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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 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:

(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]