



National Grain and Feed Association

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Docket No. 2004N-0133
Electronic Record; Electronic Signatures**

The National Grain and Feed Association submits this statement in response to the Food and Drug Administration's notice requesting public comments on various topics concerning its regulations on electronic records and electronic signatures in Part 11 (21 CFR part 11).

Established in 1896, the NGFA consists of 1,000 grain, feed, processing, exporting and other grain-related companies that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. With more than 350 member companies operating commercial feed mills and 30 integrated livestock and poultry feed manufacturing operations, the NGFA is the nation's largest trade association representing feed manufacturer interests. The NGFA also consists of 35 affiliated state and regional grain and feed associations, as well as two international affiliated associations.

The NGFA commends FDA for undertaking a wholesale reexamination of its existing regulations, which throughout this document we will refer to as "Part 11," under which the agency considers electronic records and signatures equivalent to paper records and handwritten signatures.

For purposes of this rulemaking, the NGFA's statement conveys the perspective and views of medicated feed manufacturers required to maintain records under FDA's predicate rules governing current good manufacturing practices (CGMPs) [21 CFR Part 225].

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At the outset, the NGFA reiterates its previous statement¹ that the existing Part 11 regulations originally promulgated on March 20, 1997 were written at the request of – and with input provided by – the human pharmaceutical manufacturing industry. It is our understanding that FDA’s Center for Veterinary Medicine (CVM) initially considered Part 11’s potential application to the animal drug manufacturing sector, but did not consider the impact on the animal feed manufacturing industry. To our knowledge, the animal feed and human food industries were neither notified nor engaged by their respective FDA Centers seeking input into the development of the rulemaking. Nor did the food processing and medicated animal feed manufacturing industries comment during the initial rulemaking. Indeed, it was not until several years later that the potential application of Part 11 to the medicated animal feed manufacturing sector was recognized.

It was then that representatives of the NGFA and the American Feed Industry Association met on Feb. 13, 2001 with officials from FDA/CVM to express concerns over how Part 11 might be applied to medicated feed manufacturers that utilize computerized records to comply with FDA’s CGMPs. During this meeting, FDA officials indicated that FDA/CVM in October 2000 had reviewed its interpretation regarding the application of Part 11 on the medicated feed industry. Further, it is our understanding that CVM did so at the direction of FDA’s Office of Regulatory Affairs, which subsequent to publication of the final rule had determined that the Part 11 regulations applied to all industries regulated by FDA, rather than just the pharmaceutical industry.

Thus, the existing Part 11 regulations are written in a way that makes them most appropriate for the pharmaceutical manufacturing sector. Specifically, these rules were developed primarily for the development and submission of data in support of human and animal drug approvals. Indeed, the general section of the Code of Federal Regulations [21 CFR Part 11] under which these regulations were developed is not specific to medicated animal feed manufacturing.

The NGFA previously supported FDA’s withdrawal of its Compliance Policy Guide 7153.17 [*“Enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures”*], as well as previously issued Part 11-related draft guidance documents concerning electronic records and electronic signatures, validation, glossary of terms, time stamps and maintenance of electronic records, because they no longer represented the agency’s overall approach to Part 11. Likewise, we commended the agency for issuing new draft guidance that stated that FDA will take a risk-based approach to Part 11 and exercise enforcement discretion during the reexamination period with respect to certain provisions [*computer validation, audit trail, legacy systems, record-copying and record-retention.*]

¹ NGFA Statement submitted to FDA Dockets Management Branch on Docket Nos. 03-D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539; “Draft Guidance for Industry on Part 11, Electronic Records, Electronic Signatures – Scope and Application.” April 28, 2003.

The NGFA believes strongly that as FDA considers revisions to its Part 11 regulations, it needs to recognize the different and widely divergent types of industries and products affected. For instance, for medicated feed manufacturers, the types of records and signatures developed and maintained for compliance with the medicated feed CGMPs pertain to the following:

- Master production records (e.g., medicated feed formulas, labels, and manufacturing procedures related to the production of medicated feeds).
- Production records (e.g., production history, including micro and macro batching, pelleting, packaging or bulk load out, feed formulation, labeling and sequencing/flushing of medicated feeds).
- Distribution records.
- Records associated with the receipt, use and inventory of animal drugs in medicated feeds.

In addition, each of the aforementioned records requires signatures or initials of responsible persons completing and/or reviewing these records.

