FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

March 27, 2019

Steve Mandernach, Executive Director
Steve Moris, President
Association of Food and Drug Officials
2550 Kingston Road, Suite 311
York, Pennsylvania 17402

Re: Food and Drug Administration (FDA) Responses to 2018 Association of Food and Drug Officials (AFDO) Resolutions

Dear Messrs. Mandernach and Moris:

FDA greatly appreciates the opportunity to work with AFDO to advance shared public health goals through federal, state, and local collaborations and partnerships. This letter is in response to your 2018 resolutions adopted during the very productive and successful 122nd Annual Educational Conference in Burlington, Vermont. We regret the delay in responding.

During the last AFDO Board meeting, we agreed that more frequent face-to-face meetings between key FDA senior officials and the AFDO Board would be beneficial. While we will continue to respond to all AFDO resolutions in writing, we believe these face-to-face meetings will offer an excellent opportunity for us to have continued dialogue on each of these topics.

FDA would like to thank AFDO for your continued partnership and collaboration towards enhancing an Integrated Food Safety System and working to advance food and medical product safety. We look forward to our continued public health partnership.

Sincerely,

Melinda K. Plaisier
Associate Commissioner for Regulatory Affairs
Office of Regulatory Affairs (ORA)

Susan T. Mayne, Ph.D.
Director
Center for Food Safety and Applied Nutrition (CFSAN)

Attachment: 2018 AFDO Resolutions and FDA Responses

Resolution #2018-1: Kratom

Summary: AFDO advises FDA of the states' concern with the safety of kratom, and the current distribution and sale of kratom as a drug replacement, supplement, or food. AFDO requests FDA to provide its best guidance to state food and/or drug safety programs on approaches for dealing with kratom.

FDA Response: Given the dynamic, pre-decisional nature of this topic, ORA/CFSAN senior leadership and AFDO agreed during the 2018 fall board meeting to handle this issue via informal meetings.

Resolution #2018-2: Liquid Nitrogen and Dry Ice Used as Food and Beverage Ingredients (Revised and Resubmitted)

Summary: AFDO asks FDA to examine current industry use of liquid nitrogen and dry ice in retail to determine if they are compatible with the requirements of FDA Model Food Code and, if use is not prohibited, identify appropriate controls to ensure consumer safety. AFDO advises FDA of the need for federal leadership on the matter of liquid nitrogen and dry ice used as food and beverage ingredients and for providing guidance and technical assistance to the states on appropriate regulatory intervention in order to avoid the creation of a patchwork of state regulations covering this issue.

FDA Response: FDA shares AFDO's interest in assuring the safety of liquid nitrogen and dry ice used as food and beverage ingredients and welcomes the opportunity to collaborate with AFDO on this area of mutual interest. As noted in FDA's response to AFDO's 2016 Resolution on this issue, FDA is particularly interested in input on (1) the concerns, incidence, and relative risk of accidental ingestion of liquid nitrogen and dry ice at food establishments in the United States, and (2) to identify approaches that minimize these concerns, incidence, and risks.

Since that time, FDA is aware of the increasingly widespread use of liquid nitrogen and dry ice in classroom settings, gastronomy, and for recreational purposes. In retail food and food service establishments, liquid nitrogen is used in the rapid freezing of foods (such as ice cream), to process dry herbs and spices, and to rapidly chill beverages. Both liquid nitrogen and dry ice are used for their smoke effect in beverages or foods to enhance presentation and consumer appeal. Typically, liquid nitrogen and dry ice are introduced to the food or beverage immediately before consumption.

Safety concerns associated with the use of liquid nitrogen and dry ice in beverages at retail are based on both the physical state of the substances and accidents surrounding their use rather than on any toxicity associated with either substance. While retail food-related incidences of accidental ingestion or direct contact with liquid nitrogen and dry ice in the United States are low, injuries have been severe.

FDA is taking several steps to address the recent media reports of injuries as part of an overall approach to educate consumers, industry, and regulators. On August 30, 2018, FDA issued a safety advisory (Dragon's Breath Advisory) to alert consumers and retailers of the potential for serious injury from eating, drinking, or handling food products prepared by adding liquid nitrogen at the point of sale, immediately before consumption.

Other measures include:

- An interpretation of the FDA Food Code was issued on October 31, 2018 to address whether the 2017 FDA Food Code prohibits the use of liquid nitrogen and dry ice in the preparation or service of food in retail and foodservice establishments. The interpretation can be found at: https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/UCM624588.pdf

- Continuing internal work to assess associated risks and hazards, as well as applicable regulatory options and any potential mitigation strategies.

FDA remains in support of collaborative efforts with AFDO to identify specific needs for regulators and to further monitor the social trends surrounding the use of liquid nitrogen and dry ice in beverages at food establishments. For example, we are interested in having a dialogue on any gaps AFDO sees in communicating the risks of the use of liquid nitrogen in the preparation of foods at retail.

Resolution #2018-3: FDA Traceability Guidance

Summary: AFDO requests FDA provide industry guidance on traceability in order to better control and minimize risks to companies and consumers. This guidance should be geared toward implementing seamless traceability programs that can provide manufacturers the ability to take quick, comprehensive action at any time should the need to withdraw a product arise.

