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MEMORANDUM

From: Joseph A. Levitt
Mary B. Lancaster

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Re: **FDA Releases Plant and Animal Biotechnology Innovation Action Plan**

The U.S. Food and Drug Administration (FDA) recently released its Plant and Animal Biotechnology Innovation Action Plan ("Action Plan"). 1/ The Action Plan provides an overview of the key priorities FDA expects to pursue through 2020 to support innovation in plant and animal biotechnology. As highlighted in FDA Commissioner Gottlieb's statement, the agency is committed to fostering innovative advances in the field while ensuring the safety of plant and animal biotechnology products used by consumers. 2/ The Action Plan identifies three concepts as critical to FDA's success in fulfilling its goal: 1) advancing public health by promoting innovation; 2) strengthening public outreach and communication; and 3) increasing engagement with domestic and international partners.

Background

Since 2015 FDA has been partnering with U.S. Environmental Protection Agency (EPA) and U.S. Department of Agriculture (USDA) to modernize the regulatory framework for biotechnology products. More recently, in January 2017, FDA published a draft Guidance for Industry, "Regulation of Intentionally Altered Genomic DNA in Animals," 3/ as well as a Request for Comments on questions related to use of genome editing in new plant varieties used for food for humans and animals. 4/ Building on this momentum, FDA's Action Plan outlines the agency's next steps in developing "an efficient, science-based pathway to market for safe [plant and] animal biotechnology-derived products." 5/ Some items in the action plan are already underway, and FDA expects implementation of the plan to continue through 2020. 6/

1/ Plant and Animal Biotechnology Innovation Action Plan, available at: https://www.fda.gov/downloads/Safety/Biotechnology/UCM624517.pdf.
2/ Press Announcement, Statement from FDA Commissioner Scott Gottlieb, M.D., and Deputy Commissioner Anna Abram on the FDA's new plan to advance plant, animal biotechnology innovation (Oct. 30, 2018), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM624541.htm.
3/ 82 Fed. Reg. 6561.
4/ 82 Fed. Reg. 6564.
5/ Action Plan at 3.
6/ Action Plan at 1.

Advancing Public Health by Promoting Innovation

On December 3, 2018, FDA's Center for Veterinary Medicine (CVM) will host a public webinar titled "Genome Editing in Animals." 7/ Together with FDA's Center for Biologics Evaluation and Research (CBER), CVM will address the benefits and potential risks of genome editing in animals, as well as common misconceptions about FDA's regulation of products derived from genome editing. 8/ FDA is also establishing a new pilot program, the Veterinary Innovation Program (VIP), which will aim to provide greater certainty in the regulatory process, encourage development and research, and support an efficient and predictable pathway to approval for certain innovative animal products. 9/

Forthcoming Guidance

1. Animal Biotechnology

Next year (2019), FDA intends to take action on three animal biotechnology issues: (1) Issue guidance clarifying FDA's regulatory approach of intentional genomic alterations in animals, outlining when FDA intends to exercise enforcement discretion or when it intends to enforce the requirement for an approved new animal drug application. 10/ The guidance will introduce three, flexible FDA review categories: (a) FDA decision not to enforce approval requirements with no prior review; (b) FDA decision not to enforce approval requirements following a review of data that address specific risk questions; and (c) FDA decision to review for approval with data requirements proportionate to the risk associated with the particular product. (2) Issue guidance establishing an alternative type of file as a repository for information exchanges with the FDA's Center for Veterinary Medicine (CVM) for products that are in the early development stages or that are developed for pure research and that may never progress to a marketable product. (3) Update FDA website to provide a list of specific animals or categories of animals with intentional genomic alterations for which FDA has made a risk-based determination to exercise enforcement discretion with regard to pre-market approval requirements.

2. Plant Biotechnology

In early 2019, FDA intends to publish for public comment a Guidance document explaining how FDA's current regulatory policy for foods derived from new plant varieties applies to foods produced using genome editing. 11/ Over the next two years, the agency will update its existing procedures for voluntary premarket consultations with industry. 12/

7/ CVM Public Webinar: Genome Editing in Animals, registration available at: https://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm624216.htm.
8/ Action Plan at 3.
9/ Action Plan at 4.
10/ Action Plan at 4.
11/ Action Plan at 5.
12/ Action Plan at 5.

Strengthening Public Outreach and Communication

The second pillar in the Action Plan involves "a robust public communication strategy." 13/ FDA intends to actively engage with stakeholders throughout the upcoming regulatory drafting process, hold public meetings in coordination with the issuance of guidance documents, and perform active outreach to industry, particularly small developers and animal producers and farmers. Through these channels of communication, the agency hopes to explain its science-based regulatory approach and increase public and stakeholder understanding of the regulatory frameworks.

Increasing Engagement with Domestic and International Partners

Finally, FDA hopes to increase coordination and regulatory alignment with its domestic and international public health partners. The agency is open to exploring existing or new memoranda of understanding with foreign governments and will continue to work domestically within the Coordinated Framework established between FDA, USDA, and EPA. FDA also hopes to build stronger public-private relationships to maximize dialogue about how biotechnology tools can be used to address ecological, environmental, and public health challenges.

Conclusion

FDA's Action Plan balances the broad goal of establishing a more efficient, less resistant path forward for biotechnology innovation with the need to ensure safe products for consumers. The agency continues to invest resources into public education and emphasize the importance of stakeholder participation in building a flexible regulatory approach to new products.

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We will continue to monitor developments on FDA's proposed frameworks relating to biotechnology innovation in plant and animal products. Please contact us if you have any questions.

13/ Action Plan at 5.