory or regulatory requirements:
- (1) *Abbreviated application* applies to an abbreviated new drug application and an abbreviated new animal drug application.
  - (2) *Active moiety* means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex chelate or clathrate) of the molecule responsible for the physiological or pharmacological action of the drug substance.
  - (3) *Agency* means the Food and Drug Administration (FDA).
  - (4) *Increased use* of a drug or biologic product may occur if the drug will be administered at higher dosage levels, for longer duration or for different indications than were previously in effect, or if the drug is a new molecular entity. The term “use” also encompasses disposal of FDA-regulated articles by consumers.
  - (5) *Responsible agency official* means the agency decisionmaker designated in the delegated authority for the underlying actions.
- (c) The following acronyms are used in this part:

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- (1) CEQ—Council on Environmental Quality.
- (2) CGMP—Current good manufacturing practice.
- (3) EA—Environmental assessment.
- (4) EIS—Environmental impact statement.
- (5) The act—Federal Food, Drug, and Cosmetic Act.
- (6) FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act.
- (7) FONSI—Finding of no significant impact.
- (8) GLP—Good laboratory practice.
- (9) GRAS—Generally recognized as safe.
- (10) HACCP—Hazard analysis critical control point.
- (11) IDE—Investigational device exemption.
- (12) IND—Investigational new drug application.
- (13) INAD—Investigational new animal drug application.
- (14) NADA—New animal drug application.
- (15) NDA—New drug application.
- (16) NEPA—National Environmental Policy Act of 1969.
- (17) OTC—Over-the-counter.
- (18) PDP—Product development protocol.
- (19) PMA—Premarket approval application.

[62 FR 40592, July 29, 1997, as amended at 64 FR 399, Jan. 5, 1999; 69 FR 17291, Apr. 2, 2004]

### § 25.10 Policies and NEPA planning.

- (a) All FDA’s policies and programs will be planned, developed, and implemented to achieve the policies declared by NEPA and required by CEQ’s regulations to ensure responsible stewardship of the environment for present and future generations.
- (b) Assessment of environmental factors continues throughout planning and is integrated with other program planning at the earliest possible time to ensure that planning and decisions reflect environmental values, to avoid 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 environmental 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 con-

tained 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 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