National Grain
and Feed Association
www.ngfa.org ngfa@ngfa.com

1400 Crystal Drive, Suite 260
Arlington, VA 22202

P: (202) 289-0873
F: (202) 289-5388

February 5, 2018

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

RE: Review of Existing Center for Veterinary Medicine Regulatory and Information Collection Requirements – Request for Comments and Information; Docket No. FDA–2017–N–5104

The National Grain and Feed Association (NGFA) submits this statement in response to the Food and Drug Administration (FDA) Center for Veterinary Medicine's (CVM) request for comments and information to help the agency identify existing regulations and related paperwork requirements that could be modified, repealed or replaced, consistent with the law, to achieve meaningful burden reduction while allowing FDA to achieve its public health mission and fulfill statutory obligations.

FDA's request pertains to the implementation of previously issued Executive Orders (EO) related to regulatory reform – EO 13771 entitled *"Reducing Regulation and Controlling Regulatory Costs"* and EO 13777 entitled *"Enforcing the Regulatory Reform Agenda."* EO 13771 stated that the policy of the Executive Branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources, and that it is essential to manage the costs associated with complying with federal regulations. EO 13777 was issued with the purpose of alleviating unnecessary regulatory burdens and directed each federal agency to establish a Regulatory Reform Task Force to evaluate existing regulations and identify those that may merit repeal, replacement or modification.

The NGFA, established in 1896, consists of more than 1,000 grain, feed, processing, exporting and other grain-related companies that operate more than 7,000 facilities and handle more than 70 percent of all U.S. grains and oilseeds. Its membership includes grain elevators; feed and feed ingredient manufacturers; biofuels companies; grain and oilseed processors and millers; exporters; livestock and poultry integrators; and associated firms that provide goods and services to the nation's grain, feed and processing industry. The NGFA also consists of 34 affiliated State and Regional Grain and Feed Associations, and has strategic alliances with Pet Food Institute and the North American Export Grain Association.

The NGFA appreciates this opportunity to provide comments on existing FDA regulations and information collections for the agency's consideration for repeal, replacement or modification. As indicated in the comments that follow, we believe there are several existing regulatory requirements that can be revised to achieve meaningful regulatory burden reduction while allowing FDA to fulfill its public health mission and statutory obligations.

FDA Should Amend Medicated Feed and VFD Regulations to Eliminate 21 CFR Part 11 Requirements

Name of the Regulations: Current Good Manufacturing Practice (CGMP) for Medicated Feed; Veterinary Feed Directive (VFD); Electronic Records; Electronic Signatures
Type of Product or FDA Center Regulating the Product: CVM
Citation to Code of Federal Regulations and Statutory Citation (as applicable): 21 Code of Federal Regulations (CFR) Part 225; 21 CFR Part 558; 21 CFR Part 11
Approved Information Collection and OMB Control Number (as applicable): N/A
Description of Concern: The NGFA and American Feed Industry Association (AFIA) on Aug. 25, 2016 and Feb. 27, 2017 submitted joint citizen petitions requesting FDA amend its regulations so that Part 11 electronic records and electronic signature requirements do not apply to any records required to be established and maintained under CGMP regulations for medicated feeds in Part 225 and VFD regulations in Part 558. The requested exemptions from Part 11 for all medicated feed CGMP- and VFD-related records would be consistent with FDA's recent decision to exempt from Part 11 compliance all documents required to be established and maintained under the FDA Food Safety Modernization Act (FSMA) regulations for CGMP, hazard analysis and risk-based preventive controls for animal food and human food (21 CFR Parts 507 and 117). An exemption would benefit the regulated industry by allowing it to complete its recordkeeping obligations in a more efficient and effective manner. Further, an exemption would benefit FDA, by enabling industry to provide documents to FDA for review (and copying, if warranted) in electronic form so that establishment inspections of manufacturers and distributors of medicated feed can be conducted more efficiently.
Available Data on Cost or Economic Impact: As stated in the petitions, to the best of NGFA's knowledge, none of its members that are in the business of manufacturing and distributing medicated feed – including those that are part of large corporations – currently have a computer system that is fully Part 11-compliant. The costs associated with developing and maintaining a Part 11-compliant computer system are

extremely burdensome. Based on informal inquiries, NGFA and AFIA generally are aware that the cost of developing a computerized electronic records and electronic signatures system in full compliance with Part 11 was about $150,000 per facility at the time that Part 11 requirements were adopted in 1997. With inflation, that cost is roughly $225,000 today.

