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GlaxoSmithKline

Harmire Road
Barnard Castle
County Durham
DL12 8DT

Tel. +44 (0)1833 690600
Fax. +44 (0)1833 692300
www.gsk.com

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville
MD 20852
USA

20-Dec-2001

Dear Sir/Madam

Re: Comments on; "Draft FDA Guidance for Industry; Electronic Records; Electronic Signatures, Validation" Docket No. 00N-1543

GlaxoSmithKline, a research-based pharmaceutical company, is engaged in the discovery, development, manufacture, and sale of pharmaceutical products. We welcome the opportunity to submit comments on aspects of the Draft Guidance.

General Comment:

1) It is suggested that rather than publish a separate document the definitions covered in this Draft Guidance might be better positioned as an update to the FDAs existing Glossary of Terms for Computerised Systems published in 1995. A single source of reference for FDA terminology would avoid those seeking advice on terminology having to search multiple FDA guidance documents.

Specific Comments:

1) It is suggested that the definition for Computer Systems Validation in Section 3 'Definitions' should not be limited to Part 11. Computer validation is not specific to Part 11 but rather a general concept based on the principle of quality assurance. We recommend a definitive definition be prepared for all food, drug and cosmetic industry sectors. The definition of computer system validation should emphasise validation focus on the computer application, the adoption of a life cycle approach (including development, operation and maintenance, and decommissioning), testing against pre-determined specifications, and traceability through documentary evidence.

2) The definition of Electronic Record in Section 3 'Definitions' is all encompassing; it includes all raw data, all temporary/transient data, and all meta-data including audit trails. The Part 11 preamble makes reference to predicate rules when determining which electronic information constitutes an Electronic Record. It is suggested that the definition of Electronic Record be refined to acknowledge the role of predicate rules when identifying electronic records and hence clearly exclude what is outside scope such as temporary/transient data.

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Glaxo Wellcome Operations is a business name of Glaxo Operations

3) Since the issue of this FDA Draft Guidance a new edition of the GAMP Guide referred to in Section 4 'References' has been published by ISPE. Consequently it is suggested that the reference to GAMP3 be updated with a reference to GAMP4.

We appreciate the opportunity to comment. Thank you for your consideration.

Sincerely

Dr Guy Wingate
Director, Global Computer Validation