MEMORANDUM

From: Martin J. Hahn
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Re: USDA’s AMS Issues Proposed Rule on National Bioengineered Food Disclosure Standard

On May 3, the U.S. Department of Agriculture's (USDA’s) Agricultural Marketing Service (AMS) issued its proposed rule implementing the National Bioengineered Food Disclosure Standard (NBFDS) passed by Congress in July 2016. 1/ AMS is proposing a crop-based approach, where disclosure would be required when a food is or contains a crop, or a derivative of a crop, that is included on one of two lists to be developed by the agency. The first list would include crops that are commercially available in bioengineered (BE) forms where the BE form has been highly adopted, such as canola, field corn, soybean, and sugar beet. The second list would include list crops commercially available in a BE form but adopted at a rate of less than 85 percent, such as non-browning cultivars of apple, sweet corn, papaya, potato, and summer squash. In addition to the three disclosure options listed in the statute – text, symbol, or digital/electronic link – AMS proposes to allow use of a text message disclosure option.

The proposed rule does not address a key threshold question of whether highly refined ingredients and foods, such as high-fructose corn syrup from BE corn, will require disclosure under the standard. The AMS discussion in the preamble to the proposed rule focuses on whether the highly refined ingredient “contains modified DNA” from the BE crop, indicating AMS is of the view a food or food ingredient must contain genetically modified DNA to fall within the definition of a BE food. AMS also did not reach a tentative conclusion on the appropriate threshold for the amount of a bioengineered substance that requires disclosure, and instead proposed three alternative thresholds – (1) 5% inadvertent presence of BE material in a particular ingredient, (2) 0.9% inadvertent presence of BE material in a particular ingredient, or (3) 5% BE ingredients by weight (present intentionally).

AMS is proposing to align the NBFDS compliance date with the Food and Drug Administration's (FDA's) newly finalized compliance dates for the nutrition labeling and serving size rules, i.e., January 1, 2020, or January 1, 2021 for small food manufacturers with less than $10 million in annual food sales. 2/ Under the proposed rule, the compliance dates for the new nutrition labeling

and serving size rules and the NBFDS rule would be harmonized. Notably, AMS is also proposing additional flexibility for manufacturers to continue to use any food labels printed prior to the compliance date until their inventory is exhausted or until January 1, 2022, whichever date comes first.

AMS is providing a 60-day comment period, with comments due on July 3. The agency also plans to hold a webinar; details will be forthcoming via a Federal Register notice. This memorandum provides background information on the proposed rule, followed by a summary of the highlights of the proposed standard.

Background

The NBFDS, passed by Congress on July 29, 2016, requires AMS to conduct rulemaking to establish a standard requiring disclosure of certain bioengineered foods and foods that may be bioengineered. 3/ The law also established national uniformity and federal preemption of state and local genetic engineering labeling requirements.

The statute also directs the agency to conduct a study to identify potential technological challenges related to electronic or digital disclosure methods. AMS completed this study, through Deloitte Consulting LLP, and published the results on its website in September 2017. 4/ Last summer, AMS also sought public input on 30 questions posted on its website, with comments due in August 2017. The agency received over 112,000 responses, which are posted on the AMS website. 5/

In terms of scope of the new standard, the law does not require AMS to define the terms “non-GMO” or similar claims via rulemaking, but does state that certification of a food under USDA’s National Organic Program is considered sufficient to make claims about the absence of bioengineering in the food, such as “non-GMO.” The statute also says that the fact that a food is not required to bear a mandatory BE disclosure statement does not, by itself, mean the food may bear a “non-GMO” claim.

Throughout the rule, AMS places emphasis on seeking to minimize the costs of implementation and compliance for the industry, as these costs could be passed onto consumers. The agency also states it has tried to create clear and straightforward requirements, with appropriate flexibility.

Scope of Standard

AMS proposes that determining whether a food is a BE food requiring disclosure would be a 6-step process. Below we outline the proposed AMS process, including relevant definitions.

(1) Who is responsible for the disclosure?

