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CSKI Products on Government List of "Counterfeit Drug Products," Pharmacies Ordered to Stop Selling.

Eight products manufactured by China Sky One Medical, Inc. (NASDAQ: CSKI) appear in a Chinese government notice of "counterfeit drug products," which states that pharmacies should "immediately stop the sale" of these products.

The government document is titled "Notice of the Ministry of Health of the People's Republic of China," dated November 5, 2009, and is available on the China State Food and Drug Administration website. Click here for the full Notice, and click here for a translation.

The Ministry of Health notice states that the listed products "deceive and mislead consumers in the promotion of their efficacy." The notice also states that the listed products are only disinfectants, but are "passed off as drugs to defraud and mislead consumers."

Out of 91 products on the list, eight are identified as being manufactured by CSKI's main operating subsidiary, Harbin Tian Di Ren Medical Science and Technology Co., Ltd. ("TDR"). All eight are identified with the "Kangxi" brand name. CSKI separately identifies "Kang Xi" in its 10K as the trademark used on all of its traditional-Chinese-medicine products.

At least three of CSKI's products on the Ministry of Health notice are identified individually in CSKI's 10K: the Coryza Spray, the Tinea Pedis Spray, and the Tinea Pedis Powder. Also, "Gynecopathy Cleaning Spray" on the government list appears to be the same product as the "Gonorrhea Cleaning Spray" in the 10K.

CSKI's disclosures concerning product sales in the company's SEC-filed financial statements are not sufficiently detailed to understand the impact of the government order. However, six of the eight CSKI products on the government list are identified as sprays. CSKI states in its 10Q filed November 16, 2009 that sales of spray products comprised 14% of total sales in the nine months ended September 30, 2009.

The Chinese government order to stop selling eight of CSKI's products seems to be material to CSKI's operating condition, yet CSKI has provided no disclosure of the order to U.S. investors.

CSKI being cited for deceptive or misleading marketing practices does not appear to be isolated to the November Ministry of Health Notice.

The Beijing Drug Administration website contains a notice and a list dated December 2009, which Google translates as "illegal medical device advertising." Kang Xi hemorrhoid magnetized ointment is item 6 on the list. As stated above, Kang Xi is the trademark on all CSKI TCM products, according to CSKI's 10K. "Hemorrhoids magnetic

ointment" is one of CSKI's best-selling products, representing 8% of total CSKI sales in the third quarter of 2009 and 11% of sales in 2008, according to CSKI's third quarter earnings conference call and August 2009 investor presentation, respectively. The violation, or "illegal reason," is described in the last column. For the Kang Xi hemorrhoid ointment the violation pertains to assertions and guarantees of effectiveness, according to a translation.

An example of advertising for the hemorrhoid ointment can be seen here.

In August 2009, the Jiangsu Health Department released a list of 31 substandard products. Kang Xi products are listed as numbers 8 to 15, the same products cited in the November list from the Ministry of Health. Additionally, in June 2009, TDR was apparently fined by the Guangzhou City Industry and Commerce Administration for violation of "The People's Republic of China Advertising Law."

In April 2009, a Seeking Alpha article, "Revealing the Shoddy Practices of China Sky One Medical," by Cabeza Howe, showed evidence of CSKI's numerous prior citations for advertising violations and false marketing claims.