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24th April 2003

**RE: Comments on "Draft FDA Guidance for Industry; Electronic Records;
Electronic Signatures, Scope and Application" Docket No. 03D-0060.**

Dear Sir/Madam:

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 We welcome the opportunity to submit comments on aspects of this Draft Guidance.

General Comments:

- 1) We support and agree with many of the Agency's stated reasons for recognizing and understanding the need to further review Part 11 in terms of its implementation while recognizing that a more narrowly defined scope and application fully supports the interest we all share in protecting the public health.
- 2) We believe that further clarification in the final Part 11 guidance on the requirements of 21 CFR Part 11 would be helpful. For example, does the use of phrases in it such as 'interpreted narrowly' in fact change existing regulatory requirements concerning electronic records and electronic signatures?
- 3) FDA's Guidance on Computerized Systems Used in Clinical Trials (1999) makes a number of references to Part 11, some of which appear to be inconsistent with those being suggested in this Draft Guidance. For example, the Clinical Guidance calls for all software (applications, operating systems and tools, including those used for development) to be available for reconstruction throughout the record retention period. This goes beyond requirements in Part 11 and this Draft Guidance. We recommend the Clinical Guidance and other relevant Agency guidance documents not yet withdrawn be included in the FDA's re-examination of Part 11 and its interpretation.

03D-0060

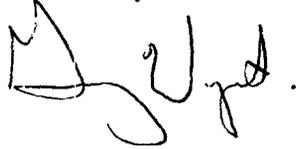
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Specific Comments:

- 1) Section I INTRODUCTION: includes phrases relating to regulatory discretion such as “we will not normally take regulatory action”. This raises significant opportunity for ambiguity and inspection variation. We believe it would be better if the Agency further clarifies which items in 21 CFR Part 11 continue to apply in full, no longer apply, or are under review to improve the clarity of the guidance.
- 2) Section III DISCUSSION: B.2 Details of Approach-Scope of Part 11-Definition of Part 11 Records. We request clarification on identifying electronic records that must adhere to the controls specified within 21 CFR Part 11. We believe a search of predicate rules for keywords such as ‘record’ and ‘data’ is sufficient. We also request clarification of what additional electronic records supporting regulatory submissions to the Agency fall within the scope of 21 CFR Part 11. Without such guidance an extremely wide scope of application will be required to ensure prospective compliance.
- 3) Section III DISCUSSION: B.2 Definition of Part 11 Records. We request additional clarification on identifying ‘general signings’ that must adhere to the controls specified within 21 CFR Part 11. We believe a search in predicate rules for the keyword such as ‘signature’ and its derivatives such as ‘sign’ and ‘signed’ is sufficient to identify ‘general signings’.
- 4) Section III DISCUSSION: C.3 Legacy Systems discusses legacy systems in use prior to 21 CFR Part 11 becoming effective. We request that the Agency clarify whether this will be an ongoing exemption and what the Agency’s position is on subsequent upgrades to these systems. We suggest that a risk assessment can be used to determine whether 21 CFR Part 11 controls are required based on how reliable and secure records have been over the operational life of a legacy system--is this clear as to meaning?.
- 5) Section III DISCUSSION: C.4 Copies of Records discusses the acceptability of common portable file formats for submissions of records to the Agency. We would like to suggest the guidance is revised to reference a list of other acceptable common file formats.
- 6) Section III DISCUSSION: C.4 Copies of Records & Section III DISCUSSION: C.5 Record Retention. We support the opportunity to copy and archive electronic records to non-electronic media and propose. We suggest that methods to facilitate record retrieval should be appropriate to the use.

GlaxoSmithKline supports the Agency in its decision to review aspects of Part 11. We recognise the difficulty the Agency has in being completely definitive in this area and appreciate the opportunity to comment. Thank you for your consideration.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Guy Wingate', with a stylized flourish at the end.

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Director, Global Computer Validation

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