AMERICAN HEALTH CARE

DRUG PRODUCTS & SAFETY NEWS

FDA Approves Probuphine

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The U.S. Food and Drug Administration (FDA) approved Probuphine, the first buprenorphine implant for the maintenance treatment of opioid dependence. Probuphine is designed to provide a constant, low-level dose of buprenorphine for six months in patients who are already stable on low-to-moderate doses of other forms of buprenorphine, as part of a complete treatment program.

Until today, buprenorphine for the treatment of opioid dependence was only approved as a pill or a film placed under the tongue or on the inside of a person's cheek until it dissolved. While effective, a pill or film may be lost, forgotten or stolen. As an implant, Probuphine provides a new treatment option for people in recovery who may value the unique benefits of a six-month implant compared to other forms of buprenorphine, such as the possibility of improved patient convenience from not needing to take medication on a daily basis. An independent FDA advisory committee supported the approval of Probuphine in a meeting held earlier this year. Probuphine should be used as part of a complete treatment program that includes counseling and psychosocial support. Probuphine consists of four, one-inch-long rods that are implanted under the skin on the inside of the upper arm and provide treatment for six months. Administering Probuphine requires specific training because it must be surgically inserted and removed. Only a health care provider who has completed the training and become certified through a restricted program called the Probuphine Risk Evaluation and Mitigation Strategy (REMS) program should insert and remove the implants. If further treatment is needed, new implants may be inserted in the opposite arm for one additional course of treatment. The FDA is requiring postmarketing studies to establish the safety and feasibility of placing the Probuphine implants for additional courses of treatment.

Probuphine is marketed by San Francisco-based Titan Pharmaceuticals Inc. and Braeburn Pharmaceuticals based in Princeton, New Jersey.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

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