

## § 26.2

(f) *Regulatory system* means the body of legal requirements for GMP's, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

[63 FR 60141, Nov. 6, 1998; 64 FR 16348, Apr. 5, 1999]

### § 26.2 Purpose.

The provisions of this subpart govern the exchange between the parties and normal endorsement by the receiving regulatory authority of official good manufacturing practices (GMP's) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the parties, which is the cornerstone of this subpart.

### § 26.3 Scope.

(a) The provisions of this subpart shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community (EC) before products are marketed (hereafter referred to as "preapproval inspections") as well as during their marketing (hereafter referred to as "postapproval inspections").

(b) Appendix A of this subpart names the laws, regulations, and administrative provisions governing these inspections and the good manufacturing practices (GMP's) requirements.

(c) Appendix B of this subpart lists the authorities participating in activities under this subpart.

(d) Sections 26.65, 26.66, 26.67, 26.68, 26.69, and 26.70 of subpart C of this part do not apply to this subpart.

### § 26.4 Product coverage.

(a) The provisions of this subpart will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the European Community (EC)) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both parties as listed in appendix B of this subpart.

(b) Human blood, human plasma, human tissues and organs, and veteri-

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nary immunologicals (under 9 CFR 101.2, "veterinary immunologicals" are referred to as "veterinary biologicals") are excluded from the scope of this subpart. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals, and medicinal gases are also excluded during the transition phase; their situation will be reconsidered at the end of the transition period. Products regulated by the Food and Drug Administration's Center for Biologics Evaluation and Research or Center for Drug Evaluation and Research as devices are not covered under this subpart.

(c) Appendix C of this subpart contains an indicative list of products covered by this subpart.

[63 FR 60141, Nov. 6, 1998, as amended at 70 FR 14980, Mar. 24, 2005]

### § 26.5 Length of transition period.

A 3-year transition period will start immediately after the effective date described in § 26.80(a).

### § 26.6 Equivalence assessment.

(a) The criteria to be used by the parties to assess equivalence are listed in appendix D of this subpart. Information pertaining to the criteria under European Community (EC) competence will be provided by the EC.

(b) The authorities of the parties will establish and communicate to each other their draft programs for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programs will be carried out, as deemed necessary by the regulatory authorities, for post- and preapproval inspections and for various product classes or processes.

(c) The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the parties will ensure that efforts are made to save resources.

(d) Equivalence assessment for authorities added to appendix B of this subpart after the effective date described in § 26.80(a) will be conducted as

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described in this subpart, as soon as practicable.

### § 26.7 Participation in the equivalence assessment and determination.

The authorities listed in appendix B of this subpart will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

### § 26.8 Other transition activities.

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

### § 26.9 Equivalence determination.

(a) Equivalence is established by having in place regulatory systems covering the criteria referred to in appendix D of this subpart, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g., postapproval or preapproval) or product classes or processes.

(b) The parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of nonequivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

### § 26.10 Regulatory authorities not listed as currently equivalent.

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

### § 26.11 Start of operational period.

(a) The operational period shall start at the end of the transition period and

its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

(b) In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in § 26.12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the parties will agree on procedures for exercising this option.

(c) In the European Community (EC), the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC (see appendix A of this subpart) provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the World Health Organization Certification Scheme on the Quality of Medicinal Products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

### § 26.12 Nature of recognition of inspection reports.

(a) Inspection reports (containing information as established under § 26.8), including a good manufacturing practice (GMP) compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing party, except under specific and delineated circumstances. Examples of such circumstances include indications of