Specifically, the NGFA believes that a literal interpretation of existing Part 11 compliance requirements as applied to the manufacturers of human and animal drugs is inappropriate for those complying with the aforementioned medicated feed CGMPs. Further, we believe that “lumping” the medicated animal feed manufacturing sector in with the pharmaceutical and other industry sectors would contravene the agency’s stated intent of developing a risk-based approach to Part 11, and would result in precisely the kind of adverse consequences that FDA states in the notice that it wants to avoid, namely:

- unnecessarily restrict the use of electronic technology in a way that is inconsistent with FDA’s stated intent;
- significantly increase capital outlays and compliance costs; and/or
- discourage innovation and technological advances without providing a significant public health benefit to man or animals.

Further, in the case of medicated animal feed manufacturers, applying Part 11 indiscriminately could cause certain manufacturers to reduce their use of medications in rations in an effort to exempt themselves from Part 11’s requirements. In effect, the cost of undertaking the required modifications to computer systems may exceed benefits associated with manufacturing medicated feeds. This could have a negative affect on both animal welfare and food safety.

In the remainder of this statement, the NGFA provides responses to each of the questions posed by FDA. But we want to make clear here that our “bottom-line” view is that FDA needs to fundamentally change its approach if it is to truly implement a risk-based Part 11. Specifically, the NGFA believes that FDA should determine whether and how to apply Part 11 based upon the affected industry sector and the applicable predicate FDA rules with which each sector is required to comply. **In that regard, the NGFA strongly recommends that FDA determine through its current Animal Feed Safety System (AFSS) initiative whether and how to apply Part 11 to the medicated feed manufacturing industry.** The AFSS [Docket No. 2003N-0312], launched by FDA/CVM September 2003, is intended to be a comprehensive, risk-based approach to animal feed safety.

The following are the NGFA’s responses to each of the questions posed by FDA in its April 8, 2004 notice:

A. Part 11 Subpart A – General Provisions.

1. ***FDA Question:*** *In the part 11 guidance document, we clarified that only certain records would fall within the scope of part 11. For example, we stated that under the narrow interpretation of its scope, part 11 would apply where records are required to be maintained under predicate rules or submitted to FDA, and when persons choose to use records in electronic format in place of paper format. On the other hand, when persons use computers to generate paper printouts of electronic records, those paper records meet all the requirements of the applicable predicate rules, and persons rely on the paper records to perform their regulated activities, FDA would generally not consider persons to be “using electronic records in lieu of paper records” under Sec. 11.2(a) and (b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11. We are interested in comments on FDA’s interpretation of the narrow scope of part 11 as discussed in the part 11 guidance and whether part 11 should be revised to implement the narrow interpretation described in the guidance.”*

NGFA Response: Our concerns over the application of Part 11 to the medicated feed manufacturing sector would **not** be mollified by FDA clarifying that it does not apply to situations in which persons use computers to generate paper printouts of electronic records, and those records meet all of the requirements of the applicable predicate rules and persons rely on those paper records to perform their regulated activities. The previously cited records (master production records, production records, distribution records and animal drug receipt, use and inventory records) required to be maintained under the medicated feed CGMPs [21 CFR Part 225] are FDA-predicate rules. Granted, some small, single-facility commercial medicated feed mills continue to generate these records by hand or to print out and rely upon paper copies of computer records (and thus would not be subject to Part 11 based upon FDA’s guidance). But most medicated feed

manufacturers – particularly larger firms – use electronic programs in the development, storage and use of these records because doing so improves the accuracy and integrity of the records themselves, while reducing business costs attributable to fewer man-hours and fewer human errors. FDA's suggested clarification would provide no regulatory or economic relief to these firms. Instead, it would defeat the purpose of maintaining electronic records and signatures for these purposes, or impose substantial additional financial costs that could not be passed on to customers given the highly competitive nature of the industry. Further, as FDA/CVM is aware, the medicated feed CGMPs are not enforced uniformly across the industry. Thus, regulation for compliance with Part 11 also would be focused on a relatively few medicated feed manufacturers, creating additional disparities in costs incurred by those subjected to such oversight.

2. *FDA: "We are interested in comments on whether revisions to definitions in part 11 would help clarify a narrow approach and suggestions for any such revisions."*

NGFA Response: Revisions to definitions in Part 11 would help narrow their applicability. But as explained in our response to question 1, such action would not go far enough for the medicated feed manufacturing sector. As noted in the preface to this statement, the NGFA strongly believes that the predicate rule requirements for medicated feed CGMPs established under 21 CFR Part 225 should be exempt from Part 11 requirements, and that the records should be evaluated for compliance with Part 225 requirements on a case-by-case basis. Under current medicated feed mill inspections, such records are reviewed on a routine basis. To our knowledge, neither the industry nor FDA have experienced adverse food or feed safety issues attributable to problems involving the accuracy or integrity of electronic records or electronic signatures in compliance with Part 225.

