Message

From: Ex. 6
Sent: 5/14/2017 1:17:52 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
Subject: mosquitos

https://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm533600.pdf

https://www.fda.gov/animalveterinary/newsevents/cvmupdates/ucm536949.htm

raft guidance for industry on mosquito-related products
As part of the Strategy, the FDA and EPA committed to considering mechanisms that would enable EPA to regulate certain mosquito-related products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) when the developer claims they are intended to control mosquito population levels, and the FDA to regulate them under the FD&C Act when the developer makes other claims, such as a disease prevention claim.

The FDA's draft Guidance for Industry #236, developed in coordination with EPA, describes the FDA's understanding that mosquito-related products intended to function as pesticides by preventing, destroying, repelling, or mitigating mosquitoes for population control purposes are not "drugs" under the FD&C Act, and, when the guidance is finalized, will be regulated by EPA under FIFRA. Under the draft guidance, FDA would continue to have jurisdiction over mosquito-related products that meet the FD&C Act drug definition, such as those intended to prevent, treat, or cure a disease.

The FDA encourages public comments on draft guidance #236 for 30 days starting on January 19, 2017. These activities, together with the recent release of the final 2017 Update to the Coordinated Framework for the Regulation of Biotechnology, are part of an ongoing effort to modernize the regulatory system for biotechnology products.