Given that the feed industry is a very competitive industry characterized by low profit margins, feed manufacturers and distributors simply cannot absorb the costs of installing electronic systems that are compliant with Part 11 without raising prices. Thus, these costs, if incurred – which would not result in any discernable public health or animal health benefits – undoubtedly would be passed on ultimately to U.S. and foreign consumers. Rather than raise prices, it is NGFA's and AFIA's understanding that the feed industry has elected not to maintain records required by the medicated feed CGMP and VFD regulations in electronic form, and rather opt for much less efficient paper recordkeeping – to the detriment of FDA and the industry.

Proposed Solution:

The NGFA believes that the citizen petitions provide an appropriate opportunity for FDA to issue a "direct final rule" under the procedures set forth in FDA's Nov. 21, 1997 guidance entitled *"Direct Final Rule Procedures."* Considering the agency's approach in promulgating 21 CFR Parts 117 and 507, we believe it is unlikely that there will be any "significant adverse comment," as that term is defined in the direct final rule guidance. Therefore, we urge FDA to amend its regulations so that Part 11 electronic records and electronic signature requirements do not apply to any records required to be established and maintained by Parts 225 and 558.

FDA Should Eliminate Drug Establishment Registration for Facilities Holding a Medicated Feed Mill License

Name of the Regulations:

New Animal Drugs; Biological Products; Bulk Drug Substance

Type of Product or FDA Center Regulating the Product:

CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

Section 510 of the Federal Food, Drug, and Cosmetic Act (FFDCA); Section 351 of the Public Health Service Act, 21 CFR Part 207.3

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

To manufacture certain medicated animal feeds, FDA requires facilities to obtain and renew, as required, an FDA-issued medicated feed mill license and complete annual registration as a drug establishment.

In accordance with the Food and Drug Administration Amendments Act (FDAAA), FDA transitioned the required drug establishment registration from a relatively simple paper submission process to an extremely complicated and burdensome electronic submission via FDA's Electronic Submissions Gateway. The difficulty of the electronic submission process is exemplified by FDA's guidance document, "*Step-by-Step Instructions for Creating SPL Files For Electronic Drug Establishment Registration and Drug Listing v2.0*," which contains ***22 pages of complex and highly technical information*** on how to create the required Structured Product Labeling (SPL) file for use in drug establishment registration. This document is just one of multiple guidance documents issued by FDA to attempt to explain how to navigate the cumbersome and difficult process of making electronic submissions.

Although the electronic submission requirement has now been in place for several years, it still creates a significant regulatory burden, particularly for small- and mid-sized firms that do not employ specialized computer staffs to administer information technology systems.

Available Data on Cost or Economic Impact:

N/A

Proposed Solution:

The NGFA urges FDA to eliminate the requirement that facilities holding a medicated feed mill license also complete annual drug establishment registration. We believe that the FFDCA provides FDA with the authority to do so under Section 510(g)(5), which states "the Secretary may by regulation exempt from the application of this section [drug establishment registration] upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health." Clearly, annual drug establishment registration by facilities holding a medicated feed mill license is not necessary to protect public health.

FDA Should Recognize the Association of American Feed Control Officials' *Official Publication* List of Official Definitions for Feed Ingredients

Name of the Regulations:

Approval of Feed Ingredients

Type of Product or FDA Center Regulating the Product:

CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

N/A

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

For decades, FDA and the Association of American Feed Control Officials (AAFCO) have utilized a successful process to define ingredients that are acceptable for use in animal feed and pet food. This process allows FDA to review and approve safety and utility data submitted by the ingredient's sponsor and AAFCO to review and approve the ingredient definition. After AAFCO approval, ingredient definitions are published in the AAFCO *Official Publication* (OP), which is referenced in state feed laws as defining acceptable ingredients for use in animal feed and pet food. In addition, many foreign governments recognize the AAFCO ingredient definitions when evaluating the adequacy of U.S. feed ingredients for use within their countries.

