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August 25, 2016

Division of Dockets Management
Food and Drug Administration
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CITIZEN PETITION

The American Feed Industry Association (AFIA) and National Grain and Feed Association (NGFA) respectfully submit this petition under Sections 503(f), 512(m), and 701(a) and (h) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. §§ 353(f), 360b(m), and 371(a) and (h), respectively, and 21 C.F.R. § 10.40, § 10.115, Part 11, and § 558.6 to remove an unnecessary and costly regulatory burden in a manner consistent with other recent agency decisions. Specifically, this petition requests that the agency amend its regulations to provide that the Part 11 electronic records and electronic signature requirements do not apply to: (i) Veterinary Feed Directives (VFDs) issued by veterinarians to their clients for the use of animal drugs in medicated feed that are limited to use pursuant to a VFD as a condition of drug approval, and (ii) records required to be created or maintained by feed manufacturers and distributors related to medicated feeds containing VFD drugs.

The requested exemption from Part 11 for all VFD-related records would be consistent with FDA's recent decision to exempt from Part 11 compliance all documents related to new requirements under the FDA Food Safety Modernization Act (FSMA) for current good manufacturing practice, hazard analysis, and preventive controls for animal and human food. An exemption would also benefit the Food and Drug Administration (FDA), by enabling industry to provide documents to FDA for review (and copying, if warranted) in electronic form so that establishment inspections can be conducted efficiently.

A. ACTION REQUESTED

This petition requests that the FDA take the following action:

1. FDA should publish a direct final rule, pursuant to FDA's November 21, 1997 guidance entitled "Direct Final Rule Procedures," to adopt the following new regulations:

a. New subsection (k) at the end of 21 C.F.R. § 11.1, to read as follows:

> (k) This part does not apply to records required to be established or maintained by § 558.6 of this chapter. Records that satisfy the requirements of § 558.6 of this chapter, but that are also required under other applicable statutory provisions or regulations, remain subject to this part.

b. New subsection (g) at the end of 21 C.F.R. § 558.6, to read as follows:

> (g) Do I need to comply with FDA's electronic records requirements for VFD records? No. Records that are established or maintained to satisfy these VFD requirements and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the usual requirements of electronic records of part 11. However, records that satisfy the VFD requirements of this section, but that are also required under other applicable provisions, remain subject to part 11.

2. If FDA is unable to publish such a direct final rule so that, in the absence of significant adverse comment, it would go into effect on or about January 1, 2017, FDA should announce in a "Level 2" guidance that, as a matter of enforcement discretion until such a direct final rule can take effect, FDA does not intend to enforce the requirements of Part 11 with respect to any electronic records created or maintained solely to satisfy regulatory requirements imposed by § 558.6.

B. STATEMENT OF GROUNDS

1. The Petitioners

This petition is submitted jointly by American Feed Industry Association (AFIA) and National Grain and Feed Association (NGFA).

AFIA is devoted exclusively to representing the business legislative and regulatory interests of the U.S. animal feed industry and its suppliers. AFIA, founded in 1909, also is the recognized leader on international industry developments. Members include more than 600 domestic and international companies and state, regional, and national associations. Member companies are livestock feed and pet food manufacturers, integrators, pharmaceutical companies, ingredient suppliers, equipment manufacturers, and companies which supply other products and services to feed manufacturers.

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 industries. NGFA has more than 350 member companies operating feed manufacturing and integrated livestock and poultry operations. NGFA also consists of 29 affiliated state and regional grain and feed associations.

2. Factual Background

Congress established the VFD category of animal drugs in 1996 to provide a mechanism for involving a veterinarian, in the context of a valid veterinarian-client-patient relationship, in the decision to use certain new animal drugs that are administered in medicated feed. The VFD process avoids the host of practical problems that would arise under the pharmacy laws of a number of states with "prescription" medicated feed. If FDA had approved "prescription" animal drugs for use in medicated feeds, feed manufacturing plants in many states would be subject to the same requirements that apply to retail pharmacies, such as requirements for a registered pharmacist, a pharmacy counter, and a patient counseling area. Through the VFD process, FDA got the veterinarian involvement and oversight it desired, and the feed industry avoided the nonsensical application of state pharmacy requirements to a context for which they were never intended. Thus, the VFD requirements in Section 503(f) of the FDC Act, 21 U.S.C. § 353(f), were and are a "win-win."

AFIA and NGFA have a strong interest in the VFD process dating to the mid-1990s, when AFIA led a broad-based coalition, including NGFA, which drafted the VFD language that was enacted into law as part of the Animal Drug Availability Act of 1996. The first VFD animal drug was approved later that year, and our member firms have 20 years of experience in manufacturing and distributing medicated feeds containing FDA-approved VFD animal drugs.

