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October 13, 2023

VIA FIRST CLASS U.S. MAIL
AND ELECTRONIC MAIL

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20903
commissioner@fda.hhs.gov

Re: FDA Authority / State Bans On Food Ingredients And Additives

Dear Commissioner Califf,

I am writing to you today to request that the U.S. Food and Drug Administration defend its legal, fiduciary and moral responsibility as our nation's chief and centralized food safety agency and demonstrate that its science-based regulatory rigor and leadership has helped make the U.S. food system the envy of the world.

As you know and might agree, Governor Newsom and the California legislature, in enacting AB 418, have completely overstepped their area of expertise, telling the American people that the Biden Administration's FDA is incapable of keeping the food supply safe by implementing a ban on certain food ingredients through legislative fiat. Undoubtedly, the action in California has led and will lead to similar legislative proposals in other states which could result in bans of additional food ingredients that completely decentralizes FDA's authority and create a massive patchwork of requirements for U.S. food manufacturers.

In this situation, we are faced with a lack of federal expertise and authority which is needed to dispel myths and consumer confusion permeating from California and correct misinformation related to the food ingredients and additives that were banned in that state.

Food expert and toxicologist James Coughlin called the entire process in California "unnecessary and unscientific" – and we in the confectionery industry agree with him. The organizations behind California's new law are openly calling for replacing FDA's authority with a state-by-state patchwork of laws wherein state legislators make food safety decisions without any scientific basis.

The broader food industry and American consumers need to know that the FDA is prepared to prevent that slippery slope from becoming a reality, and that it has done and will continue to do the job the Congress has given it for more than 117 years: to evaluate, at a national level, the safety of food ingredients and additives. Decisions regarding the safety of the U.S. food supply belong in the hands of our foremost food safety experts, not politicians.

As you know, there are limited or no alternatives for some of the ingredients subject to the California ban. The U.S. Department of Agriculture estimated that it could take a decade or longer to develop and obtain FDA approval for a safe replacement for a color additive. This impact is particularly relevant in today's inflationary environment as consumers are feeling the pinch when it comes to the high cost of groceries, and the cost of reformulation will be substantial and ultimately passed on to consumers in the form of higher prices.

There has been a significant amount of public attention and media coverage given to the food ingredient and additive ban in California, including some who say that the state is being proactive by moving faster than FDA. But much of this commentary is built on falsehoods that are unfortunately all too easy to accept at face value and has been made by those who do not know or understand FDA's review processes. It's time for FDA to get off the sidelines and clear up this misinformation, because the fact of the matter is that California is out of its depth when it comes to national food safety standards and regulatory processes. That expertise and authority rests with the FDA alone. Unlike FDA's processes, the legislative process is not transparent and does not solicit and consider stakeholder feedback to make a determination based on the totality of scientific and real-world evidence.

Take the case of brominated vegetable oil (BVO) for example. As you well know, FDA conducted two scientific studies on its own, found new data related to safety risks and initiated steps to remove BVO from the food supply in this country. This is how our food safety system was designed to work, and it's a real-time example of it working. California blatantly ignored FDA's review of BVO with its new law and passed a ban on BVO and other ingredients without any scientific analysis.

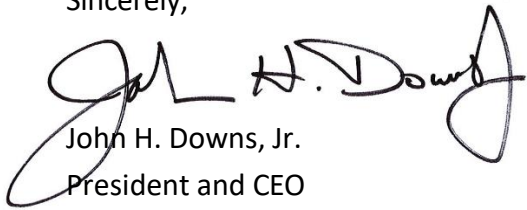
This is exactly what we need from the FDA related to the ingredients banned in California. We believe it is past time for the FDA to lean into this conversation, because a state banning FDA-approved food ingredients and additives undermines consumer trust and creates confusion around food safety. It replaces a uniform national food safety system with a patchwork of inconsistent state requirements that increase food costs.

I would be remiss if I did not mention the great progress that FDA is making on modernizing its review process, which NCA strongly supports, including overhauling its technology, increasing amount of data inputs and hiring additional staff to meet the growing demands of the organization. FDA's food ingredient and additive program will also be enhanced under the oversight of Jim Jones, FDA's newly appointed Deputy Commissioner of Foods.

Food safety is the number one priority for U.S. confectionery companies, and we do not use any ingredients in our products that do not comply with the FDA's strictest safety standards. Thank you for all that you and your staff have done to ensure that our country's food system is safe and secure. I look forward to hearing back from you on ways in which FDA can get more involved in ensuring that our country avoids a patchwork of inconsistent state requirements that increase food costs and maintains a uniform national food safety system.

We welcome the opportunity to discuss our request and the issues in this letter further if you believe it will be helpful to your review. You may reach me at John.Downs@CandyUSA.com.

Sincerely,

A handwritten signature in black ink, appearing to read "John H. Downs, Jr.", with a large, stylized flourish at the end.

John H. Downs, Jr.
President and CEO
National Confectioners Association (NCA)

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