

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 premarket notification for devices has been made publicly available, the release of the environmental document before approval of human drugs, animal drugs, biologic products, and devices is inconsistent with statutory requirements imposed on FDA. Appropriate environmental documents, comments, and responses will be included in the administrative record to the extent allowed by applicable laws.

§ 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 360j(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 rule-making 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 sub-

sequent 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 areawide 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 will be made in accordance with 40 CFR 1506.6 and part 20 of this chapter. 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 of the drug, animal drug, biologic product, or device. Those comments can form the basis for the agency to consider beginning an action to withdraw the approval of applications for a drug, animal drug, or biologic 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, or devices has already been disclosed before the agency approves

§ 25.60

the action, the agency will make diligent effort (40 CFR 1506.6) to involve the public in preparing and implementing the NEPA procedures for EIS's while following its own disclosure requirements including those listed in part 20, §§ 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 Division of Dockets Management (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]

Subpart F—Other Requirements

§ 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 1957, 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.

(3) The export of products (or emissions) that in the United States are prohibited or strictly regulated because their effects on the environment create a serious public health risk.

(4) Potential environmental effects on natural and ecological resources of global importance designated under the Executive Order.

(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

21 CFR Ch. I (4-1-04 Edition)

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.

PART 26—MUTUAL RECOGNITION OF PHARMACEUTICAL GOOD MANUFACTURING PRACTICE REPORTS, MEDICAL DEVICE QUALITY SYSTEM AUDIT REPORTS, AND CERTAIN MEDICAL DEVICE PRODUCT EVALUATION REPORTS: UNITED STATES AND THE EUROPEAN COMMUNITY

Sec.

26.0 General.

Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

26.1 Definitions.

26.2 Purpose.

26.3 Scope.

26.4 Product coverage.

26.5 Length of transition period.

26.6 Equivalence assessment.

26.7 Participation in the equivalence assessment and determination.

26.8 Other transition activities.

26.9 Equivalence determination.

26.10 Regulatory authorities not listed as currently equivalent.

26.11 Start of operational period.

26.12 Nature of recognition of inspection reports.

26.13 Transmission of postapproval inspection reports.

26.14 Transmission of preapproval inspection reports.