In 2007, Congress enacted FDAAA, which requires FDA to promulgate regulations to define "ingredient standards and definitions with respect to pet food." Although FDAAA requires "ingredient standards and definitions" for only pet food ingredients, the vast majority of ingredients defined as acceptable for use are used for both animal feed and pet food products. Therefore, the FDAAA requirement essentially extends to all ingredients defined for use in both animal feed and pet food – the ingredients listed in the AAFCO OP.

To date, FDA has not completed rulemaking to define ingredient standards and continues to work within AAFCO to establish feed ingredient definitions via a memorandum of understanding originally signed in August 2007, and subsequently renewed to remain in effect currently. However, FDA has indicated that it believes many ingredients currently defined in the AAFCO OP will need to regain FDA approval either through its animal food petition process or be generally recognized as safe (GRAS). If FDA proceeds with such an approach, ingredient sponsors likely would need to spend hundreds of thousands of dollars for ingredients to be reapproved through food additive petitions or GRAS notifications.

Available Data on Cost or Economic Impact:

N/A

Proposed Solution:

As previously expressed to FDA, the NGFA believes that the intent of FDAAA was for the agency to define ingredient standards and definitions by promulgating regulations that adopt by reference those already listed within the AAFCO OP. Requiring existing AAFCO-defined feed ingredients that already have a history of safe use in animal feed and pet food to go through re-approval processes would not enhance animal feed and pet food safety, but would result in the animal food industry potentially expending millions of dollars for no benefit.

To avoid such an outcome, NGFA again requests that FDA adopt, through rulemaking and/or guidance document, ingredient definitions listed in the AAFCO OP as ingredient standards required under FDAAA.

FDA Guidance Should Indicate "Holding" Includes Activities Performed as a Practical Necessity for the Distribution of Food

Name of the Regulations:

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Type of Product or FDA Center Regulating the Product:

Center for Food Safety and Applied Nutrition (CFSAN); CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

21 CFR Part 117; 21 CFR Part 507

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

Parts 117 and 507 contain exemptions specific to certain establishments and facilities that "hold" certain foods. FDA's definition for "holding" states that "holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not

include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks."

Pertaining to the definition of "holding," FDA, within its draft guidance for industry issued in August 2016 – entitled *"Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry"* – states, "activities performed as a practical necessity for the distribution of [a] food are limited to only those activities that are truly necessary, as a practical matter, to any holding and distribution of the food in question. It would not be appropriate to consider activities optionally performed to add value to a food product as 'holding' on this basis, because such activities are not truly necessary to the distribution of the food."

To provide further thinking on this topic, FDA in its draft guidance compares "packing" to "holding," stating the two definitions are separate, but also acknowledging that some activities associated with putting food in a container are practical necessities for distributing food and considered "holding" for FDA's purposes. The NGFA believes such an acknowledgement by FDA – that some activities associated with putting food in a container are practical necessities for distributing food and considered "holding" – is appropriate and essential.

At facilities that are solely engaged in holding raw agricultural commodities for further distribution or processing (e.g., grain elevators), grain may be put in a container (e.g., a bag or intermodal container) as a practical necessity for distributing the food. In this situation, such an activity is inherent to "holding" because it is necessary for the practical distribution of the food. As such, FDA rightfully should not consider this activity of putting grain in a bag or an intermodal container as "packing." If FDA were to consider such activity as "packing" instead of "holding," that interpretation would cause the facility to not be solely engaged in "holding," and therefore subject to Parts 117 and/or 507. The NGFA strongly believes that such an outcome would not be consistent with a risk-based regulatory approach, would not advance human food or animal food safety and would impose unnecessary regulatory burdens and substantial costs on affected facilities.

