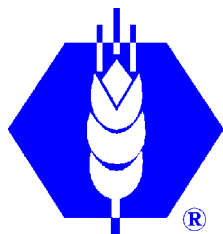


# **FDA's Bioterrorism Recordkeeping Regulations**

**...A Compliance Guide  
for Feed Dealers and Feed Stores...**



**National Grain and Feed Association**



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# Foreword

The U.S. Food and Drug Administration (FDA) on Dec. 9, 2004 issued final regulations implementing the section of the Bioterrorism Act of 2002 that requires most persons handling, storing, manufacturing, processing, packing, distributing or transporting agricultural commodities, feed, feed ingredients/additives and food products to establish, maintain and provide access to records.

This document, developed by the National Grain and Feed Association (NGFA), provides guidance specific to **feed dealers** and **feed stores** to assist these businesses in complying with those portions of FDA's bioterrorism recordkeeping requirements that apply to these type of operations.

For a more comprehensive review of FDA's bioterrorism recordkeeping regulations and their impact on other grain and feed industry sectors, readers are encouraged to obtain and review NGFA's publication entitled, *FDA's Bioterrorism Recordkeeping Regulations: A Compliance Guide for Grain Elevators, Feed Manufacturers, Feed Dealers, Integrators, Grain Processors and Transporters*. This publication is available free of charge and may be downloaded from the "Facility Security Guidance/Training Materials" section of the **NGFA/GEAPS Joint Facility Security Website**, which can be accessed through the NGFA website homepage at [www.ngfa.org](http://www.ngfa.org). Copies also may be obtained by sending an email request to [rgordon@ngfa.org](mailto:rgordon@ngfa.org).

The topics discussed and guidance provided in this document are **not intended to be formal recommendations or advice**. Nor is this document intended to be a comprehensive compilation of all of the FDA bioterrorism recordkeeping requirements that apply to all sectors of the agricultural and food industry, which span producers to the food and beverage industries. Rather, this document is intended to provide information on those aspects of the FDA bioterrorism recordkeeping regulations that directly apply to feed dealers and feed stores.

This guidance document will be updated periodically as new information becomes available. The NGFA will notify members through its *NGFA Newsletter* and *NGFA E-Alert* publications concerning future updates, and will post future versions in the "Facility Security Guidance/Training Materials" section of the **NGFA/GEAPS Joint Facility Security Website**. Readers also are reminded that this joint NGFA/GEAPS website is a valuable resource for keeping up-to-date on a wide range of developments concerning facility security and agroterrorism-prevention. Please visit the site frequently for updates.

We hope you find the information presented in this guidance document useful in complying with the FDA bioterrorism recordkeeping regulations. The NGFA encourages member companies to contact the Association with any additional questions on how these regulations may apply to specific business operations. For questions concerning the application of the FDA bioterrorism recordkeeping regulations to feed manufacturers, feeding operations and feed dealers/feed stores, NGFA members are encouraged to contact **David Fairfield**, NGFA director of feed services, either by email ([dfairfield@ngfa.org](mailto:dfairfield@ngfa.org)) or phone (712-243-4035).

We appreciate your membership in the NGFA!

# Notes



# FDA's Bioterrorism Recordkeeping Regulations

## ...How They Apply to Feed Dealers and Retail Feed Stores...

FDA's bioterrorism recordkeeping regulations pertain to those who “manufacture, process, pack, transport, distribute, receive, hold (*i.e., store*) or import food” in the United States.

The regulations adopt the same broad definition of “food” as used in the federal Food, Drug and Cosmetic Act, which includes feed, feed ingredients and other agricultural commodities “used as food or drink for man or animals.”

Such entities generally are required to establish and maintain records sufficient to identify the seller/supplier from which agricultural products are purchased – which the regulations call the “immediate previous source(s)” – and, in most cases, the buyer/receiver to which the agricultural products (e.g., feed, feed ingredients, etc.) are sold – which the regulations term “the immediate subsequent recipient,” as well as the transporters used. In essence, this is a one-step-back, one-step-forward recordkeeping obligation.

Those covered by the regulations also are required to maintain records containing information that is “reasonably available,” including information that links inbound deliveries with outbound shipments.

