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Title 21 – Food and Drugs

Chapter I – Food and Drug Administration, Department of Health and Human Services

Subchapter A – General

Part 25 – Environmental Impact Considerations

Subpart E – Public Participation and Notification of Environmental Documents

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.

Editorial Note: Nomenclature changes to part 25 appear at 88 FR 45065, July 14, 2023.

§ 25.52 Environmental impact statements.

- (a) If FDA determines that an EIS is necessary for an action involving investigations, approvals, or market authorizations for drugs, animal drugs, biologic products, devices, or tobacco products, an EIS will be prepared but will become available only at the time of the approval or market authorization of the product. The EIS will in all other respects conform to the requirements for EIS's as specified in 40 CFR part 1502 and 1506.6(f).
- (b) Comments on the EIS may be submitted after the approval or market authorization of the drug, animal drug, biologic product, device, or tobacco product. Those comments can form the basis for the Agency to consider beginning an action to withdraw the approval or market authorization of applications for a drug, animal drug, biologic product, or tobacco product, or to withdraw premarket notifications or premarket approval applications for devices.
- (c) In those cases where the existence of applications and premarket notifications for drugs, animal drugs, biologic products, devices, or tobacco products has already been disclosed before the Agency approves the action, the Agency will ensure appropriate public involvement consistent with 40 CFR 1506.6 and part 1503 in preparing and implementing the NEPA procedures related to preparing EISs while following its own disclosure requirements including those listed in part 20 and §§ 312.130(b), 314.430(d), 514.11(d), 514.12(b), 601.51(d), 807.95(e), 812.38(b), and 814.9(d) of this chapter.
- (d) Draft and final EIS's, comments, and responses will be included in the administrative record and will be available from the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

[62 FR 40592, July 29, 1997, as amended at 68 FR 24879, May 9, 2003; 80 FR 57535, Sept. 24, 2015]