

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters for Discussion:* The meeting will include the initial review, discussion, and evaluation of applications received in response to "Emerging Infections Programs", FOA CK17-1701.

*Contact Person for More Information:* Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 718-8833.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Catherine Ramadei,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2016-16581 Filed 7-13-16; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-P-4224]

#### **Determination That PARAFON FORTE DSC (Chlorzoxazone) Tablets, 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that PARAFON FORTE DSC (chlorzoxazone) tablets, 500 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and this determination will allow FDA to continue to approve ANDAs for chlorzoxane tablets, 500 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993-0002, 301-796-8767.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, is the subject of NDA 011529, held by Janssen Research & Development, LLC, and initially approved on August 15, 1958. PARAFON FORTE DSC is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, is listed in the "Discontinued Drug Product List" section of the Orange Book.

Flamingo Pharmaceuticals Ltd. submitted a citizen petition dated November 7, 2015 (Docket No. FDA-2015-P-4224), under 21 CFR 10.30, requesting that the Agency determine whether PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were

withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PARAFON FORTE DSC (chlorzoxazone) tablets, 500 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-16635 Filed 7-13-16; 8:45 am]

**BILLING CODE 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.*

[FR Doc. 2016–16684 Filed 7–13–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2016–D–1659]

### Bacterial Vaginosis: Developing Drugs for Treatment; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Bacterial Vaginosis: Developing Drugs for

Treatment.” The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of bacterial vaginosis (BV).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 12, 2016.

**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–D–1659 for “Bacterial Vaginosis: Developing Drugs for Treatment; Draft

Guidance for Industry; Availability.” 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.