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AUTHORITY: 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500-1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531-533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123-124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356-360.

SOURCE: 62 FR 40592, July 29, 1997, unless otherwise noted.

Subpart A—General Provisions**§ 25.1 Purpose.**

The National Environmental Policy Act of 1969 (NEPA), as amended, directs that, to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements. The regulations in this part implement section 102(2) of NEPA in a manner that is consistent with FDA's authority under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. This part also supplements the regulations for implementing the procedural provisions of NEPA that were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508 and the procedures included in the "HHS General Administration Manual, part 30: Environmental Protection" (45 FR 76519 to 76534, November 19, 1980).

§ 25.5 Terminology.

(a) Definitions that apply to the terms used in this part are set forth in the CEQ regulations under 40 CFR part 1508. The terms and the sections of 40 CFR part 1508 in which they are defined follow:

- (1) Categorical exclusion (40 CFR 1508.4).
- (2) Cooperating agency (40 CFR 1508.5).
- (3) Cumulative impact (40 CFR 1508.7).
- (4) Effects (40 CFR 1508.8).
- (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