IMPORTANT SAFETY INFORMATION

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.

<Date>

Dear Pharmacist:

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 buprenorphine-containing products. Patients prescribed benzodiazepines or other CNS depressants should be cautioned to use them only as directed by their prescriber.
- Instruct patients to keep buprenorphine-containing 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. Patients should be advised that if a child is exposed to buprenorphine-containing products, medical attention should be sought immediately.
- Advise patients that buprenorphine-containing products contain an opioid that can be a target for people who abuse prescription medications or street drugs. Patients should be cautioned to keep their products in a safe place, and to protect them from theft.
- Instruct patients never to give buprenorphine-containing 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 this medication is against the law.

Pharmacist Action

Pharmacists are encouraged to read the enclosed educational brochure entitled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists. Each time you fill a prescription for a buprenorphine-containing product, make sure to:

- Verify that the prescription you receive is from a prescriber who is in compliance with the provisions of DATA 2000.
- Keep in mind that a limited supply of buprenorphine-containing products should be dispensed during the initiation of therapy. This is due to the need of prescribers to closely and frequently assess the patients’ needs, their symptoms, and potential risk of misuse, diversion, and abuse.
- Provide the Medication Guide to patients each time the medicine is dispensed.
• Remind patients who are picking up induction doses to return as directed to the doctor's office so that they can be supervised while taking the medication
• Provide appropriate patient counseling on safe use of buprenorphine-containing products
• Be vigilant in detecting fraudulent prescriptions or simultaneous prescriptions for the same patient from multiple prescribers

Medication Guide
The BTOD REMS includes product specific Medication Guides on the safe and effective use of buprenorphine-containing products, and the importance of participating in psychosocial support with important information to be reviewed with patients. It is important that you provide a Medication Guide to your patients or their caregivers with each dispensing and encourage them to read it.

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 Pharmacists educational brochure and Full Prescribing Information.

Additional copies of the educational brochure, 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

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Enclosures: Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Pharmacists