The proposed rule would apply to three potentially regulated entities: manufacturers, importers, and retailers. If a food is packaged prior to receipt by a retailer, then either the food manufacturer or the

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importer of record would be responsible for the disclosure. 6/ If a retailer packages the food, then the retailer would be responsible. 7/

(2) Is the particular product at issue a “food”?  

AMS proposes to adopt the definition of “food” in the Federal Food, Drug, and Cosmetic Act (FFDCA), but is modifying it to make clear that pet food and animal feed are not covered by the proposed rule, per the NBFDS statute. AMS also clarifies that dietary supplements, processing aids, and enzymes are all considered “food.”

(3) Does the food fall within the scope of the NBFDS?  

The statutory disclosure standard does not include all “food” within its scope, but rather is limited to:

1. foods that are subject to the labeling requirements of the FFDCA, and
2. certain foods that are subject to the labeling requirements of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), or the Egg Products Inspection Act, provided that either:
   a. the most predominant ingredient of the food would independently be subject to the FFDCA labeling requirements; or
   b. if the most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the FFDCA labeling requirements.

In order to identify the predominance of ingredients, AMS will look to the first ingredient in the ingredient list on the food label, following the FDA requirements for identifying the ingredients in the order of descending predominance by weight. AMS gives the example that a soup with an ingredient list of – broth, carrots, chicken, etc. – would fall within the scope of the standard because chicken is not the second-most predominant ingredient after broth. (It is a separate question as to whether the soup would require disclosure as a BE food; if, for example, the soup contained some other ingredient that met the definition of BE food, it would require a disclosure). In contrast, AMS provides an example of a canned ham where pork is the primary ingredient followed by other ingredients such as corn syrup. The canned ham would not be subject to the disclosure requirements because pork is the first ingredient, regardless of whether the corn syrup is derived from BE corn.

(4) Is the food a BE food?  

As relevant to the “BE food” definition, AMS discusses the following terms:

6/ With respect to imported foods, AMS is considering establishing equivalency agreements with other countries, under which AMS would recognize that certain countries’ BE labeling requirements are comparable to the U.S. standard. Importers of products labeled in compliance with a partner country’s BE food labeling law would only need to demonstrate with records that the food came from the partner country.

7/ AMS proposes that retailers would be responsible for complying with the BE disclosure of bulk food. AMS proposes that the disclosure could appear using any of the options for on-package disclosure, and would be required to appear on signage or other materials on or near the bulk item.
“Bioengineering.” AMS proposes to directly incorporate the statutory definition of this term without further interpretation – i.e., “food (A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.”

“Conventional Breeding.” The proposed rule does not define the term “conventional breeding,” but AMS suggests a few potential definitions in the preamble.

“Found in Nature.” AMS has not defined the term “found in nature” in the proposed rule, but suggests that one factor AMS could consider in determining whether a specific modification could be found in nature is whether it has intellectual property protection. The agency reasons that “products of nature” are not patentable subject matter, but also emphasizes that the intellectual property inquiry would be just one factor in the determination.

Importantly, AMS has not reached a decision on a key question of whether the definition of “bioengineering” or “bioengineered food” will include highly refined ingredients, such as refined sugar from sugar beets. AMS explains that it received comments with two conflicting viewpoints on whether such ingredients should be covered – one advocating that HRI do not “contain” modified DNA and therefore do not fall within the statutory definition; and the other arguing that highly refined ingredients contain modified genetic material before being processed and that the finished product should be presumed to contain at least some trace amount of modified genetic material. AMS asks for comments on which position is a better interpretation of the statute.

In determining whether a food is a “BE food,” the proposed rule directs regulated entities to consider two questions:

a. Does the food appear on either of the two AMS lists of BE foods that are commercially available in the U.S?

