May 26, 2020

Commissioner Stephen Hahn, MD
US Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines; Guidance for Industry

Dear Commissioner:

Established in 1943, the AAAAI is a professional organization with more than 7,000 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. A/I practitioners understand the difficulty manufacturers face associated with ensuring an adequate food supply for Americans, and that these challenges are among a broad range of issues of concern for the Food and Drug Administration (FDA or Agency) in responding to the pandemic. We recognize that it is in response to these challenges that the Food and Drug Administration recently released final guidance titled Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines. In this guidance, the Agency appropriately requires that any such omissions or substitutions appropriately acknowledge the potential significant health consequences for those with food allergies, including life-threatening allergic reactions such as anaphylaxis.

We appreciate that FDA has emphasized the importance of safety by clarifying that “[m]anufacturers should avoid substitutions that could result in a safety concern without making a conforming label change or providing other means to inform consumers of the change.” We also appreciate that the Agency has taken a very inclusive view of food allergies, not only considering the eight major food allergens defined at section 201(qq) of the FD&C Act but also noting other foods recognized by other countries (e.g., sesame, celery, lupin, buckwheat, molluscan shellfish, and mustard), as well as foods which may cause adverse events (e.g., glutamates and sulfites).

A/I practitioners understand the difficulty manufacturers face associated with ensuring an adequate food supply for Americans, and that these challenges are among a broad range of issues of concern for the Food and Drug Administration (FDA or Agency) in responding to the pandemic. We recognize that it is in response to these challenges that the Food and Drug Administration recently released final guidance titled Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines. In this guidance, the Agency appropriately requires that any such omissions or substitutions appropriately acknowledge the potential significant health consequences for those with food allergies, including life-threatening allergic reactions such as anaphylaxis.

We appreciate that FDA has emphasized the importance of safety by clarifying that “[m]anufacturers should avoid substitutions that could result in a safety concern without making a conforming label change or providing other means to inform consumers of the change.” We also appreciate that the Agency has taken a very inclusive view of food allergies, not only considering the eight major food allergens defined at section 201(qq) of the FD&C Act but also noting other foods recognized by other countries (e.g., sesame, celery, lupin, buckwheat, molluscan shellfish, and mustard), as well as foods which may cause adverse events (e.g., glutamates and sulfites).
Given the importance of protecting our patients, we urge FDA to closely monitor label and contents changes made following this guidance, and provide appropriate oversight where health and safety may be of concern. Further, we ask that the Agency quickly provide consumer friendly information regarding these label changes so that our patients are well informed.

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We appreciate the opportunity to share the concerns of A/I professionals. Should you have questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

Mary Beth Fasano, MD, MSPH, FAAAAI
President, American Academy of Allergy, Asthma & Immunology