

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 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 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.
- 26.15 Monitoring continued equivalence.
- 26.16 Suspension.
- 26.17 Role and composition of the Joint Sectoral Committee.
- 26.18 Regulatory collaboration.
- 26.19 Information relating to quality aspects.
- 26.20 Alert system.
- 26.21 Safeguard clause.

APPENDIX A TO SUBPART A—LIST OF APPLICABLE LAWS, REGULATIONS, AND ADMINISTRATIVE PROVISIONS.

APPENDIX B TO SUBPART A—LIST OF AUTHORITIES.

APPENDIX C TO SUBPART A—INDICATIVE LIST OF PRODUCTS COVERED BY SUBPART A.

APPENDIX D TO SUBPART A—CRITERIA FOR ASSESSING EQUIVALENCE FOR POST- AND PREAPPROVAL.

APPENDIX E TO SUBPART A—ELEMENTS TO BE CONSIDERED IN DEVELOPING A TWO-WAY ALERT SYSTEM.

Subpart B—Specific Sector Provisions for Medical Devices

- 26.31 Purpose.
- 26.32 Scope.
- 26.33 Product coverage.
- 26.34 Regulatory authorities.
- 26.35 Length and purpose of transition period.
- 26.36 Listing of CAB's.
- 26.37 Confidence building activities.
- 26.38 Other transition period activities.
- 26.39 Equivalence assessment.
- 26.40 Start of the operational period.
- 26.41 Exchange and endorsement of quality system evaluation reports.
- 26.42 Exchange and endorsement of product evaluation reports.
- 26.43 Transmission of quality system evaluation reports.
- 26.44 Transmission of product evaluation reports.
- 26.45 Monitoring continued equivalence.
- 26.46 Listing of additional CAB's.
- 26.47 Role and composition of the Joint Sectoral Committee.
- 26.48 Harmonization.
- 26.49 Regulatory cooperation.
- 26.50 Alert system and exchange of postmarket vigilance reports.

APPENDIX A TO SUBPART B—RELEVANT LEGISLATION, REGULATIONS, AND PROCEDURES.

APPENDIX B TO SUBPART B—SCOPE OF PRODUCT COVERAGE.

APPENDICES C–F TO SUBPART B [RESERVED]

Subpart C—“Framework” Provisions

- 26.60 Definitions.
- 26.61 Purpose of this part.
- 26.62 General obligations.
- 26.63 General coverage of this part.
- 26.64 Transitional arrangements.
- 26.65 Designating authorities.
- 26.66 Designation and listing procedures.
- 26.67 Suspension of listed conformity assessment bodies.
- 26.68 Withdrawal of listed conformity assessment bodies.
- 26.69 Monitoring of conformity assessment bodies.
- 26.70 Conformity assessment bodies.
- 26.71 Exchange of information.
- 26.72 Sectoral contact points.
- 26.73 Joint Committee.
- 26.74 Preservation of regulatory authority.
- 26.75 Suspension of recognition obligations.
- 26.76 Confidentiality.
- 26.77 Fees.
- 26.78 Agreements with other countries.
- 26.79 Territorial application.
- 26.80 Entry into force, amendment, and termination.