In the spirit of establishing a straightforward disclosure standard, AMS proposes to develop two crop lists of BE foods: (1) those that are commercially available in the U.S. with a high adoption rate, and (2) those that are commercially available in the U.S. and not highly adopted. Regulated entities would only need to determine whether the food, or an ingredient used in the food, is on either of the lists, or is produced using foods on either of the lists. The proposed lists are:

- **Commercially Available BE Foods – Highly Adopted** (i.e., 85% or higher adoption in the U.S.): Canola; Corn, Field; Cotton; Soybean; Sugar Beet
- **Commercially Available BE Foods – Not Highly Adopted**: Apple, Non-browning cultivars; Corn, Sweet; Papaya; Potato; Squash, Summer Varieties

Importantly, the lists identify the crops, but not the specific derivatives or all the varieties of the crops and foods (e.g., corn starch and soy meal). However, foods containing derivatives of the crops would be subject to disclosure, unless the covered entity can provide documentation showing they are not derived from GE crops. AMS gives the following examples of derivatives of field corn that are presumed to be GE (unless the covered entity can provide records demonstrating otherwise): corn starch, cornmeal, corn syrup, grits, corn chips, corn tortilla, and corn cereal, among others. AMS describes testing demonstrating the absence of GE material as the type of data that could be
used to support a company’s position that an ingredient derived from a highly adopted BE crop should not be considered a BE food.

AMS explains that if a product is or contains a food (or derivative of a food) on either list, companies would either (1) make a disclosure consistent with the standard, or (2) not disclose if they believe the food is not required to have a BE disclosure. If the second approach is chosen, companies would need to maintain documented verification that the food is not a BE food or that it does not contain a BE food. For foods that bear a BE disclosure, companies would not need to maintain documented verification, beyond records that AMS believes are already maintained. (More details on recordkeeping are provided later in this memorandum.)

The two crop lists would be maintained on the AMS website and would be reviewed and revised annually. Any revisions to the lists would be published in the Federal Register. AMS would provide an 18-month grace period, following the effective date of any changes to the list(s), to allow companies time to revise food labels following a revision. AMS also explains that it will consult with other government agencies, including USDA’s Animal and Plant Health Inspection Service (APHIS), the Environmental Protection Agency (EPA), and FDA, to understand if foods resulting from new technologies would be consistent with the definition of “bioengineered food” and would be commercially available. Note that BE foods that are not commercially available, including rice cultivars, pink-fleshed pineapple cultivars, and salmon, would not be included on either list.

AMS has not created a list of non-crop foods produced through bioengineering, such as enzymes, yeast, and other foods produced in controlled environments. The agency seeks comments on whether these non-crop foods should be included on the BE food lists.

The second factor companies are to consider is:

b. Do “other factors or conditions” exist that affect the food’s BE status?

The statute requires AMS to establish a process for requesting and granting a determination by the agency regarding “other factors and conditions” under which a food is considered a BE food. AMS is proposing a petition process, under which AMS would undertake rulemaking to incorporate the requested factor or condition into the definition of “bioengineered food.” AMS articulates two criteria for incorporating such factors or conditions: (1) the requested factor or condition would need to be within the scope of the statutory “bioengineering” definition, and (2) AMS would evaluate the cost of implementation and compliance, including compatibility with other food labeling requirements and consistency with international trade obligations.

AMS discusses two potential “other factors or conditions” that would affect whether a food is a BE food:

- **Incidental Additives.** AMS proposes that if an ingredient is exempt from ingredient labeling as an incidental additive under 21 CFR § 101.100(a)(3), it would not be considered a BE food. AMS explains that under its proposed approach, some enzymes will be exempt as incidental additives, while others that are declared on the label as ingredients, would be considered subject to disclosure. AMS also seeks comment more generally on whether enzymes present in food should be considered “bioengineered food.”
No Detectable Levels of Modified DNA. AMS is considering, but did not formally propose, creating an exemption for foods where the modified genetic material cannot be detected. AMS explains that if it ultimately includes highly refined ingredients within the definition of bioengineered food, this factor would provide a means to potentially exclude products where the modified DNA cannot be detected. If this factor is adopted, AMS would require companies to maintain testing records showing the modified DNA cannot be detected.

(5) Does the amount of a bioengineered substance that may be present in the food exceed the threshold?

