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Food & Drug Administration
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Food & Drug Administration
Docket No. 2004N-0133
Electronic Record; Electronic Signatures

Land O'Lakes Farmland Feed LLC ("LOLFL"), together with its subsidiaries, is a major manufacturer and distributor of animal feed, including medicated feed, and therefore has a vital interest in the above referenced rule. LOLFL also works with cooperative feed manufacturers and dealers marketing brands, such as LAND O LAKES® feed and Purina Mills products, and other independent businesses manufacturing and selling animal feed who are stakeholders in the U.S. food safety system. All of our facilities and marketing are conducted in full compliance with 21 CFR Part 225.

The above referenced rule, which we will refer to as "Part 11," provides the criteria under which FDA considers electronic records and signatures equivalent to paper records and hand written signatures. For LOLFL, these are records and signatures developed and maintained for compliance with Part 225, (Medicated Feed cGMP's). Part 11 regulations issued March 20, 1997, were developed by the agency with inputs primarily from the human and animal drug industries. These rules were developed primarily for development and submission of data in support of human and animal drug approvals.

Indeed, the major trade associations of animal feed manufacturers and marketers – the National Grain and Feed Association (NGFA) and American Feed Industry Association (AFIA) – were not aware of this rule until it was issued as final. Only after being told by FDA that the rule was applicable to medicated feed manufacturers were the industry trade associations aware of Part 11 significance to medicated feed manufacturers. NGFA and AFIA learned that this regulation applies to all industries regulated by FDA, including manufacturers of medicated feed. The regulation is applicable to any record maintained by a firm to satisfy an FDA requirement, and in our case, Part 225.

In the notice for comment, FDA notes that concerns have been raised that Part 11 requirements in some cases:

- Unnecessarily restrict the use of electronic technology in a manner inconsistent with FDA's stated intent in issuing the rule.
- Significantly increase the costs of compliance to an extent that was not contemplated at the time the rule was drafted.
- Discourage innovation and technological advances without providing a significant public health benefit.

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In brief, Part 11 records impacted by this rule for medicated feed manufacturers are as follows:

- Master Production Records (formula, label, bulletins that detail manufacturing information relative to medicated feed manufacture)
- Production records: production history including micro & macro batching, pelleting, packing or bulk load out, formulation, labeling and sequencing
- Distribution records
- Drug receipt, use and inventory

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

In this notice requesting comment, the agency asks that certain Part 11 issues be addressed. This then addresses those issues, which impact the medicated feed compliance effort.

Part 11 Subpart A – General Provisions.

1. “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.”

(Response): The above records, required to be maintained by Part 225 for medicated feed, are predicate rules. In each case, the records can be generated by hand rather than electronically. Indeed, many small, one-mill facilities continue to generate these records by hand and thus are not subject to these rules. However, LOLFL operates more than 80 facilities. The use of electronic programs in the development, storage and use of these records improves the accuracy and integrity of such records while reducing the cost of doing business due to reduced labor hours and reduced errors. When evaluating the costs for compliance with the Part 11 requirements that would be established for these records and appropriate signatures, such savings are eliminated and costs of doing business increased, discouraging the use of electronic programs for these records. If all participants in the medicated feed industry were subject to these same costs, then they could be passed on with the price of a ton of feed. But with the fragmentation of the feed industry, such

additional costs can not be justified in added value to the feed purchaser. Further, as CVM knows, enforcement of medicated feed rules is not uniform in the industry. Therefore, LOLFL would expect that enforcement of Part 11 requirements would also be focused to a few in the industry creating competitive costs issues for those targeted.

2. “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.”

(Response): The revisions to definitions in Part 11 do help to narrow their applicability, but in the case of medicated feed do not go far enough. Requirements established by Part 225 should be exempt from Part 11 requirements, and the records should be evaluated for their compliance with Part 225 requirements on a case-by-case basis. In today’s medicated feed inspections, such records are reviewed on a routine basis and neither the industry nor FDA has experienced any problems with the accuracy or integrity of electronic records in compliance with Part 225. In the review of today’s food safety systems, use of electronic records is a non-issue.

3. “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?”

(Response): We believe that the guidance is clear and does not need clarification.

B. Part 11 Subpart B – Electronic Records.

1. “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).”

(Response): LOLFL maintains that Part 225 records should be excluded from Part 11 requirements, and the feed safety risk-based assessment should become a function of CVM’s Animal Feed Safety System approach to feed safety.