But FDA's bioterrorism recordkeeping regulations provide partial exemptions for certain types of “retail food establishments.” Retail food establishments, which encompass feed dealers and feed stores, are defined as those whose annual monetary value of sales of feed, pet food, feed ingredients/additives, and other products, directly to consumers exceeds the annual monetary value of sales to all other buyers (including businesses).

Importantly, farms and feeding operations involved in the raising of livestock, dairy cattle, poultry or other food-producing animals are **not** considered to be “consumers” under these regulations, since the feed products are being fed to animals that subsequently produce food or are processed and sold as food to final consumers.

For feed dealers or feed stores, examples of sales to “consumers” would include sales of bagged feed, pet food and feed ingredients/additives that the



final purchasers feed directly to their own animals – again, **unless** the feed is to be used in animals that will be sold as food or used to produce food for sale.

Because the dollar value of sales by most feed dealers is to farms and feeding operations – instead of direct to final consumers – most feed dealers likely will **not** qualify as a retail establishment.

## Records Required to be Kept by Feed Dealers/Feed Stores

Given this backdrop, here are several questions-and-answers concerning the kinds of records that feed dealers and feed stores are required to establish and maintain under FDA's bioterrorism recordkeeping regulations:

**1. Q: What kinds of records are feed dealers or feed stores are required to keep?**

**A:** That depends on type of sales and operations that occur at the feed dealer's or feed store's business.

Let's start with feed dealers and feed stores that do **not qualify as "retail food establishments"** under FDA's definition. So, here we're talking about stores where 50 percent or more of their annual monetary value of sales of feed, pet food, feed ingredients/additives and other products are to farms, feeding operations and other businesses **rather than** to final consumers. These type of establishments are required to establish and maintain records containing "reasonably available" information identifying the following:

- The **immediate previous source** (e.g., the supplier/seller) from which the feed product was received and the **immediate subsequent recipient** (e.g., the buyer/receiver) to which the feed product was shipped. Information is to include the name, address and telephone numbers of the immediate previous source and immediate subsequent recipient, and, if available, their fax numbers and email addresses. **There is one extremely important exception:** Feed dealers and feed stores are **not** required to maintain records of the immediate subsequent recipient (the buyer/receiver) or the transporter **if the shipment is directly to a final consumer**. Again, the definition of "consumer" does not include farms, feeding operations or other businesses.
- An **adequate description** of the type of feed shipped by the firm, such as the product name or other descriptors commonly found on a label or feed tag.

- The **date** the product was received and/or shipped.
- The **quantity** received and/or shipped, as well as the **packaging** (e.g., bag, tote, etc.) used. **Importantly**, FDA’s regulations require that those placing feed into direct contact with its finished container, such as a feed bag, establish and maintain records on that container if that is the packaging that will be received by the final consumer. But the container/package recordkeeping requirement does not apply to feed being shipped to a business (which includes farms) that subsequently will use or repackage the product before sale to a final consumer. Nor does it apply to feed being shipped in bulk (e.g., truck or railcar), since these are not classified as “finished containers” from which such products will be received by final consumers.
- The **lot or code number** (or other identifier) of products received and/or shipped to the extent such information exists. **Very importantly, lot numbers do not need to be created for purposes of this regulation.** Further, this particular recordkeeping requirement concerning lot/code numbers applies only to persons who manufacture, process or pack a food, feed, feed ingredient/additive, or agricultural product, not to those whose sole activities are to store and/or ship (distribute) such products. Feed dealers and feed stores who are **not** engaged in manufacturing, processing or packing feed are **not** required to establish and maintain records containing the lot numbers of the feed products they receive and distribute, even if lot numbers exist for such products.

In addition, if a feed dealer or feed store is engaged in the activities of manufacturing, processing or packing feed, the requirement to establish and maintain records on lot numbers of products received -- and to link such lot numbers to products shipped -- applies only to feed products related to those manufacturing/processing/packing activities, and then only to the extent that such lot number information exists and is reasonably available.