3. *FDA: In the part 11 guidance, we announced that we did not intend to take enforcement action to enforce compliance with the validation, audit trail, record retention, and record copying requirements of part 11 in the manner described in the part 11 guidance. We emphasized that records must still be maintained or submitted in accordance with the underlying predicate rules, and the agency could take regulatory action for noncompliance with such predicate rules. We are interested in comments on the need for clarification in part 11 regarding which records are required by predicate rules and are therefore required to be part 11 compliant?*

NGFA: We believe that the revised guidance published in August 2003 is clear and unambiguous. Part 11 should be amended to reflect comparable language.

B. Part 11 Subpart B – Electronic Records.

1. **FDA:** *As mentioned previously, the part 11 guidance identified four areas where we do not intend to take enforcement action under the circumstances described in the part 11 guidance, including the validation, audit trail, record retention, and record copying requirements of part 11. The part 11 guidance further recommends that decisions on whether or not to implement part 11 requirements on validation, audit trail, record retention, and record copying should be based on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity. We are interested in comments on whether there are other areas of part 11 that should incorporate the concept of a risk-based approach, detailed in the part 11 guidance (e.g., those that require operational system and device checks).*

NGFA: As expressed previously, the NGFA believes that records related to the medicated feed CGMPs contained in 21 CFR Part 225 should be excluded from Part 11 requirements and instead be addressed as part of FDA/CVM's Animal Feed Safety System initiative that is developing a comprehensive, risk-based approach to feed safety hazards. The NGFA believes that FDA should determine whether and how to apply Part 11 based upon the affected industry sector and the applicable predicate FDA rules with which each sector is required to comply.

2. **FDA:** *Is additional clarity needed regarding how predicate rule requirements related to subpart B can be fulfilled?"*

NGFA: As stated previously, the NGFA believes that FDA should determine whether and how to apply Part 11 based upon the affected industry sector and the applicable predicate FDA rules with which each sector is required to comply. Such clarity can be provided through that sector-specific process.

3. **FDA:** *Under the current part 11, the controls that apply to electronic records that are maintained also apply to electronic records that are submitted to FDA. Should the requirements for electronic records be separate from electronic records maintained to satisfy predicate rule requirements?*

NGFA: The NGFA believes that Part 11 requirements applicable to electronic records maintained for submission to FDA **should be distinct from, and treated differently than**, those records maintained for compliance with medicated feed CGMP [Part 225] predicate rules.

4. **FDA:** *The controls for electronic records in subpart B distinguish between open systems (an environment where system access is not controlled by persons who are responsible for the content of electronic records that are on the system) and closed systems (an environment where system access is controlled by persons who are responsible for the content of electronic records that are on the system). Should part 11 continue to differentiate between open systems and closed*

systems?"

NGFA: Were medicated feed manufacturers interpreted to have "open" systems, such requirements under Part 11 would far exceed what is required to comply with CGMP records. Further, we believe the costs would be prohibitive, amounting to millions of dollars across the industry. In addition, our members have checked with vendors of computer software and report that many are unaware of the potential applicability of Part 11 rules. Those vendors that are aware of Part 11 have not taken steps yet to bring their products into compliance, and we believe this process would take an estimated five years or longer, depending upon the demand crunch imposed on such vendors.

Most importantly, the NGFA has major concerns that even if such a conversion were implemented to make medicated feed mill computer systems Part 11-compliant, there would be no demonstrable resulting benefit in terms of improvements to feed safety or public health. FDA's current focus on food safety systems is a far better use of time and resources for protecting public health than applying Part 11 requirements to medicated feed records.

Comments Pertinent to Individual Controls in Subpart B:

1. **FDA:** *The part 11 guidance identified validation as one of the four areas where we intend to exercise enforcement discretion in the manner described in the guidance. Should we retain the validation provision under Sec. 11.10(b) required to ensure that a system meets predicate rule requirements for validation?*

NGFA: FDA/CVM has used regulatory discretion in the enforcement of validation provisions on software and hardware used for compliance with Part 225. This discretion has been based upon lack of need, and a sound compliance record by the industry. Indeed if the agency were to enforce the validation provisions, feed manufacturers likely would find it necessary to revert to paper-reliant systems, thereby losing much of the efficiency and improved accuracy currently derived from using electronic systems. While legacy systems can be excluded from validation requirements, they continue to be enhanced and updated, making them subject to Part 11 requirements. For these reasons, the NGFA believes FDA/CVM should continue to be permitted to exercise enforcement discretion over the application of Part 11 requirements to medicated feed CGMP requirements promulgated under Part 225.

