§ 21.73  Accuracy, completeness, timeliness, and relevance of records disclosed from Privacy Act Record Systems.

(a) The Food and Drug Administration shall make reasonable efforts to assure that a record about an individual in a Privacy Act Record System is accurate, relevant to a Food and Drug Administration purpose, timely, and complete before such record is disclosed under § 21.71.

(b) Paragraph (a) of this section shall not apply to disclosures that are required under part 20 of this chapter (the public information regulations) or made to other Federal Government departments and agencies. Where appropriate, the letter disclosing the information shall indicate that the Food and Drug Administration has not reviewed the record to assure that it is accurate, relevant, timely, and complete.

§ 21.74  Providing notice that a record is disputed.

Whenever an individual has filed a statement of disagreement with the Food and Drug Administration concerning a refusal to amend a record under § 21.51(a)(2) or with another agency that provides the record to the Food and Drug Administration, the Food and Drug Administration shall in any subsequent disclosure under this subpart provide a copy of the statement of disagreement and a concise statement by the agency, if one has been prepared, of the reasons for not making the amendment(s) requested.

§ 21.75  Rights of legal guardians.

For the purposes of this part, the parent of any individual who is a minor or the legal guardian of any individual who has been declared to be incompetent due to physical or mental incapacity or age by a court of competent jurisdiction may act on behalf of the individual.
Subpart F—Other Requirements

25.60 Environmental effects abroad of major agency actions.


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 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).


(11) Lead agency (40 CFR 1508.16).


(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:
§ 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.
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§ 25.20 Actions requiring preparation of an environmental assessment.

Any proposed action of a type specified in this section ordinarily requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§25.30, 25.31, 25.32, 25.33, or 25.34:

(a) Major recommendations or reports made to Congress on proposals for legislation in instances where the agency has primary responsibility for the subject matter involved.

(b) Destruction or other disposition of articles condemned after seizure or whose distribution or use has been enjoined, unless categorically excluded in §§25.30(d) or 25.32(h).

(c) Destruction or other disposition of articles following detention or recall at agency request, unless categorically excluded in §§25.30(d) or 25.32(h).

(d) Disposition of FDA laboratory waste materials, unless categorically excluded in §25.30(m).

(e) Intramural and extramural research supported in whole or in part through contracts, other agreements, or grants, unless categorically excluded in §25.30(e) or (f).

(f) Establishment by regulation of labeling requirements, a standard, or a monograph, unless categorically excluded in §§25.30(k) or 25.31(a), (b), (c), (h), (i), or (j), or 25.32(a) or (p).

(g) Issuance, amendment, and enforcement of FDA regulations, or an exemption or variance from FDA regulations, unless categorically excluded in §25.30(h), (i), or (j), or §25.32(e), (g), (h), or (p).

(h) Withdrawal of existing approvals of FDA-approved articles, unless categorically excluded in §§25.31(d) or (k), 25.32(m), or 25.33(g) or (h).

(i) Approval of food additive petitions and color additive petitions, approval of requests for exemptions for investigational use of food additives, the granting of requests for exemption from regulation as a food additive under §170.39 of this chapter, and allowing notifications submitted under 21 U.S.C. 348(h) to become effective, unless categorically excluded in §25.32(b), (c), (i), (j), (k), (l), (o), (q), or (r).

(j) Establishment of a tolerance for unavoidable poisonous or deleterious
§ 25.21 Extraordinary circumstances.

As required under 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (see 40 CFR 1508.27 for examples of significant impacts). Examples of such extraordinary circumstances include:

(a) Actions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment; and

(b) Actions that adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Flora and Fauna to be endangered or threatened or wild flora or fauna that are entitled to special protection under some other Federal law.

§ 25.22 Actions requiring the preparation of an environmental impact statement.

(a) There are no categories of agency actions that routinely significantly affect the quality of the human environment and that therefore ordinarily require the preparation of an EIS.

