



9<sup>th</sup> October 2002

**US FDA MARKETING APPROVAL FOR  
RECKITT BENCKISER'S SUBUTEX<sup>®</sup> & SUBOXONE<sup>®</sup>**

Reckitt Benckiser plc announced today that its new treatments for opiate dependence, Suboxone<sup>®</sup> (buprenorphine/naloxone) and Subutex<sup>®</sup> (buprenorphine) 2mg and 8mg tablets have been approved by the US Food and Drug Administration for the treatment of opiate dependence. These products were developed under a Cooperative Research and Development Agreement between Reckitt Benckiser and the National Institutes of Health's National Institute on Drug Abuse in the USA over the past ten years.

Subutex and Suboxone will become useful additions to the available range of pharmacotherapies that can help opiate-dependent patients overcome their addiction. The major benefit of Subutex/Suboxone is that qualified physicians in the US will now be able to treat patients with these products in the privacy of the Doctor's office rather than only from the limited number of existing drug treatment programs.

Subutex first received marketing approval in France and was launched in February 1996 by Schering-Plough under licence from Reckitt Benckiser. Since then the product has been launched in 24 countries. Licence income from these sales forms a modest but growing contribution to Reckitt Benckiser's core Health & Personal Care category.

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**For further information on Reckitt Benckiser plc**

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**FIRST NEW ADDICTION TREATMENT PRODUCTS IN 30 YEARS APPROVED FOR  
IN-OFFICE TREATMENT**

**Qualified Physicians Have New Weapon to treat addicted patients  
With Office-Based, Private Treatment Regimen**

Reckitt Benckiser plc (RB.L) announced today that the U.S. Food and Drug Administration (FDA) has granted marketing approval for SUBOXONE<sup>®</sup> (buprenorphine hydrochloride/naloxone hydrochloride) and SUBUTEX<sup>®</sup> (buprenorphine hydrochloride), sublingual tablets for the treatment of opioid dependence.

SUBOXONE and SUBUTEX are the first therapies approved for in-office prescribing under the federal Drug Addiction Treatment Act of 2000 (DATA). The new medications and the new in-office model offer a discreet, effective and convenient new treatment option.

“The approval of SUBOXONE and SUBUTEX is a much anticipated step toward opening up access to treatment for patients with opioid dependence who currently have little or no treatment options,” said Herbert D. Kleber, MD, professor of psychiatry and director, Division of Substance Abuse at the College of Physicians and Surgeons of Columbia University and the New York State Psychiatric Institute. “These treatments have potential for tremendous impact in combating opioid dependence, especially in formerly underserved communities.”

There are up to one million opioid-addicted patients in the U.S., including those who are addicted to heroin and prescription pain medications. The estimated annual cost to society of opioid addiction is more than \$20 billion.

The problem affects people in a variety of communities. Only about 15 percent of these heroin-dependent individuals are in treatment, partly because of limited access to treatment centers, which, until now, were among the only places to offer treatment. In addition to lack of access and privacy, current options for treating opioid dependence often have a high rate of relapse and can be fraught with other problems.

“People addicted to opioids like heroin and prescription pain medications are faced with a number of obstacles to getting effective treatment,” said Dr. Kleber. “We need to change the way we think about addiction. Science has shown that opioid addiction is a chronic, relapsing brain disease, not a character flaw, failure of will or lack of self-control. So we need to stop talking about ‘addicts’ and start referring to them as ‘patients’ – people who have a disease that medication can relieve.”

SUBOXONE and SUBUTEX

SUBOXONE is a combination of two proven medications, buprenorphine and naloxone. Buprenorphine, a partial opioid agonist, reduces withdrawal symptoms and blocks the effects of subsequently administered opioids, which suggests that it may help reduce illicit opioid use. Because it contains naloxone, SUBOXONE is highly likely to produce intense withdrawal symptoms if misused intravenously by

opioid-addicted individuals, however, when used as prescribed naloxone has no effect.