FDA Response: We agree with AFDO that traceability is very important to public health. Efficiently tracking and tracing FDA-regulated products will enable FDA to work with stakeholders, including industry producers, to quickly remove harmful products or ingredients from the supply chain. FDA is very committed to pursuing a tracking and tracing initiative with stakeholders and it is a top priority of Frank Yiannas, new Deputy Commissioner for Food Policy and Response, and the FDA Foods Program. With regards to guidance, FDA's priority is the traceability rulemaking required by Section 204 of the FDA Food Safety Modernization Act (FSMA), and we are devoting considerable resources to this task.

Resolution #2018-4: FDA/OHAFO Work Planning Consistency

Summary: AFDO advises FDA of its view on the critical importance of work planning between FDA Districts and the states. AFDO advises FDA that this work planning should include inspection and investigation activities, training, and auditing and be applied in a consistent manner uniformly among all OHAFO Districts.

FDA Response: Work planning consistency across divisions and states is an important objective of FDA. In addition to the fact that the inventory for the states will be reduced to two categories, full PC and limited scope PC, and GMP, we need to match the contract work with the high risk/non-high risk and Preventive Controls (PC) inspection needs, consider the inspectional expertise within the state, and the number of inspections that

are referenced in each state's contract. We are also using tools like GIS and Tableau to generate and strategically use data in ways that we have not used before. We need to standardize the work planning process throughout the field and as part of our interactions with the states. A start is to complete the updating of the Partnership for Food Protection (PFP) Best Practices "Model for Local Federal/State Planning and Coordination of Field Operations and Training" document that was first issued in October 2013. FDA recently provided some language to PFP for consideration in revising the document, and we look forward to working with PFP and AFDO to complete revision of this best practices document.

Following ORA's realignment in May 2017, ORA has been developing standard operating procedures (SOPs) to standardize processes across the ORA divisions. This includes work planning with the states. Our new work planning SOP provides a level of consistency among the divisions with how they work plan with the states and also references the PFP Best Practices document.

Resolution #2018-5: Regulator Preventive Controls Training for State Officials

Summary: AFDO requests FDA to work with AFDO to address those influencing factors listed in AFDO's survey by identifying strategies to resolve these matters (i.e., using alternative training measures and employing triage or trigger-based inspections). AFDO recommends that FDA address the priorities for FDA contracted inspections over the next 5 years, so the states can develop their contract proposals accordingly.

AFDO requests an urgent need for FDA to develop and provide a management training course to allow for evaluating performance of state regulatory officials who will be conducting the independent Food Preventive Control inspections. Further, these management officials also must be able to explain the technical aspects of the inspections to the policy makers, legal affairs, professionals and respond to other stakeholder concerns.

FDA Response: FDA has established a train-the-trainer approach for the implementation of Preventive Controls (PC) training for both human and animal food inspections. We have increased the instructor pool and trainers available to train on PC regulatory inspections in both the human and animal food arena. FDA has offered FD254 (PC Human Food Inspections for Regulators) since FY16 and has trained both state and FDA regulatory personnel. As the PC inspections are conducted for large, small, and very small firms, adjustments to the inspection approach, as well as training approach, are needed to continuously improve the newly established program.

FDA ORA, specifically the Office of Training Education and Development (OTED), looks forward to continued collaboration with AFDO in resolving mutually agreed upon areas where additional training options could be considered. AFDO has greatly assisted in helping to prioritize the FY19 training seats for the PC Human Food Inspections for Regulators course.

FDA/ORA/OTED now has an additional online training course that provides an overview of FDA's PC Human Food Inspections for Regulators course (FD254). This new course entitled, "FD255W100 – Overview of Preventive Controls for Human Food Inspections for Compliance Officers, Supervisory, Consumer Safety Officers, and other Food Program Supervisors/Managers," is developed specifically for regulatory managers

and compliance officers. It is available through FDA/ORA's Learning Management System at: https://orauportal.fda.gov/stc/ora/psciis.dll?COURSE=ora&CODE=FD255W100. Upon completion of this course, regulatory officials will know the key components/concepts of the FD254 PC HF regulators course, recognize systems thinking concepts and soft skills, and become familiar with technical content associated with FD254 regulators inspection course through a frequently asked questions section.

Prior to taking the course, participants must complete the following prerequisite online training courses:

- FD8000R – 21 CFR 117 Modernized Good Manufacturing Practice (GMP) Inspections https://orauportal.fda.gov/stc/ora/psciis.dll?COURSE=ora&CODE=FD8000R; and
- FD254W100 – Introduction to Preventive Controls for Human Food for Regulators https://orauportal.fda.gov/stc/ora/psciis.dll?COURSE=ora&CODE=FD254W100

Course duration is as follows:

- 6 readings (159 total pages)
- 10 narrated video modules (@ 156 minutes total)
- 3 round-table question/answer style discussions (@ 126 minutes total)

FDA/ORA/OTED is sharing this important online training course through our normal course distribution process and is also working with FDA's ORA, Office of Partnerships to market and communicate the course and its location in FDA ORA's learning management system. Currently, FDA is also considering other avenues by which to communicate this new training tool.

FDA believes this online training program for managers and compliance offices of regulatory personnel will address the necessary technical needs of PC inspections, provide pertinent resources, and will assist the states in developing the necessary performance evaluation of your staff who conduct food PC inspections.