Risk Evaluation and Mitigation Strategy (REMS) Document
Emtricitabine/Tenofovir Disoproxil Fumarate Shared System REMS Program

I. Administrative Information
Initial Shared System REMS Approval: 06/2017
Most Recent REMS Update: 07/2018

II. REMS Goals
The goals of the REMS for the emtricitabine/tenofovir disoproxil fumarate for a Pre-exposure Prophylaxis (PrEP) Indication are:

To inform and educate prescribers and uninfected adults and adolescents at risk for acquiring HIV-1 infection about:

- The importance of strict adherence to the recommended dosing regimen
- The importance of regular monitoring of HIV-1 serostatus to avoid continuing to take emtricitabine/tenofovir disoproxil fumarate for a PrEP indication, if seroconversion has occurred, to reduce the risk of development of resistant HIV-1 variants
- The fact that emtricitabine/tenofovir disoproxil fumarate for a PrEP indication must be considered as only part of a comprehensive prevention strategy to reduce the risk of HIV-1 infection and that other preventive measures should also be used

III. REMS Requirements
The emtricitabine/tenofovir disoproxil fumarate applicants must provide training to healthcare providers who prescribe emtricitabine/tenofovir disoproxil fumarate for a PrEP indication.

The training includes the following educational materials: Training Guide for Healthcare Providers, Healthcare Provider Education Slide Deck, Important Safety Information for Healthcare Providers, Important Safety Information for Adults Who Don’t have HIV, Agreement Form for Initiating emtricitabine/tenofovir disoproxil fumarate for Pre-exposure Prophylaxis (PrEP), Checklist for Prescribers, Safety Information Fact Sheet for Prescribers, and Important Safety Information for Adolescents Who Don’t have HIV. The training must be available online or in a hardcopy format by mail.
To inform healthcare providers about the REMS Program and the risks and safe use of emtricitabine/tenofovir disoproxil fumarate, the emtricitabine/tenofovir disoproxil fumarate applicants must disseminate REMS communication materials according to the table below:

<table>
<thead>
<tr>
<th>Target Audience</th>
<th>Communication Materials &amp; Dissemination Plans</th>
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<tbody>
<tr>
<td>Healthcare providers who are likely to prescribe emtricitabine/tenofovir disoproxil fumarate for a PrEP indication</td>
<td>REMS Letters: <strong>Dear Health Care Provider Letter</strong>, <strong>Professional Society REMS Letter</strong> with attachment: <strong>Safety Information Fact Sheet for Prescribers</strong></td>
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1. Email within 60 calendar days of the approval of the REMS modification (05/15/2018)
   a. Send by mail within 60 calendar days of the date the first email was sent if a healthcare provider's email address is not available or the email is undeliverable.
   b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.
   c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.

2. Make available via link from the emtricitabine/tenofovir disoproxil fumarate REMS Program Website.

3. Disseminate through to the following professional societies and request the letter or content be provided to their members.
   a. HIV Medicine Association/Infectious Diseases Society of America; American Academy of HIV Medicine; Association of Nurses in AIDS Care; National Medical Association; American Academy of Family Physicians, American Society of Addiction Medicine; American College of Obstetricians and Gynecologists; National Association of Community Health Centers, National Association of City and County Health Officials; American College of Preventative Medicine; National Association of Public Hospitals; American Pharmacists Association; American Academy of Pediatrics; American Association of Nurse Practitioners; American Association of Physician Assistants; American College of Physicians

To support REMS Program operations, emtricitabine/tenofovir disoproxil fumarate applicants must:
1. Establish and maintain a REMS Program Website, www.ftc-tdf-preprems.com. The REMS Program Website must include the capability to complete the healthcare provider training online and the option to print the prescribing information, Medication Guide, and REMS Materials. All product websites for consumers and healthcare providers must include a prominent REMS specific link to the REMS Program Website. The REMS Program website must not link back to the promotional product websites.

2. Make the REMS Program Website fully operational and all REMS materials available through website and the phone number (1-800-625-7471) to request a paper copy of the training materials within 60 calendar days of REMS modification (05/15/2018).

3. Establish and maintain a validated, secure database of healthcare providers who report completing the training.

4. Ensure healthcare providers are able to report completion of training: online and by postage paid business reply card.

IV. REMS Assessment Timetable

The emtricitabine/tenofovir disoproxil fumarate NDA Applicants must submit REMS Assessments to the FDA every 18 months from the date of initial approval of the REMS (06/08/2017). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. The emtricitabine/tenofovir disoproxil fumarate NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the emtricitabine/tenofovir disoproxil fumarate REMS:

Training and Educational Materials

Prescriber:
1. Training Guide for Healthcare Providers
2. Healthcare Provider Education Slide Deck
3. Important Safety Information for Healthcare Providers
4. Safety Information Fact Sheet for Prescribers

Patient:
5. Important Safety Information for Adults Who Don’t have HIV
6. Important Safety Information for Adolescents Who Don’t Have HIV

Patient Care Forms
7. Agreement Form for Initiating emtricitabine/tenofovir disoproxil fumarate for Pre-exposure Prophylaxis (PrEP)

8. Checklist for Prescribers

**Communication Materials**

9. Dear Health Care Provider Letter

10. Professional Society REMS Letter

**Other Materials**

11. REMS Program Website