Available Data on Cost or Economic Impact:

N/A

Proposed Solution:

FDA's draft guidance, *Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities; Draft Guidance for Industry*, offers some examples associated with grain-related activities to draw distinctions between "packing" and "holding." For example, the draft guidance states "… we [FDA] consider placing grain in a silo to be a practical necessity for distribution of the grain, and therefore 'holding' grain. Placing grain in a silo is not 'packing' grain, even though a silo might in some sense be

considered a 'container.' Similarly, we consider that loading food into a vehicle is not 'packing,' even though a vehicle might in some sense be considered a 'container.' Loading food into a vehicle as a practical necessity for distribution of the food is 'holding' (regardless of whether the food being loaded is in a container(s), or is loaded directly into the vehicle 'in bulk')."

To clarify further that some activities associated with putting food in a container are practical necessities for distributing food and considered "holding," the NGFA strongly recommends that FDA include an additional grain-related example within its final guidance that clearly indicates the agency considers the activity of putting grain in a container (e.g., a bag or intermodal container) when performed as a practical necessity for distribution as "holding."

FDA Should Modify the CGMP and Preventive Controls Requirements to Better Reflect Risks Posed to Food Safety – "Solely Engaged" Exemptions

Name of the Regulations:

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Type of Product or FDA Center Regulating the Product:

CFSAN; CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

21 CFR Part 117; 21 CFR Part 507

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

FFDCA Section 418 (m) provides FDA the authority to exempt or modify preventive controls requirements for certain facilities:

> *(m) Authority With Respect to Certain Facilities - The secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.*

Although FDA did in some respects exempt from or modify the preventive controls requirements for certain facilities during rulemaking that established Parts 117 and 507, the NGFA believes the agency has authority to provide additional exemptions and modifications so that the requirements are further applied in a risk-based manner while still assuring food safety.

Specifically, the NGFA believes that FDA should modify existing regulations and their application to the exemptions that apply to establishments and facilities "solely engaged" in certain activities. These exemptions refer to the primary subparts that contain CGMP and preventive controls requirements: subpart B (CGMPs), subparts C and G (human preventive controls) and subparts C and E (animal food preventive controls).

The relevant exemptions are as follows:

- Exemption from human food CGMP requirements - Part 117, subpart B does not apply to the following:
  - Establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities (RACs) (117.5(k)(1)(iii))
  - Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts (without additional manufacturing/processing, such as roasting nuts) (117.5(k)(1)(v))

- Exemption from human food preventive controls requirements - Part 117, subparts C and G do not apply to:
  - Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (117.5(j))
  - Facilities solely engaged in the storage of unexposed packaged food (117.7(a))

- Exemption from animal food CGMP requirements - Part 507, subpart B does not apply to the following:
  - Establishments solely engaged in the holding and/or transportation of one or more RACs (507.5(h)(1))
  - Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts and hulls (without manufacturing/processing, such as grinding shells or roasting nuts) (507.5(h)(2))
  - Establishments solely engaged in ginning of cotton (without manufacturing/processing, such as extracting oil from cottonseed) (507.5(h)(3))

- Exemption from animal food preventive controls requirements - Part 507, subparts C and E do not apply to:
  - Facilities that are solely engaged in the storage of RACs (other than fruits and vegetables) intended for further distribution or processing (507.5(g))

- Facilities solely engaged in the storage of unexposed packaged animal food that does not require time/temperature control to significantly minimize or prevent the growth of, or toxin production by, pathogens (507.10(a))

Of particular relevance to the exemptions is FDA's definition for "facility," which, as stated in 21 CFR 1.227, means, in relevant part, "any establishment, structure, or structures under one ownership at one general physical location…that manufactures/processes, packs, or holds food for consumption in the United States….A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership....".

Pertaining to the exemptions, FDA on Oct. 19 issued draft guidance for industry entitled "*Application of the "Solely Engaged" Exemptions in Parts 117 and 507"* to assist establishments and facilities determine whether they are "solely engaged" in certain activities.

In general, FDA's draft guidance states that the "solely engaged" exemptions provided within the regulations apply when the entire facility is only engaged in specified food-related activities for which a "solely engaged" exemption exists. More specifically, FDA states that a facility can be exempt from both CGMP and preventive controls requirements, for Parts 117 or 507 or both parts, only so long as it is engaged in any combination of activities that are exempt from CGMP and preventive controls requirements, and not engaged in activities that would be subject to those requirements.

