

## Food and Drug Administration, HHS

## § 26.1

- 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.
- 26.81 Final provisions.

AUTHORITY: 5 U.S.C. 552; 15 U.S.C. 1453, 1454, 1455; 18 U.S.C. 1905; 21 U.S.C. 321, 331, 351, 352, 355, 360, 360b, 360c, 360d, 360e, 360f, 360g, 360h, 360i, 360j, 360l, 360m, 371, 374, 381, 382, 383, 393; 42 U.S.C. 216, 241, 242i, 262, 264, 265.

SOURCE: 63 FR 60141, Nov. 6, 1998, unless otherwise noted.

#### § 26.0 General.

This part substantially reflects relevant provisions of the framework agreement and its sectoral annexes on pharmaceutical good manufacturing practices (GMP's) and medical devices of the “Agreement on Mutual Recognition Between the United States of America and the European Community” (the MRA), signed at London May 18, 1998. For codification purposes, certain provisions of the MRA have been modified for use in this part. This modification is done for purposes of clarity only and shall not affect the text of the MRA concluded between the United States and the European Community (EC), or the rights and obligations of the United States or the EC under that agreement. Whereas the parties to the MRA are the United States and EC, this part is relevant only to the Food and Drug Administration's (FDA's) implementation of the MRA, including the sectoral annexes reflected in subparts A and B of this part. This part does not govern implementation of the MRA by the EC, which will implement the MRA in accordance with its internal procedures, nor does this part address implementation of the MRA by other concerned U.S. Federal agencies. For purposes of this part, the terms “party” or “parties,” where relevant to FDA's implementation of the MRA, should be considered as referring to FDA only. If the parties to the MRA subsequently amend or terminate the MRA, FDA will modify this part accordingly, using appropriate administrative procedures.

#### Subpart A—Specific Sector Provisions for Pharmaceutical Good Manufacturing Practices

##### § 26.1 Definitions.

(a) *Enforcement* means action taken by an authority to protect the public from products of suspect quality, safety, and effectiveness or to assure that products are manufactured in compliance with appropriate laws, regulations, standards, and commitments made as part of the approval to market a product.