- The **transporter** from which the inbound delivery was received and/or the outbound product was shipped. Information is to include the transporter name, address and telephone number, and, if available, the fax number and email address. **There is one important exception:** Feed dealers and feed stores are **not** required to maintain records of the transporter used to haul the feed product if the shipment is directly to a final consumer. Again, the definition of “consumer” does not include farms, feeding operations or other businesses.
- **“Reasonably available” information** that links inbound deliveries with outbound shipments. FDA states that for **commingled products held in bulk storage**, such as grain or feed products, the “reasonably





available” information for an outbound shipment from such a bin is the identity of all potential sources of the grain or feed that had been delivered into the bin prior to the shipment. For example, if a feed dealer holds feed in bulk storage, the regulation requires that the feed dealer be able to identify all possible supplier sources and deliveries that could comprise the composite outbound shipment from that bin.

In the case of **identity-preserved or dedicated storage** for grains, feeds or feed ingredients, FDA states that the “reasonably available” information is the identity of the specific sources and those deliveries of each grain, feed or feed ingredient that is used to make up a finished feed product. For example, if a feed dealer mixes feed from grain and other feed ingredients, then the feed dealer is required to establish and maintain records to identify the specific sources and shipments of each grain and feed ingredient used to produce the mixed finished feed.

FDA addresses the issue of what it believes is “reasonably available” information to link inbound deliveries with outbound shipments in guidance the agency provided to industry on Nov. 10, 2005. In the guidance, the following question is posed to FDA: “A feed mill receives ingredients and commingles individual shipments into bins which are never completely empty. Over the course of a year, a hundred or more lots could theoretically be part of any food drawn from a bin. Would the feed mill have to provide all these lot numbers for food it releases?”

In its response, FDA states: “Yes....When a food is released by a manufacturer, the firm must establish and maintain records that include information reasonably available to identify the specific source of each ingredient used to make every lot of finished product....FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with specificity to the outgoing product, and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product.”

**2. Q: What about feed dealers and feed stores that do meet the definition of a “retail food establishment?”**

- A: For such establishments whose annual monetary value of sales direct to final consumers exceed the dollar value of sales to businesses (including farms and feeding operations), a different set of requirements apply.
- First, as noted previously, retail stores generally are required to establish and maintain records of inbound purchases/deliveries of feed products received from their “immediate previous source(s)” (*e.g., suppliers and associated transporters*) following the previously noted guidelines. The one exception applies to retail feed stores that have 10-or-fewer full-time equivalent employees. [*See more discussion on this 10-or-*

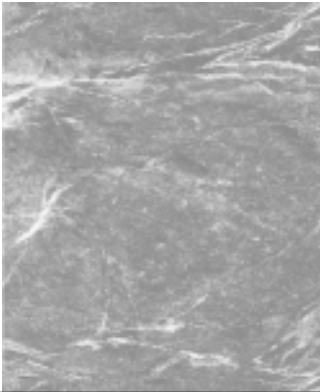


*fewer-employee exemption below.]*

- Second, all retail stores, regardless of size and just like all others subject to this regulation, are **not** required to establish and maintain records identifying the “immediate subsequent recipients” (e.g., *buyers/receivers*) or the transporters used to ship sales of feed, pet food products, etc., made directly to **final consumers**.
- Retail feed dealers and retail feed stores are required to establish and maintain records identifying **sales/deliveries** to businesses and other non-consumer “immediate subsequent recipients” (including to farms and feeding operations), as well as the transporters used for these shipments, **to the extent such information is “reasonably available.”** In this regard, FDA states that retail feed establishments do not have to go to extraordinary lengths to determine if the sale is to a consumer or a business; the recordkeeping obligation applies “only to the extent the information is reasonably available, (such as) when the purchaser has an existing commercial account” with the retail store, FDA states.
- As noted previously, feed dealers and feed stores that employ 10 or fewer full-time employees **and** meet the definition of a retail food establishment are exempt from the requirements under FDA’s bioterrorism regulations to establish and maintain records of their immediate previous source and immediate subsequent recipients, as well as the transporters used. However, they are required to provide FDA with access to existing records they otherwise already may keep as part of their normal business operations if FDA meets the legal threshold for accessing such records (discussed later in this document). Again, importantly, to qualify for this exemption, the store must meet the eligibility criteria in the definition for “retail food establishment” – namely, the majority of dollar value of product sales directly to “consumers” must exceed the annual monetary value of such sales to all other buyers (including farms, feeding operations and other businesses).