2. **FDA:** *The part 11 guidance identified record retention and record copying requirements as areas where we plan to exercise enforcement discretion in the manner described in the part 11 guidance. Are there any related predicate rule requirements that you believe are necessary to preserve the content and meaning of records with respect to record copying and record retention? What requirements would preserve record security and integrity and ensure that records*

are suitable for inspection, review, and copying by the agency?

NGFA: For the reasons previously cited, we believe that all medicated feed CGMP records promulgated under 21 CFR Part 225 should be subject to enforcement discretion by FDA/CVM concerning Part 11 compliance. Electronic Part 225 records are more accurate and improve feed safety compliance in many ways. The ultimate beneficiaries are feed customers, who receive a higher-integrity product at a lower cost than otherwise would be the case. Compliance with Part 11 will move many users of electronic records and procedures back to paper recordkeeping systems kept by hand. This would not be in the public interest. Conversely, as noted previously, applying Part 11 indiscriminately could cause some other manufacturers to reduce their use of medications in rations in an effort to exempt themselves from Part 11's requirements. In effect, the cost of undertaking the required modifications to computer systems may exceed benefits associated with manufacturing medicated feeds. This could have a negative affect on both animal welfare and food safety.

3. *FDA: Should audit trail requirements include safeguards designed and implemented to deter, prevent, and document unauthorized record creation, modification, and deletion?*

NGFA: Our members estimate audit-trail requirements would increase costs substantially on an initial investment, and on an ongoing basis. Several member companies have examined this issue very carefully, and do not find any added value from this additional investment in human resource time and computer programming costs spent solely for FDA-compliance purposes. Such investment of human and capital resources could detract from feed and food safety measures that are much more important to public health.

4. *FDA: Section 11.10(k) requires appropriate controls over systems documentation. In light of how technology has developed since part 11 became effective, should part 11 be modified to incorporate concepts, such as configuration and document management, for all of a system's software and hardware?*

NGFA: We believe that the additional control over system documentation, in the case of Part 225 compliance, would not have a feed safety benefit. These additional controls would result in more reliance upon paper records kept by hand rather than automating such functions, which has been shown in the medicated feed industry to improve product safety and reduce product cost.

C. Part 11 Subpart C – Electronic Signatures

FDA: Within the context of subpart C, we would like interested parties to address the following: Section 11.10(d) requires that system access be limited to

authorized individuals, but it does not address the handling of security breaches where an unauthorized individual accesses the system. Should part 11 address investigations and follow-up when these security breaches occur?

NGFA: We do not believe that Part 11 should be required for electronic signatures on medicated feed CGMP Part 225 records, and therefore this question is not applicable.

D. Additional Questions

1. *FDA: What are the economic ramifications of modifying part 11 based on the issues raised in this document?"*

NGFA: In most cases, modifying Part 11 as outlined in this notice would result in the medicated feed industry needing to upgrade computer and software systems. In many cases, entirely new computer systems and software would be required, despite the fact that existing systems are operating flawlessly and FDA/CVM has not raised this matter as a feed safety concern. Considering the diverse nature of the medicated feed industry, tremendous economic consequences would result. The NGFA believes the ultimate loser would be feed customers and the public, as the result most likely would be a return to paper-reliant systems that are not as accurate, nor as efficient, as today's electronic systems. As explained previously, the NGFA believes CVM is in the best position to address any pertinent Part 11-related requirements for medicated feed CGMPs as part of its AFSS initiative.

2. *FDA: Is there a need to clarify in part 11 which records are required by predicate rules where those records are not specifically identified in predicate rules? If so, how could this distinction be made?*

NGFA: As they pertain to the medicated feed sector, the NGFA believes that predicate rules are clear and need no further identification.

3. *FDA: In what ways can part 11 discourage innovation?*

NGFA: Part 11 will discourage innovation among the medicated feed industry when it comes to part 225 compliance by:

- causing many medicated feed manufacturers to revert to hand-kept paper records to avoid the costs and complexities resulting from FDA's application of Part 11 requirements for electronic records and signatures. Given the fiercely competitive nature and the overcapacity that exists in the medicated feed industry, any additional costs likely would be borne by the feed manufacturer, particularly since a significant percentage of the industry currently relies on manual records. In effect, the cost of compliance with

Part 11 requirements would offset the economic advantages of utilizing electronic records.

