IMPORTANT DRUG WARNING

Subject: Risk Evaluation and Mitigation Strategy (REMS) for buprenorphine-containing transmucosal products for opioid dependence due to their risks of accidental overdose, misuse, and abuse.

Dear Prescriber:

You are receiving this letter because you are a prescriber certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000).

The purpose of this letter is to inform you of a Risk Evaluation and Mitigation Strategy (REMS) called the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) REMS program. This REMS does not apply to buprenorphine-containing products that are dispensed to patients in an Opioid Treatment Program (OTP) under 42 CFR Part 8.

The FDA has determined that a REMS is necessary to ensure that the benefits of buprenorphine-containing transmucosal products for opioid dependence outweigh the potential risks of accidental overdose, misuse, and abuse. Products containing the single active ingredient buprenorphine are indicated for the treatment of opioid dependence and are preferred for induction. Products containing buprenorphine with naloxone are indicated for the maintenance treatment of opioid dependence. These products are used as part of a complete treatment plan, including counseling and psychosocial support.

Serious Risks of Buprenorphine-containing Products

The following key messages need to be communicated to patients about the risks of accidental overdose, misuse, and abuse while taking products covered under the BTOD REMS program:

- Warn patients that it is extremely dangerous to self-administer non-prescribed benzodiazepines or other central nervous system (CNS) depressants (including alcohol) while taking these products. Caution patients prescribed benzodiazepines or other CNS depressants to use them only as directed by their prescriber.
- Instruct patients to keep these products in a secure place, out of the sight and reach of children. Accidental or deliberate ingestion by a child may cause respiratory depression that can result in death. If a child is exposed to one of these products, medical attention should be sought immediately.
- Advise patients that these products contain an opioid that can be a target for people who abuse prescription medications or street drugs. Caution patients to keep their products in a safe place, and to protect them from theft.
- Instruct patients never to give these products to anyone else, even if he or she has the same signs and symptoms. It may cause harm or death.
- Advise patients that selling or giving away these products is against the law.

Prescriber Action

Certified prescribers must read the enclosed educational brochure entitled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers. Under the BTOD REMS program, prescribers are strongly encouraged to perform and document all of the following actions:

- Verify the patient meets diagnostic criteria for opioid dependence
- Discuss the risks associated with buprenorphine-containing products, including those described in the Medication Guide
- Provide induction doses under appropriate supervision
- Prescribe a limited amount of medication to the patient that will last until the next visit
- Explain how to safely store the medication out of reach of children
- Schedule patient appointments commensurate with patient stability (weekly or more frequent visits recommended for the first month)
Consider “pill count”/dose reconciliation
Assess whether the patient is receiving the counseling/psychosocial support considered necessary for treatment
Assess whether the patient is making progress toward treatment goals, including, as appropriate, urine toxicology testing
Continually assess appropriateness of maintenance dose
Continually assess benefits of treatment outweigh the risks

Patient Monitoring and Appropriate Dosing Info

An Appropriate Use Checklist is enclosed to assist you in performing and documenting the above prescriber actions of the BTOD REMS. You may use the enclosed checklist or other means (e.g. electronic health record) specific to your office practice to document that the above actions have been completed for each patient.

Medication Guide

The BTOD REMS includes product specific Medication Guides with important information to be reviewed with patients. In addition, the Medication Guide will be dispensed with each prescription for a buprenorphine-containing transmucosal product.

Reporting Adverse Events

To report SUSPECTED ADVERSE EVENTS contact:
- The manufacturer of the product taken or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

This letter is not a comprehensive description of the risks associated with the use of buprenorphine-containing transmucosal products. Additional important safety information can be found in the Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers educational brochure and Full Prescribing Information.

Additional copies of the educational brochure, Appropriate Use Checklist, Full Prescribing Information, and Medication Guide for each product covered under the BTOD REMS, can be obtained at www.btodrems.com or by contacting the toll-free call center at 1-855-223-3922.

Sincerely,

The Buprenorphine-containing Transmucosal products for Opioid Dependence Companies

Version 1.0 Revised February 2013

Enclosures: Appropriate Use Checklist
Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers