



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1678]

The Food and Drug Administration Foods and Veterinary Medicine Program's Strategic Plan for Fiscal Years 2016-2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice and request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of the "Foods and Veterinary Medicine (FVM) Program's Strategic Plan for Fiscal Years 2016-2025" that covers activities of the Office of Foods and Veterinary Medicine, the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine, as well as related efforts by the Office of Global Regulatory Operations and Policy and the Office of Regulatory Affairs. Our strategic plan includes goals and objectives for the next 10 years including our mission to implement the FDA Food Safety Modernization Act (FSMA) enacted in 2011, as well as details on our goals of protecting and enhancing the health of both people and animals. We invite public comment on the plan.

DATES: Submit either electronic or written comments on the strategic plan at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-1678 for "FDA Foods and Veterinary Medicine (FVM) Program's Strategic Plan for Fiscal Years 2016-2025." Received comments will be placed in the docket and, except for those submitted as

"Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mia Mercer, Office of Foods and Veterinary Medicine, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8794.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

We are announcing the availability of the FVM Program's Strategic Plan for Fiscal Years 2016-2025 in order to inform the public of our goals for the next 10 years. We are implementing the modernization of FDA's regulatory framework for the FVM Program. We are focused on continuing to drive toward a more proactive, preventive, risk-informed approach to food and feed safety, nutrition, and animal health.

The FVM Program works to ensure the American public has food that is safe and nutritious and that animal drug products are safe and effective. Our priority is to obtain high rates of compliance with standards necessary to protect public health and meet consumer and other stakeholder expectations. Recognizing the unique challenges we face in the area of food safety in the 21st century, Congress enacted FSMA which requires (among other things):

- Comprehensive prevention-oriented food safety standards across the food system;
- mandated domestic inspection frequency, based on risk, to ensure high rates of compliance;
- a national integrated food safety system based on full partnership with States; and
- a new import safety system based on food safety accountability for importers, increased foreign presence, and increased collaboration with foreign governments.

Our FVM Program Strategic Plan takes this statutory framework into account, places high priority on the implementation of FSMA, and focuses on how we plan to modernize our food safety work including:

- An increased focus on obtaining compliance with preventive control standards rather than finding and responding to legal violations after an illness or outbreak has occurred;
- strengthening our technical expertise and capacity to support FDA, industry, and other stakeholders in implementing the new prevention standards;
- furthering federal, State, local, and territorial partnerships, and investing in training and capacity to ensure efficient, high quality, and consistent oversight nationwide; and
- broadening interaction with foreign partners and increasing oversight of importers, who will have more responsibility for the safety of imported foods.

Beyond FSMA's implementation, the FVM Program Strategic Plan provides details on our goals of protecting and enhancing the health of people and animals. The active engagement of all stakeholders and partners, both internal and external, is critical to the successful implementation of this plan.

## II. Electronic Access

Persons with access to the Internet may obtain the FVM Program Strategic Plan at <http://www.regulations.gov>.

## III. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

(FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. FDA Foods and Veterinary Medicine Program Strategic Plan, FY 2016-2025, available at <http://www.fda.gov/aboutfda/centersoffices/officeoffoods/ucm273269.htm>.

2. Partnership for Food Protection (PFP) Strategic Plan FY 2015 through 2020, available at <http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM423834.pdf>.

Dated: July 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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