National Grain and Feed Association

April 28, 2003

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

RE: Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539; Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures – Scope and Application"

The National Grain and Feed Association submits this statement in response to the Food and Drug Administration's notice seeking comment on its draft guidance concerning the scope and application of its 21 CFR Part 11 regulations regarding electronic records and electronic signatures.

Established in 1896, the NGFA is the U.S.-based non-profit trade association that consists of more than 1,000 grain, feed, processing and grain-related firms that operate more than 5,000 facilities and handle more than two-thirds of U.S. grains and oilseeds. More than 300 of the NGFA's member companies operate feed manufacturing and integrated feeding operations, ranging from the largest commercial feed manufacturer in North America to small grind-and-mix operations. Our member companies that manufacture medicated animal feed, in particular, have been keenly interested in the Part 11 issue.

The NGFA commends FDA for withdrawing 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Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures"*], as well as previously issued Part 11-related draft guidance documents concerning electronic records and electronic signatures, validation, glossary of terms, time stamps and maintenance of electronic records. We also commend FDA for issuing new draft guidance that states the agency will take a risk-based approach to compliance. When doing so, we urge the agency to apply this risk-based approach not only to the type(s) of regulated activities for which companies are relying on computers, but also to the relative degree of risk posed by the industry being regulated.

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We also commend FDA for stating in its draft Part 11 "scope" guidance that the agency intends to exercise enforcement discretion with respect to computer validation, audit trail, record-copying and record-retention requirements under Part 11, as well as for so-called "legacy" systems that were operational before the Part 11 final regulations became effective on Aug. 20, 1997. We strongly encourage FDA to specifically notify each of its centers of this enforcement stance to ensure implementation.

But most importantly, the NGFA commends FDA for announcing that it is embarking on a reexamination of Part 11 as it applies to all FDA-regulated products. The NGFA believes a reexamination of FDA's "Part 11" regulations is long overdue. We strongly urge the agency to consider revisions to these regulations that recognize the different and widely divergent types of industries and products that FDA regulates, and devote the balance of this statement to this important point.

These regulations were written in a way that makes them most appropriate for the pharmaceutical industry, at whose behest the Part 11 regulations were originally promulgated in 1997. This general section of the Code of Federal Regulations *[21 CFR Part 11]* is **not** specific to animal feeds, and the regulations concerning electronic records and electronic signatures were based upon input received primarily from the human and animal drug industries. The NGFA believes strongly that a literal interpretation of Part 11 compliance requirements as applied to the pharmaceutical industry is inappropriate for the animal feed manufacturing industry, is not risk-based and would result in extremely costly capital outlays to comply. The use of computer systems, the nature of the data and records, and the precision and degree of potential risk are much different, which we believe need to be acknowledged in the underlying regulations, as well as future guidance documents and compliance guides emanating from such rules.

Concerning the 1997 Part 11 regulations, it is our understanding that FDA's Center for Veterinary Medicine did consider the rules' potential application to animal drug manufacturers, but did not consider the impact on the animal feed manufacturing industry. To our knowledge, the animal feed and human food industries were not 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 notice-and-comment period. Indeed, the medicated animal feed industry was not even aware of the existence of this rulemaking until the final rule was published. And it was not until several years later that the feed industry first became aware of the potential application of the Part 11 regulations to medicated feed manufacturing operations.

Precisely because of this concern, representatives of the NGFA and the American Feed Industry Association on February 13, 2001 met with officials from FDA/CVM to express concerns over how the electronic record/electronic signature regulations might be applied to medicated feed manufacturers that utilize computer systems and are regulated by FDA for compliance with CGMPs. During this meeting, FDA officials indicated that FDA/CVM in October 2000 had reviewed its interpretation regarding the application of the electronic records/electronic signatures rule on the feed industry. 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. At that time, the representatives from the feed industry were informed by FDA that because the agency acknowledged that the electronic records/electronic signatures rule had been issued without adequate input from non-pharmaceutical industries, that FDA planned to review the rules and how to proceed relative to the rules' applicability to the food and medicated animal feed manufacturing sectors that operate under CGMPs. It is our understanding that FDA's Center for Food Safety and Applied Nutrition has made a similar commitment to the food processing industry.

In addition, in revisions to Compliance Program Guidance Manual 7371.004 *[TN 01-16]* issued on June 11, 2001, FDA/CVM referenced the application of the electronic records and signatures rule to medicated animal feed manufacturing and noted there had been "a lot of concern" registered by both the industry and FDA field personnel. FDA/CVM "clarif(ied)" in CPG 7371.004 that the Part 11 regulations apply to all FDA program areas, and said it had "concluded it is not appropriate to use inspectional discretion on whether or not to apply Part 11 requirements for CGMP inspections of the medicated feed industry." But the agency added that: "[r]egulatory significance and subsequent actions, if any, will be evaluated on a case-by-case basis...." CPG 7371.004 further stated that "...decisions on whether or not to pursue regulatory actions will be based upon and may include the following: 1) nature and extent of Part 11 deviation(s); 2) effect on product quality and data integrity; 3) adequacy and timeliness of planned corrective measures; and 4) compliance history of the establishment, especially with respect to data integrity." It is our understanding that CFSAN has adopted a similar enforcement stance for the food processing industry.

The NGA urges FDA, as a **first step** in its reexamination of Part 11 regulations as they apply to various industry sectors to direct CVM to initiate a dialogue and solicit specific feedback from the medicated animal feed manufacturing industry on an appropriate risk-based approach for this FDA-regulated sector. We encourage other FDA centers to do likewise with other affected non-pharmaceutical industries.

It is through this kind of dialogue that critical issues can be identified and addressed so that sound, risk-based, appropriate approaches can be implemented. Based upon this review, FDA will be in a much better position to determine how to revise the existing Part 11 regulations to more appropriately reflect the widely varying characteristics and relative degrees of potential risk posed by the broad range of industries that FDA regulates.

We appreciate your consideration of our comments.

Sincerely yours,

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