- triggering compliance with other rules, such as validation requirements, resulting in no added value but only compliance costs. To be successful, compliance costs also must bring value, especially in terms of added animal feed and human food safety. In this case, these additional Part 11 rules bring no such commensurate benefit.

1. *FDA: What potential changes to part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health?*

NGFA: In the case of Part 225 compliance, our previous recommendations of vesting the application of Part 11 with FDA/CVM and having FDA/CVM consider the medicated feed CGMPs under its AFSS initiative would more than adequately protect human and animal health. At the same time, it would allow FDA to meet its objective of encouraging, not retarding, technological innovation and enabling the industry and the public health to benefit from the accuracies and efficiencies gained by utilizing electronic records and signatures. The net result is more efficient medicated feed manufacturing operations, and improved product safety and affordability for feed purchasers and consumers of meat, milk and egg products.

2. *FDA: What risk-based approaches would help to ensure that electronic records have the appropriate levels of integrity and authenticity elements and that electronic signatures are legally binding and authentic?*

NGFA: We believe strongly that existing government-based inspections and enforcement conducted by FDA/CVM and State Departments of Agriculture, through state-federal partnerships, provide a risk-based approach for ensuring the integrity and authenticity elements of records maintained for medicated feed CGMP Part 225 compliance. The NGFA strongly supports FDA/CVM's inclusion of Part 225 regulations and compliance as part of its AFSS initiative, which is the best means of ensuring feed safety.

3. *FDA: The part 11 guidance announced that the agency would exercise enforcement discretion (during our reexamination of part 11) with respect to all part 11 requirements for systems that otherwise were operational prior to Aug. 20, 1997 (legacy systems), the effective date of part 11. What are stakeholder concerns in regards to modifications made to legacy systems in use as of August 1997? Can the use of risk mitigation and appropriate controls eliminate concerns regarding legacy systems?*

NGFA: As noted previously, the NGFA's concern is that modifications to legacy systems will cause such systems to be subject to full compliance with Part 11. We

believe we have articulated our concerns relative to the problems and issues associated with Part 11 requirements. Most medicated feed manufacturing companies that use electronic systems have both legacy and newer systems placed into operation since the Aug. 20, 1997 effective date of the Part 11 regulations. This means many multi-facility companies have a combination of systems that have been programmed to work together in their medicated feed CGMP Part 225 compliance efforts. Part 225 records created from such systems have been evaluated as adequate for part 225 compliance needs by FDA and state inspectors, and have not been found to present food or feed safety concerns. Several NGFA-member companies have examined closely their internal computer systems used to comply with Part 225, and have evaluated them against the requirements of Part 11. We believe the costs for such upgrades will result in a reduction in their use, and a return to paper systems that resulted in human errors that electronic systems have helped to eliminate.

4. *FDA: Should Part 11 address record conversion?*

NGFA: In the case of Part 225 compliance, Part 11 should not address record conversion.

5. *FDA: Are there provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies that have become available since part 11 was issued?"*

NGFA: We believe Part 225 requirements should not be within the jurisdiction of Part 11, and therefore have no comment. However, regulations must be flexible to adapt to technology and market needs. The NGFA again reiterates its belief that any consideration of technology impacts should, in the case of the predicate requirements of Part 225, be considered by FDA/CVM within its AFSS initiative – and not be a function of Part 11.

Conclusion

In summary, the NGFA fully supports FDA's efforts to improve feed safety to protect human and animal health. The NGFA also has publicly supported FDA/CVM's AFSS initiative, and believe it is the prudent, risk-based way to address any Part 11 issues that could affect feed or food safety.

Further, government-based inspections conducted by FDA/CVM and states are adequately overseeing medicated feed manufacturing establishments subject to Part 225 CGMPs. For these reasons, we do not believe Part 225 should be subject to Part 11 requirements applied to the pharmaceutical industry. Doing otherwise would trigger a multitude of additional costs, and compliance complexities that would far exceed any commensurate feed safety benefits.

When initially developed, Part 11 did not consider Part 225 compliance issues nor the impact such rules would have on the regulated medicated feed manufacturer. And FDA should not attempt to foist its burdensome, costly and stifling requirements upon this vital industry sector now.

Sincerely yours,



Joe Garber, Chairman
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