(b) EIS’s are prepared for agency actions when evaluation of data or information in an EA or otherwise available to the agency leads to a finding by the responsible agency official that a proposed action may significantly affect the quality of the human environment.

Subpart C—Categorical Exclusions

§ 25.30 General.

The classes of actions listed in this section and §§ 25.31 through 25.34 are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Routine administrative and management activities, including inspections, and issuance of field compliance programs, program circulars, or field investigative assignments.

(b) Recommendation for an enforcement action to be initiated in a Federal court.

(c) Agency requests for initiation of recalls.

(d) Destruction or disposition of any FDA-regulated article condemned after seizure or the distribution or use of which has been enjoined or following detention or recall at agency request if the method of destruction or disposition of the article, including packaging material, is in compliance with all Federal, State, and local requirements.

(e) Extramural contracts, other agreements, or grants for statistical and epidemiological studies, surveys and inventories, literature searches, and report and manual preparation, or any other studies that will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment.

(f) Extramural contracts, other agreements, and grants for research for
such purposes as to develop analytical methods or other test methodologies.

(g) Activities of voluntary Federal-State cooperative programs, including issuance of model regulations proposed for State adoption.

(h) Issuance, amendment, or revocation of procedural or administrative regulations and guidance documents, including procedures for submission of applications for product development, testing and investigational use, and approval.

(i) Corrections and technical changes in regulations.

(j) Issuance of CGMP regulations, HACCP regulations, establishment standards, emergency permit control regulations, GLP regulations, and issuance or denial of permits, exemptions, variances, or stays under these regulations.

(k) Establishment or repeal by regulation of labeling requirements for marketed articles if there will be no increase in the existing levels of use or change in the intended uses of the product or its substitutes.

(l) Routine maintenance and minor construction activities such as:

(1) Repair to or replacement of equipment or structural components (e.g., door, roof, or window) of facilities controlled by FDA;

(2) Lease extensions, renewals, or succeeding leases;

(3) Construction or lease construction of 10,000 square feet or less of occupiable space;

(4) Relocation of employees into existing owned or currently leased space;

(5) Acquisition of 20,000 square feet or less of occupiable space in a structure that was substantially completed before the issuance of solicitation for offers; and

(6) Acquisition of between 20,000 square feet and 40,000 square feet of occupiable space if it constitutes less than 40 percent of the occupiable space in a structure that was substantially completed before the solicitation for offers.

(m) Disposal of low-level radioactive waste materials (as defined in the Nuclear Regulatory Commission regulations at 10 CFR 61.2) and chemical waste materials generated in the laboratories serviced by the contracts administered by FDA, if the waste is disposed of in compliance with all applicable Federal, State, and local requirements.

§ 25.31 Human drugs and biologics.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

(b) Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

(c) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Withdrawal of approval of an NDA or an abbreviated application.

(e) Action on an IND.

(f) Testing and release by the Food and Drug Administration of lots or batches of a licensed biologic product.

(g) Establishment of bioequivalence requirements for a human drug or a comparability determination for a biologic product subject to licensing.

(h) Issuance, revocation, or amendment of a standard for a biologic product.

(i) Revocation of a license for a biologic product.
§ 25.32 Foods, food additives, and color additives.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Issuance, amendment, or repeal of a food standard.

(b) Action on a request for exemption for investigational use of a food additive if the food additive to be shipped under the request is intended to be used for clinical studies or research.

(c) Approval of a color additive petition to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics.

(d) Testing and certification of batches of a color additive.

(e) Issuance of an interim food additive regulation.

(f) Affirmation of a food substance as GRAS for humans or animals on FDA’s initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§170.3(l) and 181.5(a) of this chapter, if the substance or food ingredient is already marketed in the United States for the proposed use.

(g) Issuance and enforcement of regulations relating to the control of communicable diseases or to interstate conveyance sanitation under parts 1240 and 1250 of this chapter.

(h) Approval of a request for diversion of adulterated or misbranded food for humans or animals to use as animal feeds.

