

Ryan F. Quarles
Commissioner



Corporate Drive Complex
Frankfort, KY 40601
(502) 573-0282

Kentucky Department of Agriculture

May 31, 2019

Acting Commissioner Norman E. "Ned" Sharpless, M.D.
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Dr. Sharpless:

As Kentucky's Agriculture Commissioner, it is my honor to be an advocate for tens of thousands of farm families in the Commonwealth. Since the passage of the 2014 Farm Bill, many Kentucky farm families have researched and experimented with the production of industrial hemp, a crop that has deep roots in Kentucky's history. I write this letter today to offer Kentucky's support as a constructive partner to the Food and Drug Administration as it considers how to develop a regulatory framework for hemp products.

Kentucky is proud of the fact that we have built an industrial hemp program that is widely regarded as a model for other states to emulate. When the program began in 2014, 33 acres of hemp were grown in Kentucky. Last year, nearly 7,000 acres were grown and in 2019, we have around 1,000 licensed hemp growers approved to cultivate more than 56,000 acres of hemp. Growers and processors reported more than \$50 million in gross product sales in 2018, a remarkable achievement. That compares with \$16.7 million in gross product sales in 2017. Processors reported paying Kentucky farmers \$17.75 million for harvested hemp materials in 2018, up from \$7.5 million the year before. We are starting to build the critical mass of growers and processors that will benefit Kentucky for years to come.

This economic success is possible due to the work of my Administration with the Kentucky General Assembly. Under the auspices of the 2014 Farm Bill, we worked together to develop a statutory and regulatory framework for hemp production that empowered our growers and processors, built a high level of trust with our law enforcement agencies, and sought continuous improvement by streamlining program rules over time. Getting the state-level policy correct was an essential pre-condition for the hemp boom we have experienced here in Kentucky.

Getting the federal-level policy right is equally important, and the 2018 Farm Bill was a major step in the right direction. The 2018 Farm Bill laid the groundwork for the full-scale commercialization of hemp by removing hemp from the list of controlled substances and directing the United States Department of Agriculture (USDA) to make hemp growers eligible to participate in federal farm programs. It also recognized the benefit of devolving primary regulatory authority over hemp production to the states, provided that a state agency regulatory plan met certain criteria outlined in the law. I believed Kentucky's existing hemp program met the letter and the spirit of the 2018 Farm Bill and immediately submitted Kentucky's regulatory plan to the USDA on December 20, 2018: the day the Farm Bill was signed.

Since the signing of the Farm Bill, my staff and I have worked hand in hand with the leadership and staff at USDA to assist them with their implementation of the Farm Bill's hemp provisions. In recent months, Kentucky has hosted Under Secretary Greg Ibach and other members of USDA leadership to show



them how our program works. We have hosted several state delegations for the same purpose. These visits have been very beneficial in assisting them in the development of federal guidelines and state hemp programs.

With this letter, I am formally extending an offer for the Kentucky Department of Agriculture to be a constructive partner with the FDA as your agency begins the rulemaking process for cannabinoids, including cannabidiol or CBD. It is no secret that the 2018 Farm Bill reaffirmed FDA's authority to promulgate regulations related to the manufacture of hemp products under the Federal Food, Drug, and Cosmetic Act. However, I strongly urge the FDA to consider the full breadth options before you in regulating this new industry.

In addition to my role as Kentucky's Agriculture Commissioner, I serve as Second Vice President of the National Association of State Departments of Agriculture (NASDA). In that capacity, I have championed the development of consistent, national hemp policy that will benefit the entire country. Earlier this year, my NASDA colleagues and I formally adopted a new policy on hemp. It reads, in full:

- NASDA supports the production, processing and commercialization of hemp.
- NASDA encourages research in all aspects of hemp from production to finished products.
- NASDA supports consistent model legislation to assist state legislatures in their efforts to enact laws permitting hemp production within their jurisdictions in accordance with the 2018 Farm Bill.
- NASDA supports the development of uniform standards for field sampling and tetrahydrocannabinol (THC) content testing with gas chromatography (GC) methods.
- **NASDA encourages the U.S. Food & Drug Administration (FDA), in consultations with states, to develop a model regulatory framework for oversight of the processing of hemp and manufacturing of Cannabidiol (CBD) which will protect public health, comply with federal law, and foster growth in the industry.**

On behalf of the Kentuckians I represent, and my colleagues in NASDA, I urge FDA to use the states as a resource as the agency develops a model regulatory framework for oversight of the processing of hemp and manufacturing of cannabidiol (CBD) which will protect public health, comply with federal law, and foster growth in the industry.

It is especially important now, at a time when net farm cash receipts are the lowest they've been since 2013, that federal and state government agency representatives do everything they can to help new agricultural commodities emerge and thrive. As you carry out these tasks, I urge you to engage in a meaningful give-and-take discussion with those of us in state departments of agriculture who have gained valuable insights from several years' work with this new crop.

If there is anything I or my office can do to assist you in this matter, please do not hesitate to contact me.

Respectfully,



Ryan F. Quarles
Commissioner

rfq/klr