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July 22, 2019

VIA FEDEX DELIVERY
Docket Clerk
Food Safety and Inspection Service
United States Department of Agriculture
Patriots Plaza 3
1400 Independence Avenue SW
Mailstop 3782, Room 8-163A
Washington D.C., 20250-3700

Re: Petition for Change to Food Safety and Inspection Services Regulation of Generically Approved Labeling Materials

Dear Docket Clerk,

On behalf of the National Bison Association ("NBA"), the undersigned respectfully submits this Petition for change to the Food Safety and Inspection Services regulation of generically approved labeling materials. Please direct all correspondence regarding this Petition to: Robert Hibbert, Morgan, Lewis & Bockius LLP at robert.hibbert@morganlewis.com and at the address provided below.



Sincerely,
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Counsel to National Bison Association

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VIA FEDEX DELIVERY AND

EMAIL: carmen.rottenberg@usda.gov

July 22, 2019

Carmen Rottenberg
Administrator
Food Safety and Inspection Service
U.S. Department of Agriculture
1400 Independence Ave., S.W.
331-E Jamie L. Whitten Federal Bldg.
Washington, DC 20250-3700

Re: Petition for Change to Food Safety and Inspection Services Regulation of Generically Approved Labeling Materials

Dear Administrator Rottenberg:

On behalf of the National Bison Association ("NBA"), the undersigned respectfully submit this Petition to change to Food Safety and Inspection Services ("FSIS" or the "Agency") regulation of certain labeling information. The NBA and its members currently encounter significant delays associated with the FSIS review and approval of routine labeling materials, due to the fact that their establishments, and other establishments receiving voluntary federal inspection services from FSIS, are currently unable to obtain generic approval status for such materials. As we indicate in further detail below, we believe as a matter of substance that this problem can be resolved through a simple modification to the applicable FSIS labeling regulation. We also believe, as discussed below, that such modification can be accomplished expeditiously through FSIS' issuance of a direct final rule.

I. Statement of Interest

In 1995 the American Bison Association (formed in 1975) and the National Buffalo Association (chartered in 1966) merged to become the National Bison Association. The NBA is a non-profit association of producers, processors, marketers and bison enthusiasts comprising more than 1,100 members in all 50 states and 10 foreign countries. The mission of the National Bison Association is to bring together stakeholders to celebrate the heritage of American bison, to educate, and to create a sustainable future for our industry. Without a change to FSIS regulation, the NBA's

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members are placed at a significant disadvantage due to significant delays between the submission and approval of product labels.

II. Statement of Actions Requested

Petitioner respectfully requests that FSIS modify its regulation at 9 C.F.R. 412.2 as follows:

§412.2 Approval of generic labels.

(a)(1) An official establishment, or an establishment certified under a foreign inspection system in accordance with part 327, or part 381, subpart T of this chapter, or an establishment receiving voluntary inspection services in accordance with 9 CFR Part 352, is authorized to use generically approved labels, as defined in paragraph (b) of this section, and this is free to use such labels without submitting them to the Food Safety and Inspection Service for approval, provided the label, in accordance with this section, displays all mandatory features in a prominent manner in compliance with part 317 or part 381, and is not otherwise false or misleading in any particular.

(Emphasis added to identify new requested regulatory language)

III. Support for Requested Action

FSIS, pursuant to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Eggs Product Inspection Act,¹ mandates continuous inspection, at public expense, for products under its jurisdiction. It also maintains a voluntary fee for service inspection program, pursuant to 9 C.F.R. Part 352, applicable to bison and other exotic species. A prior label approval program for all labels to be applied to products under its inspection jurisdiction, both mandatory and voluntary, is also maintained by the agency.²

Over the past several decades, and most recently through a final rule issued November 2013,³ FSIS has steadily expanded those categories of labeling materials that qualify for what it terms generic approval status. All materials that fall within these categories are directly authorized for use by regulation, without the need for submission for FSIS review prior to their use. Under present regulations⁴ this concept has been expanded to the point where it is applicable to all labeling materials that do not fall within certain specified categories, most notably those labeling materials which present specialized claims that are not presently clearly defined by FSIS. The goal of the regulation, and its practical impact, is to free regulated establishments from unnecessary paperwork and the delays associated with the review process, while also freeing up agency resources for more targeted review of materials that are potentially false or misleading. Unfortunately FSIS' interpretation of its regulatory authority is that the generic program is not currently applicable to labeling of bison products and other exotic species. As a result, NBA members and other similarly situated parties are placed at a significant competitive disadvantage as they must absorb the significant delays between submission and approval that processors

¹ 21 U.S.C. § 601 et. seq., 21 U.S.C. § 451 et. Seq., 21 U.S.C. § 1031 et. seq.

² 9 C.F.R. 412.1(a); *see also*, FSIS Directive 7.221.1.

³ 78 Fed. Reg. 66826, 37 (November 7, 2013).

⁴ 9 C.F.R. 412.2.

subject to mandatory inspection can easily avoid. By way of illustration please see the attached statement of Bob Dineen, President of Rocky Mountain Natural Meats. As it indicated the delays in question can and do have tangible negative consequences in the marketplace.

IV. Procedural Concerns

The NBA and its members are concerned about the potential for significant delay that routinely is associated with the notice and comment rule making process, which typically takes a period of several years to complete. Despite the best efforts of all parties involved, the various review and procedural requirements that attend to all notice and comment proceedings and the fact that limited agency resources are frequently captured by food safety concerns and other priority matters lead to situations where long delays of this sort become inevitable. As we explain in further detail below, we believe that, in the present instance, it is unnecessary, if not inappropriate, for FSIS to require the full notice and comment process. To the contrary, the Agency has the legally appropriate option here of issuing a direct final rule without notice and comment.

