

Dear OTP Colleagues:

On July 3, 2013, Orexo US became the latest pharmaceutical company to add to the ever growing list of buprenorphine products. Orexo received approval from the U.S. Food and Drug Administration (FDA) for Zubsolv® (buprenorphine and naloxone sublingual tablets). Zubsolv is indicated for the maintenance treatment of opioid dependence and should be used as part of a complete treatment plan to include counseling and psychosocial support. Zubsolv is due to be released in September 2013.

The FDA approved Risk Evaluation and Mitigation Strategy (REMS) applies to Zubsolv as indicated for the maintenance treatment of opioid dependence. Although REMS does not apply to Zubsolv dispensed to patients admitted to an opioid treatment program, we believe you should be aware of what the REMS requires. The goals of the Zubsolv REMS are to mitigate the risks of accidental overdose, misuse, and abuse and inform prescribers, pharmacists, and patients of the serious risks associated with buprenorphine-containing products. A Medication Guide will be dispensed with each prescription for Zubsolv in accordance with 21 CFR 208.24. The Medication Guide for Zubsolv will be available through the Zubsolv REMS website (www.zubsolvrems.com).

For additional information about the REMS see Zubsolv <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM362103.pdf>.

Since the original FDA approval of Suboxone® and Subutex® in 2002, several generic products have been approved for use in the United States. For additional information about the FDA approved generic buprenorphine-containing transmucosal products for opioid dependence and the associated REMS go to <https://www.btodrems.com/SitePages/Welcome.aspx>. These generic buprenorphine product REMS also do not apply to buprenorphine-containing products that are dispensed to patients admitted to an OTP.

For additional information about Zubsolv or generic buprenorphine products please contact Anthony Campbell RPh. D.O. at <mailto:anthony.campbell@samhsa.hhs.gov> or (240) 276-2702.

Sincerely,

[Signed by H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM.]

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