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Dockets Management Branch (HFA-305)  
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**Re: Comments on, "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format", Docket No. 00N-1652**

Dear Sir or Madam:

SEC Associates, Inc. (SEC) is pleased to have the opportunity to provide comments on the above-referenced proposed rule. SEC is a regulatory compliance consulting and computer validation services firm, and as such, we have been heavily engaged in providing a range of services to FDA-regulated companies relating to both computer validation and 21 CFR Part 11.

SEC applauds FDA's efforts to increase efficiencies and reduce unnecessary work and resources for both the Agency and industry. It is our view, however, that any productivity gains may be overshadowed by setbacks to overall Part 11 progress that may result from confusion or misguided expectations generated by this rule. We believe some of the concepts in this proposed rule have merit and deserve careful consideration. We are concerned, though, that FDA may not have considered all possible repercussions that may result from this rule. Our concerns are outlined in the following sections, which are divided into Major and Minor Issues.

**Major Issues**

In the five years since Part 11 was introduced, significant industry-wide progress has been made towards compliance, thanks to the efforts of many in FDA, regulated industry, service providers, and vendors. It has not been an easy adjustment, and much remains to be done to achieve compliance across the industry. For those of us who have been working hard to move industry toward compliance, one of the toughest battles has been that of winning the minds and budgets of corporate management to the idea that part 11 controls make good business sense. It has been especially difficult convincing them that all Part 11 electronic record (e-record) controls (11.10(a) through 11.30) are equally important regardless of record type – be it an electronic batch record system, a clinical data management system, an SOP system, or a report writing system. Because Part 11 (and subsequent guidance) makes no provision for distinguishing between various types of e-records, many of us (whether or not we agreed with it) have pushed for the uniform application of Part 11 controls (including validation) across all e-record systems.

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With this proposed rule, we believe that FDA may inadvertently undermine much of the foundation for Part 11 progress that has been laid in recent years. By singling out the electronic labeling content submission as a unique and special record type, and thereby exempting it from most Part 11 provisions, we fear that FDA is opening a Pandora's Box that will be difficult to close. This rule may undo years of education that have been required to overcome resistance to the concepts embodied in computer validation and part 11 controls. Why? Because the same logic used by FDA to exempt the e-labeling records from many Part 11 controls can be applied to other e-record systems. Consider the following discussion.

Industry has maintained since Part 11's inception that electronic records are NOT all the same; there are, in fact, different types, or classes, of e-records. Industry has argued, for example, that documents (such as SOPs and many reports) are distinctly different from electronic batch records (EBRs) or instrument data files. One major distinction between these record types is that the former can be 100% visually inspected for accuracy, completeness, and correctness, whereas that is usually not the case with EBRs or instrument data files.

The proposed rule argues that most part 11 controls (including validation) are unnecessary because (a) the submitter can verify the accuracy of the record through visual inspection, and (b) the submitter must certify in writing that the record is accurate (under penalty of perjury for making willfully false statements). While this logic appears sound and seemingly risk free for this relatively simple case, what is to stop readers from applying this same logic to **any** e-record system for which these rules apply? For example, if a manufacturer can perform 100% visual inspection of the output of their electronic SOP system, and if they are willing to certify in writing as to the accuracy of the output, why cannot such a system be exempted from validation and most Part 11 controls? If a sponsor company can visually inspect the output of its electronic NDA submission system, and they are willing to guarantee its accuracy in writing (as they are required), why can't validation and part 11 controls be avoided for this system?

There are several reasons why it would not be prudent for FDA to grant the exemptions suggested above. For one, it is widely recognized that once people become comfortable with the output of a computer system, the tendency is to grow complacent and to assume that the output is correct, without the same level of inspectional rigor that was first applied. Another reason can be found in the wave of corporate accounting scandals sweeping the nation in recent months (i.e., it appears that many people appear willing to lie or mislead the government and the public for their own self interests).

It was for these reasons (and others) that validation was required by FDA in the first place. These reasons also provided much of the impetus for part 11 controls. To now say that these reasons are no longer valid for e-labeling content submission records implies that something has changed with respect to the fundamental assumptions that led to validation and part 11 controls in the first place. This proposed rule, however, provides no evidence that anything has changed. Granted, the risk appears to be minimal for inadvertent errors or intentional falsification in this particular case. But where is the line drawn between the e-records of this proposed rule and those in the examples provided earlier (e.g., SOPs and reports)? It would seem, by the logic in this proposed rule, that any e-record system for which the output can be visually inspected and certified for accuracy should be exempt from validation and most part 11 controls. Conversely, if FDA is concerned about granting such exemptions for other e-record systems (such as SOP and reporting systems), perhaps those same concerns should be applied to the e-labeling content submission records.

