

Food and Drug Administration, HHS

§ 25.45

necessary mitigating measures are implemented as a condition for approving the selected course of action.

[62 FR 40592, July 29, 1997, as amended at 69 FR 17291, Apr. 2, 2004]

§ 25.41 Findings of no significant impact.

(a) As defined by the CEQ regulations (40 CFR 1508.13), a FONSI is a document prepared by a Federal agency stating briefly why an action, not otherwise excluded, will not significantly affect the human environment and for which, therefore, an EIS will not be prepared. A FONSI includes the EA or a summary of it and a reference to any other related environmental documents.

(b) The agency official(s) responsible for approving the FONSI will sign the document, thereby establishing that the official(s) approve(s) the conclusion not to prepare an EIS for the action under consideration.

§ 25.42 Environmental impact statements.

(a) As defined by CEQ regulations (40 CFR 1508.11) and section 102(2)(C) of NEPA, an EIS should be a clear, concise, and detailed written statement describing:

- (1) The environmental impacts of a proposed action;
- (2) Any adverse effects that cannot be avoided if the action is implemented;
- (3) Alternatives to the action;
- (4) The relationship between local short-term uses of the environment and the maintenance and enhancement of long-term productivity; and
- (5) Any irreversible and irretrievable commitments of resources that would be involved in the proposed action should it be implemented.

(b) The CEQ regulations (40 CFR 1501.7 and part 1502) describe the process for determining the scope of an EIS and provide detailed requirements for the preparation of draft and final EIS's. CEQ format and procedures for preparing EIS shall be followed.

(c) Under the conditions prescribed in 40 CFR 1502.9, the agency will prepare a supplement for a draft or final EIS and introduce the supplement into the administrative record.

§ 25.43 Records of decision.

(a) In cases requiring environmental impact statements, at the time of its decision, the agency shall prepare a concise public record of decision.

(b) The record of decision shall:

- (1) State what the decision was;
- (2) Identify and discuss alternatives considered by the agency in reaching its decision;
- (3) State whether all practicable means to avoid or minimize environmental harm have been adopted, and if not, why not; and
- (4) Summarize the program for monitoring and enforcing the practicable means adopted to avoid or minimize the environmental harm.

§ 25.44 Lead and cooperating agencies.

For actions requiring the preparation of an EIS, FDA and other affected Federal agencies will agree which will be the lead agency and which will be the cooperating agencies. The responsibilities of lead agencies and cooperating agencies are described in the CEQ regulations (40 CFR 1501.5 and 1501.6, respectively). If an action affects more than one center within FDA, the Commissioner of Food and Drugs will designate one of these units to be responsible for coordinating the preparation of any required environmental documentation.

§ 25.45 Responsible agency official.

(a) The responsible agency official prepares the environmental documents or ensures that they are prepared.

(b) The responsible agency official will weigh any environmental impacts of each alternative course of action, including possible mitigation measures, and will balance environmental impacts with the agency's objectives in choosing an appropriate course of action. The weighing of any environmental impacts of alternatives in selecting a final course of action will be reflected in the agency's record of formal decisionmaking as required by 40 CFR 1505.2.

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