SUBOXONE has demonstrated a low treatment dropout rate in clinical trials. Since SUBOXONE is a partial agonist, withdrawal upon discontinuation is milder than with full agonists. SUBOXONE also exhibits a “ceiling effect” on respiratory depression, which provides a margin of safety in comparison to other opioids. This “ceiling effect” decreases the danger of overdose. Unlike SUBOXONE, SUBUTEX contains no naloxone; patients may be prescribed SUBUTEX during a short induction period, which will be closely supervised by their physician, before being switched to SUBOXONE.

### Physician Certification

DATA enables physicians who meet certain qualifying criteria to prescribe Schedules III, IV, or V narcotic drugs in the privacy of their offices. Under the DATA, qualified physicians can manage a total of 30 patients at one time. Further announcements regarding availability will be provided later.

### SUBOXONE Clinical Studies

In a comparative study, adverse event profiles were similar for subjects treated with 16 mg SUBOXONE or 16 mg SUBUTEX. The following adverse events were reported to occur by at least 5% of patients in a 4-week study.

The most common adverse events associated with SUBOXONE and placebo were respectively: headache (36 percent vs. 22 percent); withdrawal syndrome (25 percent vs. 37 percent); pain (23 percent vs. 19 percent); nausea (15 percent vs. 11 percent); and sweating (14 percent vs. 10 percent).

As with other opioid agonists, there is a risk of respiratory depression. Patients should be warned of the potential danger of not using SUBOXONE or SUBUTEX according to product information labeling and physician instructions.

SUBOXONE and SUBUTEX were developed by Reckitt Benckiser plc, U.K., and Richmond, VA.

### For Financial / Investor and General Corporate Queries

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For more information about SUBOXONE and SUBUTEX, please see full product information and visit [www.suboxone.com](http://www.suboxone.com) or call centre on +1-877 437 3314

For more information on Reckitt Benckiser please visit [www.reckittbenckiser.com](http://www.reckittbenckiser.com).

Editor's Note:

Under the Drug Addiction Treatment Act (DATA) of 2000, a physician is qualified to prescribe Schedules III, IV, or V narcotic drugs that are FDA-approved for the treatment of opioid dependence by meeting one or more of the following criteria:

- *Has been an investigator in one or more clinical trials leading to the approval of a Schedule III, IV, or V narcotic drug indicated for the treatment of opioid dependence*
- *Has been subspecialty board-certified in addiction psychiatry by the American Board of Medical Specialties*
- *Has been subspecialty board-certified in addiction medicine by the American Osteopathic Association*
- *Holds addiction certification from the American Society of Addiction Medicine*
- *Has completed no fewer than 8 hours of approved medical society training in the treatment and management of opioid dependence*
- *Has other such training/experience as the State Medical-licensing Board or Secretary of Health and Human Services deems appropriate*

Reckitt Benckiser plc

Reckitt Benckiser Healthcare's involvement in prescription drugs is a legacy of Reckitt & Colman's involvement in basic new chemical entity research in the 1960's and 1970's. Reckitt Benckiser Healthcare now focuses mainly on Over-the-Counter medicines such as Gaviscon, Lemsip, Disprin, Senokot and Fybogel.

Reckitt Benckiser plc is the world's largest household cleaning product company (excluding laundry detergent) with net revenues in 2001 of £3.4bn (\$5.25bn) and net income of £340m (\$525m). The Company has many world leading positions including in disinfecting cleaning (Lysol, Dettol), Automatic Dishwashing (Finish, Electrasol, Jet Dry), Fabric Treatment (Vanish, Spray 'nWash), Fine Fabric (Woolite) and Depilatories (Veet) and is a major player in Air Care (Air Wick, Wizard). Reckitt Benckiser operates in some 60 countries, has sales in some 180 countries and is headquartered in the UK. Reckitt Benckiser plc is listed on the London Stock Exchange.