The statute directs the agency to determine the amounts of a “BE substance” that may be present in food in order for the food to be a BE food. AMS is proposing three different alternative thresholds. The proposed rule also defines the term “BE substance” as matter that contains modified genetic material. The three potential thresholds under consideration are:

- **≤ 5 percent and inadvertent or technically unavoidable.** A food in which an ingredient contains a BE substance that is inadvertent or technically unavoidable, and accounts for no more than 5 percent of the specific ingredient by weight, would not be subject to disclosure as a result of that one ingredient.
- **≤ 0.9 percent and inadvertent or technically unavoidable.** Same as above, but with a lower percentage threshold.
- **≤ 5 percent (not inadvertent or technically unavoidable).** Under this proposed approach, “a regulated entity could use ingredients it knew were bioengineered, and not have to disclose under the NBFDS, as long as the total amount of all BE ingredients used in the products were not greater than 5 percent of the total weight of the product.”

“Inadvertent or technically unavoidable” would mean insignificant amounts of a BE substance in food that resulted from the coexistence of BE and non-BE foods in the supply chain, including on the field, during transportation, or from processing equipment. In assessing compliance, AMS would look to a company’s records. The agency states, “If a regulated entity has records to demonstrate that they source non-BE ingredients, and can demonstrate through records that they take appropriate measures to separate BE and non-BE ingredients, then the presence of any BE substance would be considered inadvertent or technically unavoidable.”

As an example, we interpret the first and second proposed alternative standards as not requiring disclosure for a food that contains wheat flour as an ingredient, when the wheat flour contains no more than 5 percent (or 0.9 percent, depending on which alternative AMS selects) by weight of BE soy due to cross contact.

(6) Are there any applicable exemptions?

AMS proposes the following exemptions from the disclosure standard:

- **Food Served in a Restaurant or Similar Retail Food Establishment.** “Similar Retail Food Establishment” is defined in the proposed rule as “a cafeteria, lunch room, food stand, saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other
food enterprises located within retail establishments that provide ready-to-eat-foods that are consumed either on or outside of the retailer’s premises.”

- **Very Small Food Manufacturers.** FDA proposes two potential thresholds for the definition of a “very small manufacturer”: a food manufacturer with (1) annual receipts less than $5 million or (2) annual receipts less than $500,000.

- **Animals Fed with Bioengineered Feed and their Products.** As required by the statute, a food derived from an animal is not to be considered a BE food solely because the animal consumed feed produced from, containing, or consisting of a BE substance. For example, if milk or eggs comes from a cow or chicken that consumed BE corn and soy, the milk or eggs would not be considered a BE food solely on that basis.

- **Certified Organic Foods.** Because the statute permits certified organic foods to be labeled as “non-GMO,” AMS reasons that foods certified as organic should also be exempt from the BE disclosure standard and companies would not be required to maintain additional records to demonstrate that the organic food is not a BE food.

**Disclosure Requirements**

For foods that require a disclosure, companies would have the option to choose any one of four disclosure options. The first three options are found in the statute; the fourth option – a text message disclosure – is proposed to address the potential that AMS might conclude consumers do not have sufficient access, while shopping, to the digital or electronic disclosure.

1. **Text Disclosure.** The text disclosure requirements would differ depending on whether the food is, contains, or is a derivative of a food on the high-adoption BE food list, or the non-high adoption BE food list. For either type of food, the term “bioengineered food,” would be used, rather than other terms like “genetically engineered.”

   a. **High adoption BE Food.** AMS proposes to require the statement to read “Bioengineered food” (for a raw agricultural commodity and foods that contain only BE food ingredients) or “Contains a bioengineered food ingredient” (for all other foods). AMS reasons that a food on the high-adoption BE foods list should be presumed to be a BE food, absent documentation verifying otherwise, so these foods would not be permitted to use the term “may.”

   b. **Non-high adoption BE Food.** Companies could choose any of the following statements, at their discretion, even if the food is known to be a BE food: “Bioengineered food,” “Contains a bioengineered food ingredient,” “May be bioengineered food,” or “May contain a bioengineered food ingredient.”

2. **Symbol Disclosure.** AMS proposes three alternative symbols and invites comments on each. 8/ The symbols are designed to communicate the BE status of a food in a non-disparaging way, as required by the statute. AMS also seeks comments on whether the words “Bioengineered” or “May be” should be incorporated into the design. The three symbols may also be displayed in black and white.

