

## Food and Drug Administration, HHS

## Pt. 26, Subpt. A, App. D

veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA), Dirección General de la Producción Agraria.

France: For medicinal products for human use: Agence du Médicament. For veterinary medicinal products: Agence Nationale du Médicament Vétérinaire.

Ireland: Irish Medicines Board.

Italy: For medicinal products for human use: Ministero della Sanità, Dipartimento Farmaci e Farmacovigilanza. For medicinal products for veterinary use: Ministero della Sanità, Dipartimento alimenti e nutrizione e sanità pubblica veterinaria-Div. IX.

Luxembourg: Division de la Pharmacie et des Médicaments.

Netherlands: Staat der Nederlanden.

Austria: Bundesministerium für Arbeit, Gesundheit und Soziales.

Portugal: Instituto da Farmácia e do Medicamento (INFARMED).

Finland: Lääkelaitos/Läkemedelsverket (National Agency for Medicines).

Sweden: Läkemedelsverket-Medical Products Agency.

United Kingdom: For human use and veterinary (non-immunologicals): Medicines Control Agency. For veterinary immunologicals: Veterinary Medicines Directorate.

European Community: Commission of the European Communities. European Agency for the Evaluation of Medicinal Products (EMA).

### APPENDIX C TO SUBPART A OF PART 26— INDICATIVE LIST OF PRODUCTS COVERED BY SUBPART A

Recognizing that precise definition of medicinal products and drugs are to be found in the legislation referred to above, an indicative list of products covered by this arrangement is given below:

- human medicinal products including prescription and nonprescription drugs;
- human biologicals including vaccines, and immunologicals;
- veterinary pharmaceuticals, including prescription and nonprescription drugs, with the exclusion of veterinary immunologicals (Under 9 CFR 101.2 “veterinary immunologicals” are referred to as “veterinary biologicals”);
- premixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (United States);
- intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (United States)/starting materials (EC).

### APPENDIX D TO SUBPART A OF PART 26— CRITERIA FOR ASSESSING EQUIVALENCE FOR POST- AND PREAPPROVAL

I. Legal/Regulatory authority and structures and procedures providing for post- and preapproval:

- A. Appropriate statutory mandate and jurisdiction.
- B. Ability to issue and update binding requirements on GMP's and guidance documents.
- C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.
- D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.
- E. Substantive current good manufacturing requirements.
- F. Accountability of the regulatory authority.
- G. Inventory of current products and manufacturers.
- H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by subpart A of this part.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

- A. Standards of education/qualification and training.
- B. Effective quality assurance systems measures to ensure adequate job performance.
- C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of inspections:

- A. Adequate preinspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.
- B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.
- C. Adequate postinspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of followup inspections and other activities where appropriate, assurance of preservation and retrieval of records.