Significantly, FDA states in the draft guidance that if any part of a facility is engaged in an activity subject to CGMP and/or or preventive controls requirements, then the entire facility is subject to the CGMP requirements, the preventive controls requirements, or both.

As an example, FDA's draft guidance states that a facility consisting of both a grain elevator that stores raw agricultural commodities for animal food use and a feed mill that manufactures animal food is not "solely engaged" in activities exempt from either its CGMP or preventive controls requirements and therefore the entire facility is subject to the Part 507 CGMP and preventive controls requirements. Using the same logic, FDA would not consider a grain elevator storing raw agricultural commodities to be exempt from Part 117 CGMPs or preventive controls requirements if it is located at the same facility as a human food processing plant, such as a flour mill.

To justify its current interpretation, which NGFA believes is flawed, illogical and misguided, FDA has stated its view that the plain meaning of "solely" is "only, completely, entirely; without another or others; singly; alone." Therefore, FDA has asserted a position that all food-related activities at the entire facility must be covered by a "solely engaged" exemption for any food-related activity at the facility to be exempt from the specified requirements.

To the contrary, NGFA believes that FDA's current interpretation and application of the "solely engaged" exemptions are not consistent with congressional intent, are illogical and do not represent a risk-based approach to food safety.

The NGFA was intimately involved during the drafting of the legislative language for the "solely engaged" exemptions provided in Section 418 (m). During that process, it clearly was the intent of the congressional drafters that such exemptions were to be applied to ***operations*** that are solely engaged in holding and distributing raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, and ***not just when the entire facility was conducting such an operation***. That is, Congress intended the exemption to be applied in a risk-based manner based on the food and type of activity being conducted regardless of what other food-related activities might occur within other operations at the same facility. This intent represents a risk-based approach to food safety, which is the cornerstone of FSMA.

The NGFA strongly believes that FDA's current interpretation of the "solely engaged" exemptions is unnecessary to protect public health. During the rulemaking process that established Parts 117 and 507, the NGFA strongly agreed with FDA's own conclusions that "outbreaks of illness associated with…agricultural commodities…have not been traced back to storage facilities solely engaged in the storage of raw agricultural commodities" and that "there would not be significant public health benefit to be gained by subjecting facilities that solely store non-fruit and vegetable raw agricultural commodities intended for further distribution or processing [to such] requirements." Indeed, FDA's economic impact analysis for the requirements was predicated on that basis.

Accordingly, the NGFA believes it is well established that the activity of holding raw agricultural commodities other than fruits and vegetables for further distribution or processing does not pose a significant risk to public health and does not warrant being subject to Parts 117 or 507 requirements.

FDA's current interpretation of how the "solely engaged" exemptions should be applied also creates illogical and unfair regulatory disparities, as well. For example, under FDA's current interpretation, a grain elevator that holds and distributes raw agricultural commodities other than fruits and vegetables that is co-located at a facility with a feed mill is subject to both the CGMP and preventive controls requirements established by Part 507. However, a grain elevator performing the ***exact same*** food-related activities that is potentially located across the street at a different facility is exempt from Part 507 requirements. The NGFA contends that this regulatory outcome simply does not make sense and is unnecessary, is not risk-based and does not contribute to improving protect public health. It only adds considerable costs and unnecessary regulatory burden.

Given the extremely limited risk to public health, it appears that FDA's definition for "facility" is the primary basis for the agency's current interpretation for how the exemptions provided for raw agricultural commodities other than fruits and vegetables should be applied. In contrast, the NGFA respectively submits that FDA's interpretation of the "solely engaged" exemptions should not simply be dependent on the agency's definition for "facility" that does not appropriately recognize and acknowledge that different food-related activities may occur within distinct and separate parts of the same "facility." Such a reliance on the existing "facility" definition results in regulatory burdens being imposed on industry that: 1) do not enhance food safety; 2) create regulatory disparities; 3) cause both industry and FDA to

expend finite resources to deal with regulatory requirements for activities that do not pose a risk to animal health or public health; and 4) add exponentially to the cost and regulatory burden without commensurate benefit.