8/ AMS has published the images of the proposed disclosure symbols at [https://www.ams.usda.gov/sites/default/files/media/ProposedBioengineeredLabels.pdf](https://www.ams.usda.gov/sites/default/files/media/ProposedBioengineeredLabels.pdf).
3. **Electronic or Digital Link.** Four components would comprise the electronic or digital link disclosure – the “scan here” statement, the electronic or digital link, the disclosure accessed through the link, and the telephone number disclosure.

   a. **“Scan here” statement.** As required by the statute, the electronic or digital link would need to be accompanied by the statement “Scan here for more food information,” or equivalent language that reflects technological changes. AMS lists the examples of “Scan anywhere on package for more food information,” and “Scan icon for more food information” as appropriate statements to accommodate various technologies.

   b. **Electronic or digital link.** AMS does not provide details on how the electronic or digital link is to appear, other than the general placement and prominence requirements noted below. Per the statute, the BE food disclosure may not be made via a website URL that is not embedded in an electronic or digital link, except for disclosures made by small manufacturers and for disclosures on very small packages.

   c. **Disclosure.** AMS proposes to require the electronic or digital link to provide the BE food disclosure on the “the product information page,” which “must be the first screen to appear on an electronic or digital device after the link is access as directed.” Stated differently, the proposed rule requires the link to “go directly to the product information page” which contains the BE disclosure. The disclosure on the product information page would need to conform to the requirements for either the text disclosure or the symbol disclosure. 9/ AMS notes that the proposed regulations do not prohibit additional information about BE food from being included in the disclosure, but if this is done, it must be done outside of the landing page that includes the BE food disclosure.

   d. **Telephone Number Disclosure.** When the electronic or digital disclosure is chosen, the disclosure must also be accompanied by a telephone number that provides access to the disclosure. AMS proposes to require that the disclosure be available regardless of the time of day, and that the telephone number must be located in close proximity to the electronic or digital link, and be accompanied by the statement “Call for more food information.”

4. **Text Message Disclosure.** In addition to the three disclosure options listed in the statute, discussed above, AMS is proposing a fourth disclosure option. AMS would make this option

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9/ The BE disclosure must also appear without any marketing or promotional material. The proposed rule includes a definition of “marketing or promotional material” that essentially refers to information used “to assist in the sale or promotion of a product.”
available in the event that the agency, upon completion of its review of the Deloitte study, concludes that consumers would not have sufficient access, while shopping, to the disclosure through electronic or digital disclosure methods. Under this option, companies would include a statement on the package that instructs consumers to “Text [number] for more food information,” where the number would be a telephone number or short code that immediately responds with the disclosure using the disclosure text discussed above.

Regardless of the format chosen for the disclosure, AMS proposes the following prominence and placement requirements.

- **Prominence.** AMS does not propose to prescribe specific text size requirements but instead is proposing to require the disclosure to be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.

- **Placement.** AMS proposes that companies would have three options for placement of the disclosure: (1) on the information panel, adjacent to the statement identifying the name and address of the manufacturer or distributor, (2) anywhere on the principal display panel (PDP), or (3) if there is insufficient space on the information panel or PDP, on an alternate panel.

Small food manufacturers could select from two additional disclosure options (in addition to the four options above). A “small food manufacturer” would be defined as one with at least $2.5 million but less than $10 million in annual receipts. 10/

1. **Telephone Number.** The telephone number disclosure, if selected as the method of disclosure, would need to be accompanied by the text “Call for more food information.” The telephone number would need to provide the disclosure at any time of the day.

2. **Internet Website Address.** If an internet website address is used to provide the disclosure, the following text would be used: “Visit [Uniform Resource Locator (URL) of the website] for more food information.”

As required by the statute, AMS is also proposing alternative reasonable disclosure options for food in small or very small packages. AMS proposes to define “small package” as one with a total surface area of less than 40 square inches and “very small package” as one with a total surface area of less than 12 square inches. Essentially, the proposal would allow for shortened versions of the accompanying text, i.e., “Scan for info” (for the digital or electronic link), “Text for info” (for the text message disclosure), or “Call for info” (for the telephone disclosure). Additionally, for very small packages only, if the preexisting label includes a website URL or telephone number that a person can use to obtain other food information, that website or telephone number may also be used for the BE disclosure. The BE symbol could also be used for disclosure on small or very small packages.