2. “Is additional clarity needed regarding how predicate rule requirements related to subpart B can be fulfilled?”

(Response): We see no need for further clarification.

3. “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 be separate from electronic records maintained to satisfy predicate rule requirements?”

(Response): LOLFL agrees that Part 11 requirements applicable to electronic records maintained for submission to FDA should be treated differently than those records maintained for compliance with predicate rules, in our case, Part 225 rules. It is our understanding that Part 11 rules were initially developed for those records developed and maintained for submission to FDA in mind.

4. “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?”

(Response): The differentiation between open and closed systems leads to the conclusion that feed mills would be open systems requiring security far beyond what is actually needed for cGMP records. We have estimated that compliance with this requirement alone, in our mills, would exceed \$7 million. Further, we estimate that it would take more than 4.5 years working with our vendors to bring our mills into compliance, and that assumes that the vendor has time to give to us, as other feed companies will have the same issues. We have checked with 5 leading industry vendors, and found that many are not aware of the applicability of Part 11 rules. Further, those that are aware of the Part 11 rules have not yet taken steps to bring their products under Part 11 requirements.

We have real concerns that, after such a conversion to bring systems into Part 11 compliance, we will lose productivity and will have not added value to our quality effort or to the protection of public health. FDA’s present focus on food safety systems is far more appropriate for protection of public health than is the Part 11 requirements being applied to medicated feed records.

”For Individual Controls in subpart B we Request Comments on the Following:

1. “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?”

(Response): The Center for Veterinarian Medicine 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, there is a real probability that feed manufacturers would be forced to return to paper systems. Manufacturers would need to closely review the tradeoffs of paper systems versus the efficiency and improved accuracy they presently derive from use of electronic systems. While legacy systems can be excluded from validation requirements, they continue to be enhanced and revised, bringing them again under present rules. LOLFL therefore requests CVM be permitted to have jurisdiction of validation requirements as they apply to Part 225.

2. "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?"

(Response): We believe that all Part 225 records should be identified for exercise of enforcement discretion in Part 11 compliance for the reasons given above. Electronic Part 225 records are more accurate and improve feed safety compliance in many ways resulting in providing the feed purchaser with a less expensive product of higher integrity. Compliance with Part 11 will move many users of electronic records and procedures back to paper hand systems. This is not in the public interest.

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

(Response): We estimate that audit trails will increase our costs on an initial investment and ongoing basis. We estimate a minimum of three additional full-time persons (\$300,000 yearly) for compliance with this requirement, in addition to a minimum \$200,000 investment in programming. We have looked at this very carefully and do not find any added value from this additional investment in staff time or programming. The costs would be strictly compliance costs. When this cost is reviewed in terms of feed safety, we believe the money can be better spent in other ways for improvement in feed safety systems for the public benefit.

4. "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?"

(Response): We believe that the additional control over system documentation, in the case of Part 225 compliance, would not add to the feed safety effort. These additional

controls would result in more reliance on paper hand records and control, versus automating, which has been shown in the medicated feed industry to improve product safety and reduce product cost.

C. Part 11 Subpart C – Electronic Signatures

”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?”

(Response): LOLFL does not believe that part 11 should be required for electronic signatures on part 225 records; therefore, this question is not applicable.

D. Additional Questions for Comment

”In addition, we invite comment on the following questions:”

“1. What are the economic ramifications of modifying part 11 based on the issues raised in this document?”

(Response): In most cases, the feed industry’s present systems will need to be upgraded to comply with Part 11 requirements, and in many cases new systems will be required. Considering the fragmentation of the feed industry in terms of those subject to part 225 today, tremendous economic consequences will result for feed industry participants. We believe the loser will be the public, as the result will be the return to paper systems, which are not as accurate or as efficient, as today’s electronic systems. CVM today is developing an Animal Feed Safety System (AFSS), which we believe is incorporating all aspects of animal feed safety under a single feed umbrella, including protection of human safety. We believe that compliance with Part 11 for Part 225, would best be left with CVM as part of the AFSS package. Otherwise, the enforcement effort is confounded with the inclusion of Part 225 compliance with the Part 11 rule, which was issued without medicated feed Part 225 requirements in mind.

“2. 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?”

(Response): We believe that predicate rules are clear and need no further identification.

3. “In what ways can part 11 discourage innovation?”