Available Data on Cost or Economic Impact:

N/A

Proposed Solution:

The NGFA strongly recommends that FDA initiate notice-and-comment rulemaking to make modifications to its "facility" definition so that the definition acknowledges the distinct and separate food-related activities that may occur at a given "facility" and more appropriately directs regulatory requirements based on risks to food safety. When the existing "facility" definition was established in 2003, we do not believe that it was foreseen that the definition would be so intricately used to establish compliance obligations associated with FSMA. Therefore, we believe it is proper to revisit the definition and make necessary modifications to make it more suitable for use in establishing regulatory obligations.

FDA Should Modify FSMA Requirements to Better Reflect Risks Posed to Food Safety – Raw Agricultural Commodities Other than Fruits and Vegetables

Name of the Regulations:

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Type of Product or FDA Center Regulating the Product:

CFSAN; CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

21 CFR Part 117; 21 CFR Part 507; 21 CFR Part 1, Subpart L

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

Parts 117 and 507 exempt from preventive controls requirements facilities solely engaged in the storage of raw agricultural commodities (other than "fruits and vegetables") intended for further distribution or processing. Further, Parts 117 and 507 exempt establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities from CGMP requirements.

In addition, FDA recently issued guidance indicating that holding and other specified farm-related activities performed by facilities on both "fruits and vegetables" (or "produce") and "non-produce" raw agricultural commodities will be the subject of enforcement discretion for preventive controls requirements established in Parts 117 and 507. Further, FDA issued a separate guidance that extends enforcement discretion for Part 1, Subpart L requirements to certain importers of grain. The NGFA commends the agency for these decisions and strongly agrees that enforcement discretion should be extended to facilities and importers that are the subject of such guidance documents.

However, FDA's recent guidance documents also indicated that the agency was not yet extending enforcement discretion for Part 117 CGMPs or Part 1, Subpart L to "produce" raw agricultural commodities, but that "produce" raw agricultural commodities will be granted enforcement discretion for Part 507 CGMPs.

When promulgating the final Part 117 and Part 507 rules, FDA chose to define grains to mean the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of raw agricultural commodities designated as food grains by FDA include barley, dent- or flint-corn, sorghum, oats, rice, rye, wild rice, wheat, amaranth, quinoa, buckwheat, cotton seed, and oilseeds for oil extraction (such as cotton seed, flax seed, rapeseed, soybeans, and sunflower seed).

In contrast, examples of raw agricultural commodities that FDA has designated as "fruits and vegetables" or "produce" and therefore not subject to the agency's enforcement discretion for Part 117 CGMPs or Part 1, Subpart L include peas, peanuts and beans (such as coffee beans, cocoa beans, kidney beans, lima beans, and pinto beans), tree nuts and seeds for direct consumption (such as pumpkin seeds, sunflower seeds, and flax seeds).

Pertaining to the designation of various raw agricultural commodities as "fruits and vegetables," the NGFA believes the clear intent of Section 418 (m) within FSMA was to exclude from the preventive controls exemption fruits and vegetables that were known or could be reasonably foreseen to be associated with outbreaks of foodborne illness. As such, we do not believe that FDA's current designation of certain raw agricultural commodities as "fruits and vegetables" meets this risk-based intent.

Specifically, the NGFA strongly disagrees with the agency's current position that pulses (dry peas, lentils, chickpeas, and dry beans) should be designated within the category of "fruits and

vegetables" or "produce," which under FDA's current enforcement policies make facilities holding or performing specified farm-related activities with such products subject to Part 117 CGMPs and importers of such products subject to Part 1, Subpart L.

Contrary to FDA's position, pulses are the edible hard seeds of plants from the legume family, which makes their origin consistent with the terminology used by the agency to define "grains." In addition, pulses are processed after holding and/or packing prior to consumption, which makes their use consistent with the terminology used by FDA to define "grains." Further, pulses are not "processed food," but typically dry in the field and are harvested in the same manner as "grains." Finally, the NGFA is not aware of food safety risks that have been associated with the holding of and/or performing farm-related activities with pulses, which, again, is consistent with the limited food safety risks related to holding or performing farm-related activities with "grains."

