Regulatory Update

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1. **At IPPE, FSIS representatives said the Govt shutdown did not affect label approvals, did not contribute to the delay; has that tune changed?**
   a. During the furlough, label review was determined to be an essential activity. The labeling department was operating, but with reduced staff, yielding a reduced review rate.

2. **The Feb Constituent update indicated the backlog was up to six weeks; is your 10-week delay anecdotal in nature then? The label submission and approval system typically provides updates as to which submissions are being reviewed.**
   a. At the time that the presentation was created, the backlog was 10 weeks. During the presentation, the constituent update was issued. The agency will continue to update the current backlog approximately every two weeks in the constituent update.

3. **What is being done to challenge Prop 12? Is there a path forward that will help prevent significant disruption of the supply chain?**
   a. The institute is in contact with multiple law firms in search of finding the most appropriate company to represent the institute and appeal Prop 12.

4. **If another establishment I partner with has a label approved can my establishment generic off their approval?**
   a. Under certain circumstances and for some claims other than organic claims. National Organic Program (NOP) supporting documentation is not transferrable. Assuming that the label has an eligible special statement or claim, companies can use the complete copy of the original label application, including all documentation that was submitted to support the claims made on the application. All documentation supporting the claim would need to be maintained on file. Each labeling scenario is unique and if there is a specific situation that needs to be discussed, please feel free to reach out to me (Roya Galindo).

5. **Does the USDA have any plans to follow the new labeling changes that FDA went through?**
    a. If the question is referring to nutritional panel labeling format, not at this time. The revised nutrition facts panel proposed rule was moved to the inactive list at FSIS, and adoption of the revised FDA format is voluntary at this time for USDA regulated products, and requires sketch approval before use.