Subject: Re: [gbird] FDA Requests Comments on Documents related to Certain Biotechnology and Mosquito-Related Products
From: Royden Saah <royden.saah@islandconservation.org>
Date: 1/20/2017 1:58 PM
To: "gbird@lists.ncsu.edu" <gbird@lists.ncsu.edu>

Thanks Todd,

A goal I have for 2017 is to strengthen the partnership significantly. I will add this to GBIRd action items if the steering Committee (David Threadgill, Peter Brown, Paul Thomas, Fred Gould, John Godwin, Toni Piaggio, Gregg Howald and Karl Campbell) would like to do this. I think it is a good idea. If you have an opinion you would like considered (either way), please communicate it to your organizational lead in the steering committee.

With Warm Regards,
Royden

From: gbird-owner@lists.ncsu.edu [mailto:gbird-owner@lists.ncsu.edu] **On Behalf Of** Todd Kuiken
Sent: Wednesday, January 18, 2017 1:58 PM
To: gbird@lists.ncsu.edu
Subject: [gbird] FDA Requests Comments on Documents related to Certain Biotechnology and Mosquito-Related Products

This is something this group should participate in both as a group submission from organizations as well as individual scientists.

Todd

FDA Requests Comments on Documents related to Certain Biotechnology and Mosquito-Related Products

Good morning,
The U.S. Food and Drug Administration released today three documents that seek public comment on issues involving products of new genome editing technologies and certain products related to mosquitoes.
The FDA is requesting public comment on a draft revised guidance on the regulation of animals with intentionally altered genomic DNA, including animals produced through the use of genome editing and genetic engineering; a request for comments related to the regulation of foods from plants produced using genome editing technologies; and a draft guidance that clarifies which mosquito-related products FDA regulates and which such products EPA regulates, regardless of whether these mosquito-related products are developed using biotechnology.

These announcements are consistent with the FDA's commitments outlined in the *National Strategy for Modernizing the Regulatory System for Biotechnology Products* (the *Strategy;* released in September 2016), which sets forth a vision for ensuring that the federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology. These FDA announcements follow the recent White House release of a 2017 Update to the Coordinated Framework for the Regulation of Biotechnology, which clarifies the current roles and responsibilities of, and coordination among, FDA, EPA, and

USDA/APHIS.

The FDA is accepting public comments on these documents beginning on January 19, 2017.

Comments will be accepted at any time, but should be submitted no later than the closing date to ensure that the FDA takes the information into consideration before making further decisions on this issue.

· Draft revised GFI #187: *Regulation of Intentionally Altered Genomic DNA in Animals*, FDA-2008-D-0394, closes on April 19, 2017

· Request for Comments: *Genome Editing in New Plant Varieties Used For Foods*, FDA-2016-N-4389, closes on April 19, 2017

· Draft GFI #236: *Regulation of Mosquito-Related Products*, FDA-2016-D-4482, closes on February 21, 2017

For More Information

· CFSAN/CVM Constituent Update: FDA Requests Comments on Documents related to Certain Biotechnology and Mosquito-Related Products

· FDA Voice: FDA's Science-based Approach to Genome Edited Products

· GFI #187: Regulation of Intentionally Altered Genomic DNA in Genetically Engineered Animals; Draft Guidance for Industry

  - Animals with Intentionally Altered Genomes – Q&A

· Genome Editing in New Plant Varieties Used for Foods; Request for Comments

  - Foods derived from plants produced using genome editing

· GFI #236: Regulation of Mosquito-Related Products; Draft Guidance for Industry
· Modernizing the Regulatory System for Biotechnology Products

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Todd Kuiken, Ph.D.
Senior Research Scholar
Genetic Engineering & Society Center
North Carolina State University
Campus Box (or CB) 7565
Raleigh, NC 27695 -7565
Phone: 919-515-2593
email: tkuiken@ncsu.edu
@drtoddoliver
Program Website: https://research.ncsu.edu/ges