(Response): Part 11 will discourage innovation for the feed industry in Part 225 compliance by:

- a. Increasing the cost of electronic records and signatures so that hand records and signatures are more economical. The cost for a ton of feed must be competitive, and any additional costs must be absorbed by the feed manufacturer. These costs will not be passed on so long as a significant portion of the feed industry continues to use hand records and, therefore, will not participate in the added costs of compliance for electronic records. The Part 11 requirements will offset electronic record savings.
- b. Triggering compliance with other rules such as validation requirements, resulting in no added value – but adding compliance costs. To be successful, compliance costs must also bring value especially in terms of added animal and human safety, and in this case, these additional rules bring no such added value.

4. “What potential changes to part 11 would encourage innovation and technical advances consistent with the agency's need to safeguard public health?”

(Response): In the case of Part 225 compliance, make enforcement of Part 11 subject to CVM jurisdiction. At the same time, CVM should make Part 225 compliance a part of the AFSS effort. This two-pronged approach would help ensure that the public is protected. In addition, the industry would be afforded an opportunity to continue to use and develop electronic records for more efficient operations, safer products of high integrity, and improved product safety for feed purchasers and consumers of meat, milk and egg products.

5. “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?”

(Response): We believe that CVM and the State Departments of Agriculture, through state-federal inspection programs, provide a risk-based approach today for ensuring the integrity and authenticity elements of Part 225 compliance. LOLFL strongly supports CVM's inclusion of Part 225 compliance in AFSS rules and enforcement, which is the best means of assuring continued feed safety.

6. “The part 11 guidance announced that the agency would exercise enforcement discretion (during our re-examination of part 11) with respect to all part 11 requirements for systems that otherwise were operational prior to August 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?”

(Response): Our concern is that modifications to legacy systems will trigger full compliance with Part 11 as noted previously in our comments. We believe we have articulated our concerns relative to the problems and issues associated with Part 11 requirements. Most feed companies that use electronic systems have both legacy and newer systems that were placed into operation following the agency's August 1997 rule. This means many multi-facility companies have a combination of systems that have been

programmed to work together in their Part 225 compliance efforts. Thus far, the industry has not had any compliance problems that result from Part 11 issues and have provided safe and effective feed products from such systems. Part 225 records have been evaluated as adequate for Part 225 compliance needs by FDA and State Inspectors, and no problems have resulted from electronic records or signatures. LOLFL has taken a detailed look at all of its systems impacting Part 225 compliance and has evaluated them against the demands of Part 11. We believe the costs for such upgrades will result in a reduction in their use and a return to paper systems, which elevate potential for human error issues that our electronic systems have helped to eliminate.

7. "Should Part 11 address record conversion?"

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

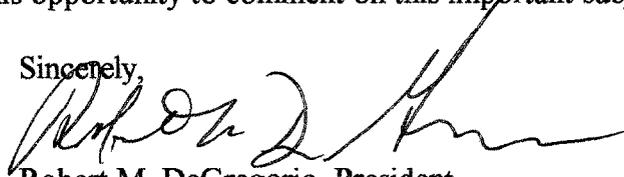
8."Are there provisions of part 11 that should be augmented, modified, or deleted as a result of new technologies that have become available since part 11 was issued?"

(Response): We believe Part 225 requirements should not be within the jurisdiction of Part 11, and therefore, have no comment. However, regulations must be fluid to change with technology and need. Any consideration for technology impacts should, in the case of predicate requirements of Part 225, be considered by CVM as within their AFSS jurisdiction, in terms of Part 225 needs, and not as a function of Part 11.

In summary, LOLFL is fully supportive of agency efforts to improve feed safety for both animals and humans. LOLFL is fully supportive of CVM's effort to develop an Animal Feed Safety System program, which we believe should include Part 11 issues. CVM and States participating in the joint inspection program are doing an adequate job of enforcement of Part 225 compliance, including record and signature integrity. As a result, they should not continue to be included in Part 11. Part 11 enforcement on Part 225 compliance will trigger a multitude of additional costs and compliance issues that go far beyond the value such requirements are perceived to provide for feed safety. Part 11, in its development, did not consider Part 225 compliance or the impact the rules would trigger for the regulated medicated feed manufacturer.

LOLFL has reviewed these requirements in considerable detail, and would be more than willing to review the details of the impact upon our electronic systems at the agency's convenience. LOLFL appreciates this opportunity to comment on this important subject.

Sincerely,



Robert M. DeGregorio, President
Land O'Lakes Farmland Feed LLC