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Press Release

WellSpring Pharmaceutical Corporation Receives [FDA](#) Approval To Market Duvoid Brand Of Bethanechol; Drug To Compete In \$50 Million+ Market

NEPTUNE, N.J., July 1 /PRNewswire/ -- WellSpring Pharmaceutical Corporation announced today that it has received FDA approval to market Bethanechol Chloride in the United States. Duvoid(R) is indicated for the management of disorders of the urinary tract and bladder. Duvoid(R) will be positioned as a generic alternative to Urecholine(R) (Odyssey). Sales of Urecholine(R) during the past 12 months were approximately \$50 million. The scored tablets in strengths of 10mg and 25mg will be marketed immediately and the 50mg will be forthcoming. The product will be manufactured by WellSpring's FDA approved, Oakville, Ontario manufacturing plant near Toronto.

WellSpring will be licensing Duvoid(R) exclusively to Abrika Pharmaceuticals of Sunrise, Florida for the sale as generic Bethanechol Chloride. Abrika specializes in the development and marketing of generic controlled release pharmaceuticals to all classes of trade in the US market. Abrika was founded in 2002 by Alan Cohen, previous founder, past Chairman and CEO of Andrx Corp. Under the terms of the manufacturing and supply agreement, the product will be manufactured by WellSpring Pharmaceutical Canada Corp. for distribution in all United States markets under the label of Abrika Pharmaceuticals. Shipments will begin to the trade in mid July. Ralph Massa, Jr., Bi-Coastal Pharmaceutical Corporation's President and Chief Operating Officer was responsible for consummating the agreement between WellSpring and Abrika. Bi-Coastal Pharmaceutical was founded in 1982 and is based in Red Bank, NJ. Massa stated the following on the agreement, "I am pleased to solidify this agreement with WellSpring on Bethanechol Chloride and that Dr. Vukovich has placed the confidence that he has in this alliance with Bi-Coastal and Abrika. I am confident that Abrika will be successful in distributing this important product into the generic marketplace and will undoubtedly maximize the potential sales of the product."

WellSpring is also considering the development of new dosage forms and new indications for Duvoid(R), which will require the submission of new applications to the FDA. Any new indications for bethanechol chloride will receive a period of market exclusivity as granted by the Waxman-Hatch Act. This would mean that substitution of Duvoid(R) by other generic forms would not be permitted for those new indications.



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WellSpring Pharmaceutical Corporation's Founder and CEO, Dr. Robert A. Vukovich commented on the new agreement: "The strategic focus of WellSpring is on the development of new and novel prescription drug products. Our decision to develop and sell this branded generic form of bethanechol will provide us with additional financial resources with which to continue the development of line extensions and new indications for the drug."

WellSpring is a new privately held pharmaceutical company founded in 1999 by Dr. Robert A. Vukovich the firm's CEO and Chairman. Dr. Vukovich previously founded and managed Roberts Pharmaceutical Corporation of Eatontown, NJ until its acquisition by Shire Pharmaceutical Group in 1999. WellSpring manufactures and sells Dyrenium(R), a potassium sparing diuretic, which is used to manage congestive heart failure and the edema associated with certain liver diseases. The firm also markets Dibenzyliline(R), a non-selective alpha-receptor blocker approved for the control of severe hypertension associated with certain cancers. The firm is developing a late stage drug, Stanate(R) for the treatment of neonatal jaundice. US rights to Stanate(R) were licensed to a sister company, InfaCare Pharmaceutical Corporation. WellSpring is located in Neptune, NJ.

Contact: WellSpring Pharmaceutical Corp. Pat Naffin Tel: (732) 938-5885 Fax: (732) 751-9328 Website: <http://www.wellspringpharm.com/> Contact: Abrika Pharmaceuticals, LLLP Dale Martin, Vice President, Corporate Development Tel: (954) 315-6600 Fax: (954) 315-6601 Website: <http://www.abrika.com/> Contact: Bi-Coastal Pharmaceutical Corp. Ralph Massa, Jr., President and Chief Operating Officer Tel: (732) 530-6606 Ext 115 Fax: (732) 530-1521 Website: <http://www.bicoastalpharm.com/>

WellSpring Pharmaceutical Corporation

CONTACT: Pat Naffin of WellSpring Pharmaceutical Corp., +1-732-938-5885, or fax, +1-732-751-9328; or Dale Martin, Vice President, Corporate Development of Abrika Pharmaceuticals, LLLP, +1-954-315-6600, or fax, +1-954-315-6601; or Ralph Massa, Jr., President and Chief Operating Officer of Bi-Coastal Pharmaceutical Corp., +1-732-530-6606, Ext 115, or fax, +1-732-530-1521

Web site: <http://www.abrika.com/>

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