Importantly, this “10-or-fewer employee exemption” applies to the individual retail food/feed store, and not the entire corporate ownership under which that store may operate. So, for example, if three retail feed stores that employ 10 or fewer full-time employees are owned by a corporation that operates dozens of such stores, each of those three stores would qualify for the exemption even though the corporate entity employs hundreds of persons corporate-wide. Further, as explained later in this guidance document, FDA under the Bioterrorism Act must meet a high legal threshold before it can gain access to normal business records that retail facilities may maintain; specifically, the agency must





have a “reasonable belief” that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

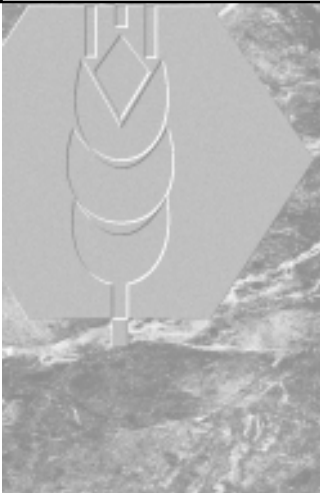
The following chart illustrates the recordkeeping requirements that apply to retail feed dealers and retail feed stores under the various scenarios outlined in response to this question.

<b>Bioterrorism Recordkeeping Requirements for Retail Food/Feed Stores<sup>1</sup></b>		
Type of Sale / Size of Store	Type of Records Required	
	Records of Suppliers/Transporters for Inbound Shipments (Immediate Previous Sources)	Records of Receivers/Transporters for Outbound Shipments (Immediate Subsequent Recipients)
Direct Sales to Final Consumers	Yes, to extent such information “reasonably available”	No <sup>2</sup>
Sales to Non-Consumers (Farms and Other Businesses)	Yes, to extent such information “reasonably available”	Yes, to extent such information “reasonably available”
10 or Fewer Full-Time Equivalent Employees	No <sup>3</sup>	No <sup>3</sup>
More than 10 Full-Time Equivalent Employees	Yes, to extent such information “reasonably available”	Yes, to extent such information “reasonably available,” unless direct sale is to final consumer

<sup>1</sup>To qualify under the definition of retail store, annual monetary value of sales of food/feed products directly to final consumers must be greater than annual monetary value of sales to all other customers (including farms, feeding operations, and other businesses)

<sup>2</sup>Applies to **ALL** entities subject to bioterrorism recordkeeping regulations, including retail stores

<sup>3</sup>Required to provide FDA with access to existing business records kept as part of normal business operations



**3. Q: What about feed dealers and feed stores that also are involved in manufacturing, processing or packing feed products for sale?**

A: If such establishments meet the criteria for being defined as a “retail food establishment,” they are subject to the requirements outlined in the response to question #2 above. If they do not qualify as a “retail food establishment” because their annual dollar sales to farms, feeding operations and other businesses exceed their annual dollar sales direct to consumers, they need to meet the requirements outlined in the response to question #1.

## What Constitutes ‘Reasonably Available’ Information for Recordkeeping Purposes?

One of the most vexing parts of FDA’s bioterrorism recordkeeping regulations is what constitutes “reasonably available” information that must be maintained in records.

FDA is intentionally vague in its regulations because a determination of what is “reasonably available” will vary depending upon the type of business and the individual circumstances that may exist. However, as noted in the response to question #1, FDA clearly recognizes in its regulations that the kind of specificity in records will depend on whether the product involved is a commingled, bulk product or an identity-preserved product. “In many instances, it will be impossible to identify the specific source of a material that is held in bulk and . . . multiple sourcing information in recordkeeping is to be anticipated for raw materials that are held in bulk form,” FDA states in the preamble to its final regulations. At another point, FDA acknowledges that “certain business practices are not amenable to linking incoming ingredients with outgoing product, and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. It is not FDA’s intent to mandate reengineering of long-standing existing processes. For this reason, the final rule requires the identification of the specific source of each ingredient that was used to make every lot of finished product only when the food is released and only if this information is reasonably available.”