(i) Approval of a food additive petition or GRAS affirmation petition, the granting of a request for exemption from regulation as a food additive under §170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive petition, color additive petition, or GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

(l) Approval of a petition for color additives used in contact lenses, sutures, filaments used as supporting haptics in intraocular lenses, bone cement, and in other FDA-regulated products having similarly low levels of use.

(m) Action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics.

(n) Issuance, amendment, or revocation of a regulation pertaining to infant formulas.

(o) Approval of a food additive petition for the intended expression product(s) present in food derived from new plant varieties.

(p) Issuance, amendment, or revocation of a regulation in response to a reference amount petition as described in §101.12(h) of this chapter, a nutrient content claim petition as described in §101.69 of this chapter, or a petition pertaining to the label declaration of ingredients as described in §101.103 of this chapter.

(q) Approval of a food additive petition, the granting of a request for exemption from regulation as a food additive under §170.39 of this chapter, or
allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance registered by the Environmental Protection Agency under FIFRA for the same use requested in the petition, request for exemption, or notification.

(r) Approval of a food additive petition, color additive, GRAS affirmation petition, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

§ 25.33 Animal drugs.
The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NADA, abbreviated application, request for determination of eligibility for indexing, a supplement to such applications, or a modification of an index listing, if the action does not increase the use of the drug. Actions to which this categorical exclusion applies may include:

(1) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;

(2) A combination of previously approved animal drugs;

(3) A new premix or other formulation of a previously approved animal drug;

(4) Changes specified in §514.8(b)(3), (b)(4), or (c)(3) of this chapter;

(5) A change of sponsor;

(6) A previously approved animal drug to be contained in medicated feed blocks under §510.455 of this chapter or as a liquid feed supplement under §558.5 of this chapter; or

(7) Approval of a drug for use in animal feeds if such drug has been approved under §514.2 or 514.9 of this chapter for other uses.

§ 25.34 Devices and electronic products.
The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on a device premarket notification submission under subpart E of part 807 of this chapter.

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.
§ 25.40

(c) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard.

(d) Approval of a PMA or a notice of completion of a PDP or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device.

(e) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice.

(f) Issuance of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes.

(g) Action on an application for an IDE or an authorization to commence a clinical investigation under an approved PDP.

(h) Issuance of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

(i) Approval of humanitarian device exemption under subpart H of part 814 of this chapter.


Subpart D—Preparation of Environmental Documents

§ 25.40 Environmental assessments.

(a) As defined by CEQ in 40 CFR 1508.9, an EA is a concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an EIS or a FONSI. The EA shall include brief discussions of the need for the proposal, of alternatives as required by section 102(2)(E) of NEPA, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted. An EA shall be prepared for each action not categorically excluded in §§ 25.30, 25.31, 25.32, 25.33, or 25.34. The EA shall focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles and shall be a concise, objective, and well-balanced document that allows the public to understand the agency’s decision. If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach.

(b) Generally, FDA requires an applicant to prepare an EA and make necessary corrections to it. Ultimately, FDA is responsible for the scope and content of EA’s and may include additional information in environmental documents when warranted.

(c) Information concerning the nature and scope of information that an applicant or petitioner shall submit in an EA may be obtained from the center or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable FDA EA guidance documents, which provide additional advice on how to comply with FDA regulations.

(d) Consistent with 40 CFR 1500.4(j) and 1502.21, EA’s may incorporate by reference information presented in other documents that are available to FDA and to the public.

(e) The agency evaluates the information contained in an EA and any public input 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 or a FONSI will be prepared. The responsible agency official examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any
necessary mitigating measures are implemented as a condition for approving the selected course of action.  


§ 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.
Subpart E—Public Participation and Notification of Environmental Documents

§ 25.50 General information.

(a) To the extent actions are not protected from disclosure by existing law applicable to the agency's operation, FDA will involve the public in preparing and implementing its NEPA procedures and will provide public notice of NEPA-related hearings, public meetings, and the availability of environmental documents.

