

The Japan Pharmaceutical Manufacturers Association (JPMA)

Date: 22/04/2003

## Comments on the draft Guidance for Industry Part 11, Electronic Records, Electronic Signatures - Scope and Application

**Docket Number: 03D-0060**

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Dear Sirs:

This is to apply for Docket Number 03D-0060; comments on the Draft Guidance for Industry "Part 11, Electronic Records, Electronic Signatures- Scope and Application" published in the Federal Register on February 25, 2003.

Below are JPMA's comments.

No.	Line	Original text	Comments and suggestions
1	Line 21	---in a statute or another part of FDA's regulations to maintain records or submit <u>information</u> to FDA,----	It seems to be better to be clarified and described concretely, what kind/which type of "information" shall be submitted to FDA; So that, the Industry will clearly see what the Agency intends to narrowly interpret the scope of Part 11, as described in Lines 34 to 35.

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2	Lines 32 to 33	FDA is embarking on a re-examination of Part 11 as it applies to all FDA regulated products.	<p>Currently, in fact, Title 21 CFR Part 11 seems to be applied to pharmaceutical and medical device production, and other areas seem to be exempted. However, section 11.1(b) of Title 21 CFR Part 11 states that the part applies to records required under any of FDA regulations if they take electronic form. Thus, intention behind the above statement is not clear for industry.</p> <p>We suggest to explicate the clause after “as”.</p>
3	Lines 32 to 33		<p>It has an unnegligible impact on compliance action plan how long the Agency will take to re-examine Part 11, and thus this guidance will be effective.</p> <p>We expect the Agency to clarify the order of re-examination period (months or years?), otherwise to provide a reference to progress reports of the re-examination like footnote four indicating CGMP initiative.</p>
4	Lines 34 to 35	“This guidance explains that, while this re-examination of Part 11 is under way, we will narrowly interpret the scope of Part 11.”	<p>This statement declares that the narrow interpretation of the scope is just a temporary step during re-examination of Part 11. But total impression of Chapters II to III (e.g. Lines 143 to 144) is that FDA is anxious that unnecessarily broad interpretation of Part 11 may increase cost and/or discourage technological advance. Contextually, it is understandable that the application of Chapter III is limited within the period of re-examination, but still Chapter III can be easily misunderstood.</p> <p>We suggest to clarify whether the provision is only applicable while the re-examination of Part 11 or survives after that, in each section in Chapter III.</p>
5	Lines 90 to 94	<p>--- we announced the withdrawal of the draft guidance for industry, 21 CFR Part 11; Electric Records; Electric Signatures, Electric Copies of Electric Records because we wanted to avoid loss of time spent by industry in an effort to review and comment on the draft guidance <u>may no longer be representative of FDA’s approach under the new CGMP initiative.</u></p>	<p>It seems to be better to be clarified and described concretely, which part(s) of the draft Guidance is/are/may be no longer representative of FDA’s approach under the new cGMP initiative; So that, the clarification/description will be of help to the Industry from the viewpoint of Part 11 compliance.</p>
6	Line 124	FDA will enforce predicate rule requirements for records that are subject to Part 11.	When non-GLP data (e.g. on pharmacokinetics and non-clinical pharmacology) are maintained electronically, will the electronic data concerned be subject to Part 11?

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7	Lines 149 to 151	Under the narrow interpretation of the scope of Part 11, with respect to records required to be maintained or submitted, when persons choose to use records in electronic format in place of paper format, Part 11 would apply.	We suggest to simply add a phrase “under predicate rules” after “maintained or submitted” to explicate the implicit meaning of the above statement.
8	Lines 153 to 154	---, and persons rely on the paper records to perform their regulated activities, <i>the merely incidental</i> use of computers in those instances would not trigger Part 11.	Especially in pre-clinical area, “ <i>the merely incidental</i> use of computers” sounds to be scarcely found; In other words, almost all the pre-clinical data obtained by using computer seems to be subject to Part 11. It will be very helpful to the Industry, if criteria of whether electronic records are subject to Part 11 or not are described concretely, taking into account the actual business practices at each our site.
	Lines 176 to 178	That is, the Agency may take your business practices into account in determining whether Part 11 applies.	
9	Lines 198 to 201	The Agency intends to exercise enforcement discretion regarding the specific Part 11 requirements for validation of computerized systems (§ 11.10(a) and corresponding requirements in § 11.30). Persons must still comply with all applicable predicate rule requirements for validation (e.g., 21 CFR 820.70(i)).	It is described that draft guidances are withdrawn (in Lines 98 to 99), and the Agency exercises enforcement discretion regarding validation of computerized systems (in Lines 198 to 200). This seems to make the Industry confused, when it comes to Validation. It may be better §11.10(a) is deleted and description like the following sentences are included: “Computer system subject to Part 11 shall be validated to meet predicate rule requirements.”
10	Lines 203 to 205	Even if there is no predicate rule requirement--- it may nonetheless be important to validate the system to ensure the accuracy and reliability of <u>the Part 11 records</u> contained in the system..	If “the records” mentioned in Line 227 are “the Part 11 records”, the term seems to be better to be expressed in the same manner.
11	Lines 278 to 279	---, and the records themselves and any copies of the required records should preserve their <u>content and meaning</u> .	It seems to be better to be clarified and described, how much meta data are included in <u>content and meaning</u> ; The clarification/description will be very important to the Industry.

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12	Lines 279 to 281	In addition, paper and electronic records and signature components can co-exist (i.e., a hybrid situation) as long as predicate rule requirements are met and the content and meaning of those records are preserved.	<p>Considering “Footnote 6 for Line 281”, the following two combinations seem to be considered not acceptable:</p> <ul style="list-style-type: none"> <li># electronic record without signature</li> <li># hand-written signature into printed-out electronic records</li> </ul> <p>But if acceptable, those two combinations seem to be better to be included into the examples of hybrid situations.</p> <p>And, unacceptable examples seem to be better to be described concretely, for example, when predicate rule requirements are enforced.</p>

Thank you for giving us the opportunity to comment on the Draft Guidance for Industry “Part 11, Electronic Records, Electronic Signatures- Scope and Application” Please contact the representative of the JPMA, Nobuharu Goto at [Goto.Nobuharu@mc.m-pharma.co.jp](mailto:Goto.Nobuharu@mc.m-pharma.co.jp), Hidetaka Mukaiyama at [mukaiyamahdt@chugai-pharm.co.jp](mailto:mukaiyamahdt@chugai-pharm.co.jp), or Toshiaki Matsuzawa at [matuzawa@yamanouchi.co.jp](mailto:matuzawa@yamanouchi.co.jp) should you have any question regarding this letter.

Sincerely,

Nobuharu Goto

The JPMA