*[Emphasis added.]*

FDA also has addressed with the NGFA the level of recordkeeping specificity applicable to delivery of commodities from farms in cases in which feed dealers or retail feed stores are required to maintain records of inbound shipments from immediate previous sources, as indicated in the following exchange:

**4. Q: What constitutes “reasonably available” information for the records that must be established and maintained for commodities received from farmers?**

A: In this regard, FDA has told the NGFA that information that identifies the landowner, tenant or name/location of the farm – or a combination of this information – will be sufficient for meeting the “reasonably available” requirement. Thus, to the extent such information is captured on scale tickets, warehouse receipts or settlement sheets, those documents will suffice. FDA also stated that records that designate the producer as both the “immediate previous source” and the “transporter” will suffice in situations when information about the transporter delivering the commodity from farms to the facility is not “reasonably available.” In addition, FDA stated that if the producer does not have a specific street address, a rural route number, post office box number and/or telephone number will suffice.





## Recordkeeping for Shipments of Feed Between Facilities Operated by Company

FDA's regulations do **not** require records for the transfer of feed products between facilities operating under the same legal entity – including vertically integrated companies – *provided* the product does not leave the “continuous control” of facilities and transportation conveyances operating under the same corporate ownership.

But legally distinct entities – including subsidiaries of a parent company – are required to maintain records when feed products are transferred between them. Further, records are required of the transfer of a shipment to an independent transporter even if the shipment involves a transfer between two facilities operated by the same legal entity, since the shipment is outside the control of the firm during the time it is in the possession of the independent hauler.

### Requirements for Maintaining Records

The following questions-and-answers provide information on several other aspects of the FDA bioterrorism recordkeeping requirements that apply to feed dealers and feed stores subject to these regulations.

**5. Q: *How must the records be maintained?***

A: FDA states that records may be kept in any format (including paper and electronic formats). FDA also does not stipulate that all of the required information be kept in one set of records or in one place. Instead, the agency stipulates that the required information be retained at the (on-site) establishment where the activities covered in the records occur, or at a reasonably accessible location.

**6. Q: *Can existing records be used to satisfy the regulation?***

A: Yes, so long as existing business records capture all of the information required under FDA's bioterrorism recordkeeping regulations. In its final rule, FDA “confirms that it is not necessary to develop a single record that contains all of the (required) information.” The agency said its “intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirements of these regulations.”

Thus, FDA does not require feed dealers or feed stores to establish a duplicate or separate recordkeeping system to comply with the regulations, so long as existing records contain the required information. Instead, FDA's regulations stipulate the kind of information that must be maintained. The agency notes that the required information can be

compiled from different records that the establishment already may be keeping. Thus, to the extent that establishments have existing business records that contain the required information, such records will suffice for FDA's purposes under the Bioterrorism Act.

**7. Q: When is compliance with the regulation required?**

A: For establishments that are subject to the bioterrorism recordkeeping requirements, the effective date depends upon the number of full-time employees at a given business (*e.g., the entrepreneurship, partnership, corporation, association, etc.*), as illustrated in the following chart:

Business Size	Total Number of Full-Time Equivalent Employees	Compliance Date
<b>Large</b>	$\geq 500$	Dec. 9, 2005
<b>Small</b>	11 to 499	June 9, 2006
<b>Very small</b>	$\leq 10$	Dec. 11, 2006


The number of full-time employees is determined by dividing the business's total number of hours of labor for which salary or wages are paid directly to employees by the number of hours worked in a year (2,080 hours, based upon 40 hours per week for 52 weeks). When performing this calculation, the hours for **all** employees for the **entire business** (not just individual establishment locations) is to be used, regardless of whether those employees are engaged in activities related to food subject to this regulation.

Importantly, the recordkeeping requirements are **not** retroactive. They apply only to covered activities (such as grain receiving and load-out; manufacturing of feed, feed ingredients, pet food; grain processing, etc.) that occur **on or after the effective dates**. For example, as reflected in the table above, records would **not** be required to be established for feed received in October 2006 by a feed dealer with 10 or fewer employees; but if that feed were shipped on or after Dec. 11, 2006, that feed dealer would be required to establish and maintain records of the outbound shipment.

**8. Q: Are water-soluble antibiotics subject to the recordkeeping requirements?**

A: FDA states that since the definition of "food" means "articles used for food or drink for man or other animals; chewing gum; and articles used





for components of any such article,” water-soluble antibiotics administered through water or as an additive in feed are covered under the regulation.

## **Record Retention and Access**

The following questions-and-answers contain information on how long firms that are required to establish records are required to keep them, as well as the conditions under which FDA can gain access to such records.