(b) Many FDA actions involving investigations, review, and approval of applications, and premarket notifications for human drugs, animal drugs, biologic products, and devices are protected from disclosure under the Trade Secret Act, 18 U.S.C. 1905, and 301(j) of the act. These actions are also protected from disclosure under FDA's regulations including part 20, §§312.130(a), 314.430(b), 514.11(b), 514.12(a), 601.50(a), 601.51(a), 807.95(b), 812.38(a), and 814.9(b) of this chapter. Even the existence of applications for human drugs, animal drugs, biologic products, and devices is protected from disclosure under these regulations. Therefore, unless the existence of applications for human drugs, animal drugs, biologic products, or devices is protected from disclosure under these regulations, the release of the environmental document before approval of human drugs, animal drugs, biologic products, and devices is protected from disclosure under these regulations.

§ 25.51 Environmental assessments and findings of no significant impact.

(a) Data and information that are protected from disclosure by 18 U.S.C. 1905 or 21 U.S.C. 331(j) or 360(c) shall not be included in the portion of environmental documents that is made public. When such data and information are pertinent to the environmental review of a proposed action, an applicant or petitioner shall submit such data and information separately in a confidential section and shall summarize the confidential data and information in the EA to the extent possible.

(b) FONSI's and EA's will be available to the public in accordance with 40 CFR 1506.6 as follows:

(1) When the proposed action is the subject of a notice of proposed rulemaking or a notice of filing published in the Federal Register, the notice shall state that no EIS is necessary and that the FONSI and the EA are available for public inspection at FDA's Division of Dockets Management. If the responsible agency official is unable to complete environmental consideration of the proposed action before a notice of filing of a food or color additive petition is required to be published under the act, and if the subsequent environmental analysis leads to the conclusion that no EIS is necessary, the final regulation rather than the notice of filing shall state that no EIS is necessary and that the FONSI and the EA are available upon request and filed in FDA's Division of Dockets Management.

(2) For actions for which notice is not published in the Federal Register, the FONSI and the EA shall be made available to the public upon request according to the procedures in 40 CFR 1506.6.

(3) For a limited number of actions, the agency may make the FONSI and EA available for public review (including review by State and area-wide information clearinghouses) for 30 days before the agency makes its final determination whether to prepare an EIS and before the action may begin, as described in 40 CFR 1501.4(e). This procedure will be followed when the proposed action is, or is closely similar to, one that normally requires an EIS or when the proposed action is one without precedent.

§ 25.52 Environmental impact statements.

(a) If FDA determines that an EIS is necessary for an action involving investigations or approvals for drugs, animal drugs, biologic products, or devices, an EIS will be prepared but will become available only at the time of the approval of the product. Disclosure
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§ 25.60

Environmental effects abroad of major agency actions.

(a) In accordance with Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions" of January 4, 1979 (44 FR 5677, January 9, 1979), the responsible agency official, in analyzing actions under his or her program, shall consider the environmental effects abroad, including whether the actions involve:

1. Potential environmental effects on the global commons and areas outside the jurisdiction of any nation, e.g., oceans and the upper atmosphere;

2. Potential environmental effects on a foreign nation not participating with or otherwise involved in an FDA activity.

(b) Before deciding on any action falling into the categories specified in paragraph (a) of this section, the responsible agency official shall determine, in accordance with section 2–3 of the Executive Order, whether such actions may have a significant environmental effect abroad.

(c) If the responsible agency official determines that an action may have a significant environmental effect abroad, the responsible agency official shall determine, in accordance with section 2–4 (a) and (b) of the Executive Order, whether the subject action calls for:

1. An EIS;

2. A bilateral or multilateral environmental study; or

3. A concise environmental review.

(d) In preparing environmental documents under this subpart, the responsible official shall:

1. Determine, as provided in section 2–5 of the Executive Order, whether proposed actions are subject to the exemptions, exclusions, and modification in contents, timing, and availability of documents.

2. Coordinate all communications with foreign governments concerning environmental agreements and other arrangements in implementing the Executive Order.