In June 2015, FDA amended the regulation on VFD animal drugs, 21 C.F.R. § 558.6, to reduce regulatory burdens and improve the efficiency of the VFD process. 80 Fed. Reg. 31,707 (Jun. 3, 2015). In the rulemaking preamble, FDA explained that the revised VFD final rule was one of "three core documents that FDA is using to announce and implement its policy framework for the judicious use of medically important antimicrobial drugs in food-producing animals." 80 Fed. Reg. at 31,708.

FDA has announced that it intends to restrict the uses of medically important antimicrobial animal drugs in food-producing animals to therapeutic uses, under the oversight of veterinarians. Thus, these drugs intended for use in medicated feed will be regulated as VFD drugs; veterinarians, animal owners, and manufacturers and distributors of medicated feeds containing VFD drugs will be subject to the VFD requirements. FDA has stated that it intends to have the great majority of these drugs limited to therapeutic uses under the VFD process by the end of 2016.

In the preamble to the June 20, 2015 VFD final rule, FDA discussed a comment that urged FDA not to require compliance with the requirements of 21 C.F.R. Part 11 regarding electronic

records and electronic signatures for VFDs transmitted and stored electronically. FDA rejected the comment. 80 Fed. Reg. at 31,714.

Despite FDA's decision in June 2015 not to grant an exemption from Part 11 compliance, FDA apparently "changed its mind" a mere 3 months later in a closely related context. As discussed below, in September 2015, FDA decided not to require Part 11 compliance in connection with the FSMA current good manufacturing practice, hazard analysis, and risk-based preventive controls requirements for animal and human food.

3. FDA Should Grant The Relief Sought

a. Compliance With Part 11 Would Be Unduly Burdensome For All Relevant Professions And Industries Associated With Medicated Feed Containing VFD Drugs

Information available to AFIA and NGFA from their members and others involved with animal agriculture strongly supports the conclusion that compliance with the Part 11 requirements would be extremely burdensome and costly for all affected professions and industries.

The majority of veterinarians that issue VFDs to their clients are in solo or small group practices that do not have the personnel, technical or financial resources needed to implement and maintain computer systems in compliance with Part 11.

To the best of AFIA's and NGFA's knowledge, none of their members that are in the business of manufacturing and distributing medicated feed – including those that are part of large corporations – have a computer system that is fully Part 11-compliant today. The costs associated with developing and maintaining a Part 11-compliant computer system would be extremely burdensome. Based on informal inquiries, AFIA and NGFA are generally 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. The feed industry is a very competitive industry characterized by low profit margins. It seems unlikely that feed manufacturers and distributors could simply absorb the costs of Part 11 compliance without raising their prices. Thus, these costs – which would not result in any discernable public health or animal health benefits – would undoubtedly be passed on ultimately to American consumers.

b. Recent Rulemakings Provide A Strong Precedent For The Relief Sought

FDA's recent final rule to establish requirements for current good manufacturing practice, hazard analysis, and risk-based preventive controls for food for animals, 80 Fed. Reg. 56,169 (Sept. 17, 2015), provides a strong precedent for the relief we seek. There, FDA had proposed that any electronic records maintained to comply with the new requirements would have to comply

with Part 11. *See* 80 Fed. Reg. at 56,320. However, in light of substantial comments received, FDA reached a different conclusion in the final rule. As explained in the preamble to the final rule:

> *** In light of the substantial burden that could be created by the need to redesign large numbers of already existing electronic records and recordkeeping, we are providing in new § 507.202(c) that records that are established or maintained to satisfy the requirements of part 507 and that meet the definition of electronic records in § 11.3(b)(6) are exempt from the requirements of part 11. As we did in the section 414 recordkeeping regulations, we also are specifying that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11. The rule provides that a facility may rely on existing records to satisfy the requirements of this rule, and this rule does not change the status under part 11 of any such records if those records are currently subject to part 11. As we did in the rulemaking to establish the section 414 recordkeeping regulations, we are establishing a conforming change in part 11 to specify in new § 11.1(j) that part 11 does not apply to records required to be established or maintained under part 507, and that records that satisfy the requirements of part 507, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11.

80 Fed. Reg. at 56,320-21.

Therefore, FDA adopted new 21 C.F.R. § 11.1(j) and § 507.202(c) to provide that records associated with the new current good manufacturing practice, hazard analysis, and the risk-based preventive controls for food for animals requirements are not subject to Part 11. FDA's companion rule on current good manufacturing practice, hazard analysis, and preventive controls requirements applicable to human food included essentially verbatim preamble language and regulatory provisions. *See* 80 Fed. Reg. 55,907, 56,088-89 (Sept. 17, 2015), 21 C.F.R. § 11.1(i) and § 117.305(g). The new regulatory provisions sought by this petition (21 C.F.R. § 11.1(k) and § 558.6(g)) would use essentially the same regulatory language.