Available Data on Cost or Economic Impact:

N/A

Proposed Solution:

The NGFA urges FDA to designate pulses as "grains" to avoid imposing unnecessary and inappropriate regulatory requirements on facilities and importers that are involved with such products.

FDA Should Modify the Preventive Controls Requirements to Better Reflect Risks Posed to Food Safety – Written Assurances

Name of the Regulations:

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals; Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Type of Product or FDA Center Regulating the Product:

CFSAN; CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

21 CFR Part 1, Subpart L; 21 CFR Part 117; 21 CFR Part 507

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

FDA on Aug. 24, 2016 issued a final rule extending the compliance dates by two years for the written assurance requirements in the customer provisions in Parts 1, Subpart L, 117 and 507 because they could result in hundreds or even thousands of written assurances needed by a single distributor and additional time was warranted for FDA to address feasibility concerns related to the provisions.

In general, these provisions provide that when a manufacturer/processor identifies a hazard requiring a preventive control (identified hazard), does not control the identified hazard, and relies on an entity in its distribution chain to address the hazard, then:

- Documentation is to be provided by the manufacturer/processor to its direct customer that the food is "not processed to control [identified hazard]" (the disclosure statement provisions); and

- Written assurance is to be provided by the customer to the manufacturer/processor that the customer is manufacturing, processing, or preparing the food in accordance with applicable food safety requirements (the written assurance provisions); and

- The customer that provides a written assurance must act consistently with the assurance and document its actions taken to satisfy the written assurance (the accountability provisions).

Pertaining to this issue, the NGFA believes that the burdensome regulatory obligation of obtaining written assurances will not enhance food safety. Existing regulatory requirements already are in place for facilities and establishments that require food needing further preparation to be safe when it reaches the final consumer. We believe that requiring food distributors to receive a written assurance from downstream entities about a disclosed hazard adds no value to assuring food safety. To the extent that an establishment or facility is not going to comply with regulatory obligations, a written assurance is not going to change this behavior.

Available Data on Cost or Economic Impact:

N/A

Proposed Solution:

The NGFA strongly recommends that the written assurance provisions and accountability provisions be ***repealed*** because these requirements will not have meaningful food safety benefits and would be extremely burdensome and costly to implement.

FDA Should Modify the Preventive Controls Requirements to Better Reflect Risks Posed to Food Safety – Effect of Prerequisite Programs on the Need for Preventive Controls for Animal Food

Name of the Regulation:

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Type of Product or FDA Center Regulating the Product:

CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

21 CFR Part 507

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

The NGFA strongly believes that FDA needs to take steps to reduce the compliance costs associated with Part 507. Further, we believe the animal food safety goals of FSMA can be accomplished by a more limited application of the regulatory requirements, which would impose a dramatically lower economic burden upon the animal food industry.

The most significant way for FDA to reduce the Part 507 regulatory burden is by establishing realistic compliance expectations associated with the use of preventive controls. As expressed in previous statements to FDA, the NGFA strongly believes that the vast majority of known or reasonably foreseeable hazards associated with animal food facilities may be mitigated adequately through the use of prerequisite programs and do not require the use of preventive controls. We believe this view is supported by the extremely limited number of animal food safety incidents that occur within the industry in comparison to the nearly 160 million tons of animal food produced annually in the United States.

Available Data on Cost or Economic Impact:

FDA's Preliminary Regulatory Impact Analysis for the supplemental notice for Part 507 (2014 proposed rule) estimated an annualized compliance cost of $93.45 million for animal food facilities. FDA's annualized compliance cost per facility ranged from $13,200 to $18,300.

In contrast, NGFA's economic analysis of the 2014 proposed rule submitted to the rulemaking docket focused exclusively on the cost to animal feed facilities (not pet food facilities) and estimated an annualized cost of $303.15 million to $616.45 million for labor and equipment redesign/reconstruction to meet CGMP provisions and implementation of written food safety plans to comply with preventive controls provisions, which equated to an annual cost per facility ranging from $39,721 to $113,799.

