[F1 ANNEX I

CHEMICAL, PHARMACEUTICAL AND ANALYTICAL STANDARDS, SAFETY AND RESIDUE TESTS, PRE-CLINICAL AND CLINICAL TRIALS IN RESPECT OF TESTING OF VETERINARY MEDICINAL PRODUCTS

Textual Amendments

F1 Substituted by Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (Text with EEA relevance).

TITLE I

REQUIREMENTS FOR VETERINARY MEDICINAL PRODUCTS OTHER THAN IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS

PART 3:

SAFETY AND RESIDUES TESTS

B. Residue tests

CHAPTER II:

PRESENTATION OF PARTICULARS AND DOCUMENTS

1. Identification of the product

An identification of the veterinary medicinal product(s) used in the testing shall be provided, including:

— composition,
— the physical and chemical (potency and purity) test results for the relevant batch(es),
— batch identification,
— relationship to the final product,
— specific activity and radio-purity of labelled substances,
— position of labelled atoms in the molecule.

The dossier of residue tests shall include:

— an index of all studies included in the dossier,
— a statement confirming that all data known by the applicant at the time of submission, whether favourable or unfavourable, are included,
— a justification for the omission of any type of study,
— an explanation of the inclusion of an alternative type of study,
— a discussion of the contribution that any study that pre-dates GLP can make to the overall risk assessment,
— a withdrawal period proposal.

Each study report shall include:

— a copy of the study plan (protocol),

— a statement of compliance with good laboratory practice, where applicable,

— a description of the methods, apparatus and materials used,

— a description of the results obtained, in sufficient detail to allow the results to be critically evaluated independently of their interpretation by the author,

— a statistical analysis of the results where appropriate,

— a discussion of the results,

— an objective discussion of the results obtained, and proposals concerning the withdrawal periods necessary to ensure that no residues which might constitute a hazard for consumers are present in foodstuffs obtained from treated animals.**]**