The number of VFD-related documents will be a tiny fraction of the number of documents related to FDA's new FSMA requirements for current good manufacturing practice, hazard analysis, and preventive controls for animal food and human food. Because FDA has already concluded that exempting those FSMA records from Part 11 compliance will not undercut FDA's regulatory oversight, it follows that FDA should reach the same conclusion for the much smaller number of VFD-related records.

An FDA decision to grant the relief sought by this petition would be supported by two additional factors. First, the Part 11 requirements were adopted in 1997. 62 Fed. Reg. 13,430 (Mar. 20, 1997). In a 2003 guidance, FDA announced:

> FDA is re-examining part 11 as it applies to all FDA regulated products. We anticipate initiating rulemaking to change part 11 as a result of that re-examination. This guidance explains that we will narrowly interpret the scope of part 11.

Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (August 2003), page 2. Granting an exemption from Part 11 for VFD-related records would be consistent with FDA's intent, as stated 13 years ago. Second, granting the relief sought by this petition would enable the feed manufacturing and distribution industries to assist FDA investigators in carrying out their oversight duties as efficiently as possible. Industry would be able to provide FDA investigators with electronic access to records, rather than having to print them out in hard copy for review. This efficiency would help conserve agency resources by enabling inspections to be conducted more efficiently and quickly.

c. FDA Should Act By January 1, 2017

FDA has announced that it intends to restrict the medicated feed uses of medically important antimicrobial drugs to therapeutic uses, under the oversight of veterinarians. Thus, these drugs intended for use in medicated feed will be subject to the VFD requirements. FDA has stated that it intends to have the great majority of these drugs limited to therapeutic uses under the VFD process by the end of 2016.

Thus, starting in 2017, there will be a tremendous increase in the number of VFDs issued by licensed veterinarians. To prevent disruptions in the use of these drugs, we believe it is important that FDA eliminate the requirement to comply with Part 11 for all VFD-related records before January 1, 2017.

d. FDA Should Proceed Using The Direct Final Rule Approach

We believe that this petition presents an appropriate opportunity for FDA to issue a "direct final rule" under the procedures set forth in FDA's November 21, 1997 Guidance entitled "Direct Final Rule Procedures." In light of comments previously submitted to FDA on the VFD proposed rule (78 Fed. Reg. 75,515 (Dec. 12, 2013)) and the agency's approach in the current good manufacturing practice, hazardous analysis, and preventive controls final rules for animal and

human food discussed above, we believe it is unlikely that there will be any "significant adverse comment," as that term is defined in the direct final rule guidance.[1]

e. If FDA Cannot Issue A Direct Final Rule In Timely Fashion, It Should Announce In A "Level 2" Guidance That It Does Not Intend To Enforce Part 11 Requirements Until A Direct Final Rule Can Go Into Effect.

In the event that FDA is unable to publish a direct final rule so that, in the absence of significant adverse comment, it will go into effect on or about January 1, 2017, FDA should announce in a guidance that, as the matter of enforcement discretion until such direct final rule can take effect, FDA does not intend to enforce requirements of Part 11 with respect to any electronic records maintained solely to satisfy regulatory requirements imposed by § 558.6.

FDA can and should issue such guidance as a "Level 2" guidance, 21 C.F.R. § 10.115(c)(2), because FDA's exercise of enforcement discretion would be consistent with existing practices, namely, the regulatory approach set forth in the new current good manufacturing practice, hazardous analysis, and preventive controls final rules for animal and human food. As a "Level 2" guidance, FDA should post the guidance on the Internet and announce that it is being implemented immediately. 21 C.F.R. § 10.115(g)(4).

C. ENVIRONMENTAL IMPACT

The relief sought by this petition is entitled to a categorical exclusion from the requirement for the preparation of an environmental assessment or an environmental impact statement because it seeks the "[i]ssuance, amendment, or revocation of procedural or administrative regulations and guidance documents," 21 C.F.R. § 25.30(h).

D. ECONOMIC IMPACT

Information regarding economic impact will be submitted on request.

[1] We are aware that there is some opposition to FDA's "judicious use of medically important antimicrobial drugs" policy. In our view, the underlying concerns of such opponents are not related to whether VFD-related records should be subject to Part 11 requirements.

E. CERTIFICATION

The undersigned organizations certify that, to their best knowledge and belief, this petition includes all information and views on to which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,

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and Education
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