TO: Napa Valley Vintners
California Association of Winegrape Growers
Hop Growers of America/U.S. Hop Industry Plant Protection Committee
Brewers Association

SUBJECT: Produce Safety Rule

DATE: March 15, 2018

Dear Stakeholder:

Thank you for your recent correspondence and dialogue with the U.S. Food and Drug Administration (FDA or the Agency) in which you expressed concern about the inclusion of winegrapes and hops as covered produce under the FDA Food Safety Modernization Act (FSMA) "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" final rule (produce safety rule). You have expressed concern that the commodities were not included on the "rarely consumed raw" list of excluded produce in the produce safety rule. In addition, you have indicated that, while realizing that you would receive the exemption for commodities that are processed to adequately reduce the presence of microorganisms of public health significance (the commercial processing exemption), you continue to have concerns about the records requirement associated with the exemption (disclosures, written assurances, record maintenance). This letter is intended to provide an update on further steps we are planning to take to address your concerns related to the record keeping requirements of the commercial processing exemption in addition to renewing our commitment to review any data your industry may have relating to consumption patterns of winegrapes and hops.

During the rulemaking, we did not include commodities such as winegrapes and hops on the list of "rarely consumed raw" produce excluded from the rule under 21 CFR 112.2(a)(1). At the time of the rulemaking, classification of produce as "rarely consumed raw" was based on consumption patterns reported in the National Health and Nutritional Examination Survey/What We Eat in America, which is the most comprehensive and robust, nationally representative dataset currently available on dietary intake in the United States. To be included on the list, consumption patterns for a commodity had to meet three criteria. The three criteria are that the commodity is consumed raw by less than 0.1 percent of the population; is consumed raw on less than 0.1 percent of eating occasions; and that consumption in any form—raw, processed, or other—was reported by at least 1 percent of a weighted number of survey respondents. We were not able to determine that produce not included on the list met these criteria. However, in the preamble to the final rule, we stated that we intended to consider updating the list of rarely consumed raw commodities in the future as appropriate, and we encouraged stakeholders who have relevant information to submit data that are sufficiently robust and representative to allow

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FDA to draw scientifically valid conclusions. FDA continues to encourage the submission of relevant data.

As noted above, we believed that grapes going to wine production and hops going to the brewing industry would qualify for the commercial processing exemption. Commodities are eligible for the commercial processing exemption if they are commercially processed to adequately reduce microorganisms of public health significance. Commodities receiving the exemption are exempt from the majority of the provisions of the produce safety rule but must meet certain documentation requirements. Those documentation requirements include a disclosure that growers must provide to their customers and a written assurance that growers must receive from their customers that perform the commercial processing, along with record maintenance requirements. The written assurance provision was included in several of the FSMA rulemakings, and concerns were expressed over the recordkeeping burden associated with providing and maintaining these assurances. In response to the concerns, FDA extended the compliance dates for requirements to obtain written assurances from customers in August 2016 (see 81 FR 57784) while we considered the best approach to address feasibility concerns. Since then, in January 2018, we issued a guidance document indicating our intent to exercise enforcement discretion with regard to the written assurances requirements in several of the FSMA rules, including the produce safety rule (https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm590646.htm).

Though there is enforcement discretion for the written assurances, I understand that there is still concern about the records requirements associated with the commercial processing exemption. Therefore, I am writing you to let you know that since our previous communications, we have continued to review the recordkeeping burden associated with the commercial processing exemption for commodities such as winegrapes and hops, and that we are working on a solution to address your concerns about these burdens. We are exploring options to allow for exemption from the records requirement as part of the commercial processing exemption for certain commodities. We will likely need to engage in rulemaking to expand the exemption. We are also considering streamlining and reducing the records requirements for those growers who have annual contracts with commercial processors.

FDA remains committed to working with the food industry throughout implementation of the produce safety rule to ensure that requirements are as practical as possible while still protecting public health. There will be more to come on these issues as we work toward implementing solutions, but I wanted to assure you that there are solutions in process.

Sincerely,

Scott Gottlieb, M.D.
Commissioner of Food and Drugs