Non-legislative rules, such as “[i]nterpretative rules, general statements of policy, or rules of agency organization, procedure, or practice,” lack the force and effect of law, and therefore are exempt from the notice and comment requirements of Section 553 of the Administrative Procedure Act (“APA”).⁵ *Nat’l Mining Ass’n v. McCarthy*, 758 F.3d 243, 250 (D.C. Cir. 2014). Even if a rule qualifies as a “procedure or practice,” the agency must still satisfy the APA’s publication and 30-day delayed effective date requirements. *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342 (4th Cir. 2001); *U.S. v. Gonzales & Gonzales Bonds and Ins. Agency, Inc.*, 728 F. Supp. 2d 1077 (N.D. Cal. 2010). In this context the Supreme Court held that courts must look to the content of the agency’s action rather than its label when deciding whether statutory notice-and-comment requirements apply. *Azar v. Allina Health Services*, 139 S.Ct. 1804, 1812 (2019).

An agency action constitutes a legislative rule, dictating the need for notice and comment only if, on its face or in practice, the action binds private parties or the agency itself with the force of law. *American Institute of Certified Public Accountants v. IRS*, 746 Fed. Appx. 1, 10 (D.C. Cir. 2018). An agency action constitutes a legislative rule if it supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy. *Casa De Maryland v. U.S. Dep’t of Homeland Sec.*, 924 F.3d 684 (4th Cir. 2019).

A rule fits within the statutory exemption for “rules of agency organization, procedure, or practice” if the rule “does not impose substantive burdens” or alter the rights or interests of the parties. *Electronic Privacy Info. Ctr. (EPIC) v. U.S. Dep’t of Homeland Sec.*, 653 F.3d 1, 5 (D.C. Cir. 2011). Because all procedural rules affect substantive rights to some extent, the distinction between substantive and procedural rules may be characterized as “one of degree depending upon whether the substantive effect is sufficiently grave so that notice and comment are needed to safeguard the policies underlying the APA.” *Id.* at 6 (aff’d in *Time Warner Cable Inc.* (2d Cir. 2013)). The “critical feature” of a procedural rule is that it covers agency actions that do not themselves alter the rights or interests of the parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency. *Nat’l Mining Ass’n v. McCarthy*, 758 F.3d 243, 250 (D.C. Cir. 2014).

⁵ 5 U.S.C. § 553(b)(A).

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Administrator
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Accommodation of the NBA's interests through issuance of a direct final rule without the need for notice and comment is clearly compatible with this legal standard. The regulatory change at issue simply provides a new procedural option for establishments operating under voluntary exotic species inspection from using labeling materials that FSIS has already concluded as a matter of overall policy do not require specialized oversight.

- NBA members and other processors of exotic species will benefit from the ability to respond more quickly and efficiently to customer demand.
- Traditional meat and poultry processors will benefit as well by removing routine exotic species labeling materials as contributing factors to the overall FSIS backlog.
- FSIS will benefit from being able to more clearly focus its available resources upon priority issues, especially the oversight of novel or potentially controversial claims as applied to labels of meat and poultry products and whenever applicable exotic species as well.

Finally, while it is difficult to imagine given the existing rule making record regarding expansion of generic approval that this action will create any controversy, FSIS can reserve the right, by requesting public comment prior to effect date of the regulatory change in question, to reverse its course in the highly unlikely event that any such comments prove to be persuasive.

V. Conclusion

As we hope this petition has outlined, we believe that a changing the generic approval regulations through the issuance of a direct final rule provides the best and most appropriate vehicle for addressing the ongoing issues with the FSIS prior approval system for exotic species labeling. Based on the law and the evidence set out above, we respectfully request FSIS change its policy on the approval of generic labels accordingly.

Sincerely,



Robert G. Hibbert
Counsel to National Bison Association

RGH/mcm

July 18, 2019

To: National Bison Association / Mr. David Carter

From: Rocky Mountain Natural Meats LLC / Bob Dineen

Re: USDA Label Approval Issues with Non-Amenable Species – specifically Bison

In November 2018 we were asked by a significant grocer customer to produce a fresh, case-ready Bison patty product. This request included the requirement to meet a specific time frame that this customer had established after they had agreed on the label as it pertained to appearance/eye appeal, nutritional panel information and shelf-life expectations of the product. We expressed to this customer that we could not meet their expected time frame because they had not taken into account the 6-8 weeks it would take for USDA label approval. The claims on this label included no antibiotics, no added hormones, vegetarian fed, and as this was four 4oz patties (16oz package) and “4 patties” statement all on the primary label. We have numerous labels with these same claims that have been previously approved by USDA but because this is 100% Bison product generic or in-house approval was not an option. The customer was very disappointed to the point of questioning our industry knowledge due to their unfamiliarity with USDA regulations as they pertain to voluntary inspection. Eventually we were able to resolve all issues and we were able to produce this requested product but not without creating an element of doubt with this customer which we believe persists to this day. Our delay in getting this product to market was a minor issue compared to the loss of confidence in our company due to our customer’s unfamiliarity with USDA regulations. This was certainly not the first time we have experienced a delay in bringing new products to market due to the USDA label approval backlog. It continues to be an issue for us to the point that we submit multiple variations of an individual product label (8oz, 12oz, 16oz; 80% lean, 85% lean, 90% lean etc.) in order to avoid future delays in the label approval process. This costs us additional time and expense along with unintentionally increasing the backlog at USDA label approval. We believe that any change in the current regulations as it pertains to generic label approval would be a very positive step in helping our small industry along with industries of other species that utilize the voluntary USDA inspection process.