More specifically, NGFA's economic analysis estimated the cost of compliance associated with implementing written animal feed safety plans that include preventive controls to be $74,078 annually per facility. This aspect of the analysis clearly illustrated that the cost to comply with Part 507 is influenced dramatically by whether animal feed facilities are required to implement preventive controls to satisfy regulatory expectations.

Preliminary feedback from NGFA-member companies that have worked over the past two years to develop programs to satisfy final Part 507 requirements indicates that the actual regulatory costs incurred align with NGFA's economic analysis for the 2014 proposed rule and significantly exceed those previously estimated by FDA.

Proposed Solution:

The NGFA believes it is essential that FDA issue written hazard analysis guidance to the industry that clearly acknowledges the animal food safety benefits derived from the use of prerequisite programs and communicates the limited need for preventive controls within animal food safety plans. Such written guidance is needed to avoid the undesirable and unnecessary outcome of industry implementing extremely costly and burdensome preventive controls simply to satisfy regulatory expectations that are not risk-based and do not enhance animal food safety. The issuance of such guidance also would appropriately allow the animal food industry to focus finite resources on aspects of production and distribution systems where genuine benefits to animal food safety can be achieved.

FDA Should Modify the Preventive Controls Requirements to Better Reflect Risks Posed to Food Safety – Low-Risk Activity/Food Combinations

Name of the Regulation:

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Type of Product or FDA Center Regulating the Product:

CVM

Citation to Code of Federal Regulations and Statutory Citation (as applicable):

21 CFR Part 507

Approved Information Collection and OMB Control Number (as applicable):

N/A

Description of Concern:

The NGFA believes that it would be appropriate for FDA to reconsider and provide additional exemptions from the preventive controls requirements established in Part 507 Subparts C and F for facilities only engaged in low-risk packing/holding activity/animal food combinations and low-risk manufacturing/processing activity/animal food combinations. The NGFA believes FDA has authority to provide additional exemptions for low-risk activity/food combinations, and doing so would significantly lessen the regulatory burden at affected facilities without compromising animal food safety or public health.

Part 507 already provides preventive controls exemptions for certain animal activity/food combinations specified in FDA's *Qualitative Risk Assessment: Risk of Activity/Animal Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm* performed by "farm mixed-type facilities" that are small or very small businesses. FDA defines a "mixed-type facility" to mean an establishment that engages in both activities that are exempt from registration under Section 415 of the FFDCA and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered.

While promulgating Part 507, FDA conducted a risk assessment to satisfy FSMA requirements to complete a science-based risk analysis and to consider the results of that analysis in determining whether to exempt small or very small businesses that are engaged only in specific types of on-farm manufacturing, processing, packing or holding activities involving certain foods that FDA determines to be low risk from the requirements of FFDCA sections 418 (preventive controls) and 421 (targeting inspection resources), or whether to modify such requirements for such facilities. As an outcome, FDA established that farm mixed-type facilities that are small or very small businesses and only conduct low-risk activity/animal food combinations specified in 507.5(e) and (f) are exempt from the requirements of subparts C and E, including the requirement for a food safety plan.

Available Data on Cost or Economic Impact: N/A
Proposed Solution: During the Part 507 rulemaking process, FDA declined to extend the exemptions provided to farm mixed-type facilities that are small or very small businesses and only conduct specified low-risk activity/animal food combinations to all facilities that are small or very small businesses. Nevertheless, the NGFA respectively requests that FDA reconsider this previous decision and provide the same exemptions to such facilities. Extending the exemptions would represent a science- and risk-based approach to food safety, provide consistency in the regulatory framework, lessen the regulatory burden at affected facilities, and allow both industry and FDA to focus resources in a more effective and appropriate manner to protect human and animal health.

Conclusion

The NGFA appreciates FDA's consideration of its views expressed in this statement, and would be pleased to respond to any questions the agency may have. The NGFA also again commits to being a fully engaged and constructive participant during FDA's implementation of FSMA.

Respectfully Submitted,

David A. Fairfield
Senior Vice President for Feed Services
National Grain and Feed Association