**9. Q: *How long do records need to be retained?***

A: The length of the recordkeeping-retention requirement depends upon how perishable the food is. Records associated with the purchase and distribution of animal feed (including pet food) must be retained for one year. Records for the purchase and distribution of grain must be kept for two years.

**10. Q: *Where must records be retained?***

A: FDA states that records can be retained at the establishment where the activities covered in the records occurred (on-site) or at a “reasonably” accessible location. Companies need to evaluate the location where records are maintained. That’s because the regulations require that establishments subject to these regulations provide FDA with access to required information “as soon as possible” and in no case later than 24 hours after the agency submits a written request.

**11. Q: *What are the record availability requirements?***

A: Under the law, FDA has access to such records and other information **only** when the agency has a reasonable belief that an article of food/feed is adulterated **and** presents a threat of serious adverse health consequences or death to humans or animals. As noted in the response to question #10, when this legal threshold is met, any records or other information to which FDA has access must be available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from time of receipt of the official request.

Importantly, Congress did not provide FDA with “audit authority” to review such records as part of routine inspections the agency may conduct. So, for instance, FDA does **not** have authority to inspect records required under the Bioterrorism Act when conducting an inspection of a licensed medicated feed manufacturer unless the legal threshold for accessing such records is met. FDA currently is reviewing ways to ensure that industry sectors covered by the bioterrorism recordkeeping regulations are aware of the requirements to maintain such records. FDA officials have told the NGFA that one way this may

be done during routine inspections is to ask if those covered are aware of the bioterrorism recordkeeping regulations and are prepared to respond to a request for access to such records within 24 hours if such a request is ever authorized. But FDA legally is prohibited from taking the next step – to ask to see such records – unless it meets the statutory threshold for accessing such records. That standard, again, is that the agency must have credible evidence that an article of food/feed is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

**12. Q: What procedures will FDA use to access records?**

A: FDA says it will adhere to the following procedures if one of its inspectors believes a feed product is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

- First, the inspector is to notify FDA’s Emergency Operations Center.
- Next, FDA’s Emergency Operations Center is to notify (either verbally or in writing) the appropriate FDA center (such as the Center for Food Safety and Applied Nutrition in the case of food or grain products, or the Center for Veterinary Medicine in the case of feed, feed ingredients or pet food), as well as FDA’s Office of Regulatory Affairs.
- FDA headquarters then will determine if the Bioterrorism Act legal threshold has been met; the scope of records access to be requested; and whether the requested records are necessary to assess whether a food is adulterated and presents a threat of serious adverse health consequences to humans or animals.
- Finally, FDA headquarters will obtain concurrence from FDA’s Office of General Counsel before a request to access records is issued. If each of the aforementioned procedural steps is met, an FDA investigator or other FDA personnel will submit a written notice – an FDA Form 482c, “Notice of Inspection” – to the owner, operator or agent in charge of the establishment (likely obtained from the facility registration also required under the Bioterrorism Act). Importantly, the notice will be directed to that specific establishment, and will be specific to records sought from that establishment. The FDA written notice will inform the establishment of the type and scope of records to which FDA is requesting access, as well as the agency’s legal authority for doing so. FDA notes that it has authority to request additional records related to the implicated article of food/feed at a later time.



**13. Q: Are there records that FDA cannot access?**

A: The law specifically prohibits FDA from having access to recipes (which encompass feed formulations); financial, pricing, personnel or research data; or sales data other than the shipment data regarding the sale of the suspect agricultural product.

**14. Q: Is there a penalty if feed dealers and feed stores do not comply with the FDA recordkeeping regulation?**

A: The Bioterrorism Act makes failure to establish or maintain records a “prohibited act” under the Federal Food, Drug and Cosmetic Act. The federal government can bring civil or criminal action in federal court against violators.

## **Conclusion**

This abbreviated guide has covered the information most pertinent to feed dealers and retail feed stores.

Readers are reminded of the availability of the NGFA’s comprehensive compliance guide that also addresses FDA bioterrorism recordkeeping requirements applicable to feed manufacturers, integrators, grain elevators, grain processors and transporters, which is available from the NGFA’s website at [www.ngfa.org](http://www.ngfa.org). Or, request a copy by contacting the NGFA at [rgordon@ngfa.org](mailto:rgordon@ngfa.org), or by calling 202-289-0873.