We recognize that the "all or nothing" argument advocated above may not be reasonable for all document-type e-records, because of subtle distinctions that can be made even within this class of e-records. FDA has recognized that these particular electronic records have a unique nature and purpose, and the Agency appears willing to acknowledge that other types of e-records may also have unique natures and purposes<sup>1</sup>. As a result, the decision regarding which part 11 provisions apply for each record type must be decided on a case by case basis. However, the result of issuing such decisions on a protracted, piecemeal schedule may have a negative impact on Part 11 progress industry-wide. Regulated companies will be reluctant to spend large sums of money to purchase or remediate systems for Part 11 compliance, if the possibility exists that FDA may eventually exempt those systems.

Also detrimental to overall Part 11 compliance progress is the statement in the proposed rule, "We may consider whether to propose amendments to the part 11 regulations as a result of our reevaluation." If changes to Part 11 are in order (and we believe that certain changes would be beneficial), then FDA should "do the right thing" and pursue the implementation of those changes. In the meantime, though, the Agency should be aware of the major dampening effect generated by such a statement. As discussed in the previous paragraph, experience has shown that if industry anticipates change on the horizon, the inclination is to do nothing (including putting current Part 11 activities on hold) until FDA clarifies its position. For company executives who are not yet convinced of the business benefits of Part 11 controls (and there are still plenty), this apparent vacillation by FDA with regard to Part 11 provides them with one more excuse to direct resources away from Part 11 solutions.

### **Minor Issue**

By excluding 11.10(a) and (c) through (h), the proposed rule argues that it is not important how the end result is achieved; only that the end result is accurate. The logic seems to be that as long as the output can be verified for accuracy via visual inspection, what happens en route to that final inspection and certification is inconsequential. This reasoning raises the following question: If only the end result matters, and in-process controls are unimportant, why does 11.10(i) matter? Why are the qualifications of the system users, etc., important, provided that they can ultimately generate an e-record that passes inspection and is certified as accurate? So what if it takes 15 tries to get it right? So what if the users were not properly trained, provided they can fumble through it to come up with a certifiable end result? If only the output matters, then it would seem that FDA should not concern itself with the qualifications of the people responsible for producing (not certifying) the record. Conversely, if FDA should be concerned about the qualifications of the users, then perhaps FDA should also be concerned about the process – not just the end result. And perhaps that process should include system validation and part 11 controls designed to ensure the accuracy, integrity, and trustworthiness of the output being generated by the system.

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<sup>1</sup> "...we are reevaluating the necessity of some of the controls in part 11 as they apply to different submissions, including records voluntarily submitted in electronic format." (From section IV, Part 11 Requirements for Electronic Submissions, Federal Register Notice of May 3, 2002, on "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format", proposed rule.)

**Conclusion and Recommendation**

This proposed rule is an excellent vehicle for prompting some much-needed discussion between all affected parties. In our view, however, it would be detrimental to industry-wide Part 11 progress to issue this rule in its current form. We respectfully suggest that FDA delay implementation of this rule indefinitely, and meet with interested parties in public meetings to formulate a workable strategy. The intent would be threefold: (1) to develop a strategy for achieving the intended goals of this proposed rule; (2) to address the issue of integrity and trustworthiness for other, similar types of e-records; and, (3) to avoid widespread confusion and damage to Part 11 progress that may result from granting a special exemption to a record-type which, on the surface, does not appear to be dramatically different from other e-records that can be verified by visual inspection.

There may be a temptation to implement this rule "as is" and deal with the fallout later. We urge the Agency to not take that route. The risk is too great. It would be better to delay implementation of this rule in order to determine the best course of action. It should be possible to develop a comprehensive list of required record types that should be exempt from Part 11, and if so, to issue them together. On the other hand, if it is determined that validation and Part 11 controls are appropriate for these types of systems, perhaps this proposed rule should be withdrawn. A third possibility is that Part 11 itself should be amended to more clearly address these issues. Whatever the outcome, we believe it is important for FDA to carefully consider the ramifications that the enactment of this proposed rule may have.

Thank you once again for the opportunity to express our views.

Very truly yours,  
SEC ASSOCIATES, INC.

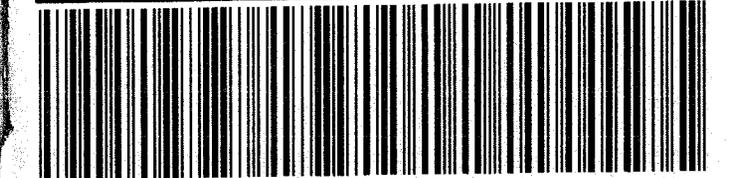


John C. McKenney, Sr.  
President

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