



April 7, 2020

The Honorable Donald J. Trump  
President  
The White House  
1600 Pennsylvania Avenue NW  
Washington, DC 20500

Dear Mr. President:

As part of the Administration's comprehensive response to the unprecedented health and economic impacts from the COVID-19 pandemic, the Biotechnology Innovation Organization (BIO) respectfully requests that the U.S. government immediately reform its approach to oversight of animals with intentional genomic alterations. We are calling on the White House to direct the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) to develop and execute a memorandum of understanding (MOU) clarifying regulatory responsibilities over these animals within 30 days.

COVID-19 highlights the interconnectedness of human, animal, and environmental health. While it would not have prevented the current pandemic, animal biotechnology holds enormous potential to safeguard society from future zoonotic diseases that frequently exact high economic and health costs, and to develop human therapeutics relevant to the current outbreak.

The Administration should act immediately to establish a sensible, science-based regulatory approval process for animal biotechnology – an approach that incentivizes research and investment and ensures safe and affordable products reach consumers as soon as possible. The U.S. government's current approach to regulating all applications of this technology as a "new animal drug" should be replaced with a new model that more appropriately draws upon existing legal authorities to safeguard animal health, food safety, and the environment.

The Administration must move in this direction as quickly as possible to enable long-delayed innovations in animal biotechnology that will help us meet and solve big challenges, including but not limited to zoonotic diseases. Acting to establish a joint agreement between USDA and FDA in the next 30 days will go a long way in helping farmers, innovators, and consumers realize the benefits these technologies bring to the people of the United States and the world.

Thank you for considering our request.

Sincerely,

A handwritten signature in black ink that reads "Jim Greenwood". The signature is fluid and cursive, with the first name "Jim" being more prominent.

James C. Greenwood  
President and CEO

cc: The Honorable Sonny Perdue, Secretary of Agriculture  
The Honorable Stephen Hahn, Commissioner, Food and Drug Administration