

§ 26.4

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 veterinary 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 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).