



Date: May 18, 2016

Subject: Recent Extension of USFDA Tobacco Control Act 2009

In May of 2016 the FDA extended authorities to all tobacco products, including e-cigarettes, cigars and Hookah. The new rulings are an extension of the Tobacco Control Act of 2009 and require extensive disclosure of ingredients in these products along with related health and toxicology information when used in this capacity. The extension and related rules can be found on the FDA website: <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm388395.htm>

Since the ruling, we have received requests for more detailed ingredient listings for some of our flavorings.

As noted previously, LorAnn's precise flavor formulas are trade secrets that we will not disclose beyond those listed on our product labels and specification sheets. Moreover, all of our flavors are intended for use in the food and beverage industry. We do not advertise, promote or recommend our flavors for use in e-cigarettes, hookah or other tobacco products..

In this latest ruling, the FDA has addressed the use of flavorings in e-cigarettes. The most important note in the disclosure verifies and reinforces the fact that while these flavors have been determined safe (GRAS) for ingestion, they have not been approved as safe for inhalation, such the case for e-cigarettes.

This is consistent with LorAnn's previous statements that we cannot verify the safety of our products outside of their intended usage:

"LorAnn Flavors are guaranteed not to be misbranded or adulterated within the meaning of the Federal Food, Drug and Cosmetic Act as amended on this date. All ingredients have been inspected and the finished product is in accordance with formulated specifications for this material. It has been processed in accordance with Good Manufacturing Practices and prescribed standards of sanitation as practiced in the industry. All ingredients are generally regarded as safe (GRAS), approved by a regulation of the F.D.A. or appear on the industry-approved register of safe ingredients for the flavor industry."

LorAnn Oils Inc. disclaims liability for any and all consequential damages arising out of and related to the use of its products. The user assumes all risks associated with the use of LorAnn products, whether used singly or in combination with other substances, and the user's sole remedy shall be limited to a full refund of purchase price or product or replacement if it fails to conform to the specification set forth as labeled. LorAnn Oils Inc. makes no warranty of any kind, either expressed or implied, as to the fitness for a particular purpose, suitability, or usage of its products.

Individuals or companies that use our flavors, emulsions, extracts, and essential oils outside their intended use, do so at their own risk and without warranty, either expressed or implied, from LorAnn Oils, Inc. or its suppliers. The user assumes all liability for loss, injury, damage or expense resulting from such uses."



LORANN OILS, INC.

www.lorannoils.com • customercare@lorannoils.com

This position to maintain the proprietary nature of the flavoring ingredients is not only a decision of LorAnn's, but also the position of many raw material providers. Even the major flavoring industry manufacturer's association (FEMA) is advocating that its members refrain from making claims that flavoring ingredients listed in its own FEMA GRAS listing are intended only for food products, and that E-liquids are not food or intended for ingestion.

The FDA ruling does state that the flavor manufacturer may elect to disclose proprietary ingredients directly to the FDA via a Tobacco Product Master File. However, with that disclosure, the flavor manufacturer must also provide health and toxicology information for those ingredients when used in this particular application (cigarettes, e-cigarettes, hookah & cigars). This is not information LorAnn Oils is able to supply and we have no intention of conducting the research and testing that would be required to provide this critical information.

Sincerely,

Carl Thelen
COO, LorAnn Oils, Inc.