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10/ This definition would be similar to FDA’s proposed rule to provide an additional year for compliance with the revised nutrition labeling requirements for manufacturers with less than $10 million in annual food sales.
Voluntary Disclosure

AMS addresses voluntary disclosure for food that is not subject to mandatory disclosure, and gives the example of a very small food manufacturer that is exempt from the standard but may nonetheless want to provide a BE disclosure. AMS proposes language that would allow for voluntary labeling for food that meets the definition of “bioengineering” in the statute. The preamble and proposed rule do not address voluntary disclosure for foods that do not meet the definition of “bioengineering,” such as products that do not contain detectable levels of modified DNA in the event the final regulation requires DNA to be detectable in refined ingredients for the food to be considered a BE food. The proposed rule does state, however, that nothing in the regulation “will prohibit regulated entities from making other claims regarding bioengineered food, provided that such claims are consistent with applicable federal law.” AMS does reiterate the statutory language that “[a] food may bear a disclosure that the food is bioengineered only in accordance with regulations promulgated by the Secretary in accordance with this subchapter.”

Recordkeeping Requirements and Compliance

AMS proposes to require that entities responsible for disclosure maintain records that are “customary or reasonable” to demonstrate compliance with the disclosure requirements. The proposed rule provides a fair amount of flexibility as to what records are kept, within the following parameters:

- If a food is on either of the two lists of BE foods (or contains such a food, or is derived from such a food), and a company does not make a disclosure, the company would need to maintain records verifying that the food is not a BE food or that it does not contain a BE food ingredient. Such documentation, AMS explains, could include supply chain documents, purchase orders, sales confirmations, bills of lading, supplier attestations, purchase receipts, written records, labels, contracts, brokers’ statements, analytical testing results, or process certifications. For instance, if a company sourced soy sauce produced from non-BE soybeans, the manufacturer could maintain its supplier contract, showing it ordered finished products that are not bioengineered, as verification to support not making a disclosure.

- If a food is on either of the two lists, and a company does make a disclosure, the company would only need to maintain records to show that the product contains a food or food ingredient on one of the BE food lists. For instance, for cornmeal derived from field corn, where the company makes a BE food disclosure, the manufacturer would only need to maintain a record that shows that the food contains cornmeal.

- If a food is not on either list, the only records required would be those that indicate the food type (e.g., peaches).

The records would need to be maintained for at least two years beyond the date the food is sold or distributed for retail sale. AMS explains that records related to detectability testing — in the event AMS adopts an “other factor or condition” relating to whether modified genetic material is detectable in the finished food — may need to be retained longer than other records in order to provide ongoing evidence that foods manufactured under a particular process do not have detectable modified genetic material.
Upon a request by AMS for records, a regulated entity would need to provide the records within five business days, unless AMS extends the deadline. If AMS needs to access the records at the entity's place of business, AMS would provide at least three business days' prior notice.

With respect to compliance, AMS makes clear that the statute does not authorize food recalls or civil penalties for violations of the disclosure standard. The statute does authorize AMS to conduct audits or examinations of records. The proposed rule provides that any interested person may file a written statement or complaint with the agency about a possible violation of the disclosure standard. If AMS determines that reasonable grounds exist for an investigation of the complaint, it may conduct an audit or examination of the records of the entity responsible for the disclosure. After completing the audit or examination, AMS would make its findings available to the entity audited. The entity could then request a hearing objecting to the AMS finding. After the conclusion of the hearing, or after 30 days from the entity's receipt of the finding, if the entity does not request a hearing, AMS would make public a summary of the results, including findings, of the audit or examination.

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Trade associations and companies are encouraged to submit comments to AMS. AMS is establishing a 60 day comment period and we suspect AMS would be reluctant to grant an extension given the agency's interest in trying to finalize the regulation as soon as practicable to allow for harmonization with the FDA nutrition labeling compliance date of January 1, 2020. We will continue to monitor the AMS's implementation of the disclosure standard. Please contact us if you have any questions regarding this or any other matter.