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Brass and Copper Holdings, Inc.

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AND COPPER COMPANY, LLC

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June 1, 2017

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Ave, N.W. 1101A
Washington, DC 20460

Dear Administrator Pruitt:

We applaud your efforts to reign in unnecessary federal regulation in your first months as the head of the U.S. Environmental Protection Agency (“EPA”). To further assist you in this effort, we bring to your attention a regulatory bottleneck that has hindered U.S. industry from bringing to market an innovation that has been scientifically proven to prevent infections and saves lives - antimicrobial copper. Currently, the EPA prevents proponents of antimicrobial copper from sharing third party, peer-reviewed scientific research on copper’s ability to reduce infections. This in turn prevents effective communication about the value of this lifesaving, cost-effective solution – even to the healthcare community who could use antimicrobial copper to help vulnerable patients avoid deadly infections. To remedy this situation, we ask you to instruct the EPA to allow producers, manufacturers, and users of antimicrobial copper to make infection reduction claims that are proven and supported by peer-reviewed research that demonstrate how copper surfaces fight infections, and, ultimately save lives.

Hospital Acquired Infections (HAIs) are a staggering problem in the United States. One out of 25 patients that enter a hospital today will develop an infection during their stay.ⁱ Every year HAIs result in more than 75,000 deaths and an estimated \$147 billion in added costs.ⁱⁱ In addition, nearly 2 million people are infected by antibiotic-resistant superbugs like MRSA in the US each year, leading the Centers for Disease Control and Prevention to warn of “catastrophic consequences” if the threat isn’t addressed.ⁱⁱⁱ

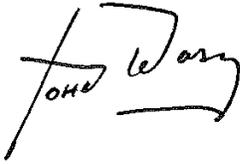
In 2008, the EPA approved copper alloys as registered antimicrobials under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”). Under these registrations, copper manufacturers are strictly limited in what claims they can make to customers. For example, the EPA has taken the position that manufacturers cannot make claims that “imply or suggest that the product can or will prevent or control disease or offer health protection” and has extended that prohibition to all “infection-related” claims, despite the fact that antimicrobial copper surfaces have been scientifically proven to prevent infections. In one multi-hospital clinical trial funded by the U.S. Department of Defense and published in the peer-reviewed journal *Infection Control and Hospital Epidemiology*, the use of antimicrobial copper surfaces in hospital intensive care units reduced microbial contamination on surfaces by 83% and cut the patient infection rate by an astounding 58%. Since that time, multiple other peer-reviewed research studies have been published that supported these findings.^{iv}

Importantly, there is no legal barrier to the EPA allowing manufacturers to share the life-saving properties of antimicrobial copper with healthcare providers. FIFRA does not prohibit EPA approval of infection-related claims.^v Instead, FIFRA only prohibits “false and misleading” statements; it has been an internal EPA policy, and not the law as written, that has prohibited statements regarding infection control. Carefully-crafted claims that are consistent with the results of well-designed clinical trials are neither false nor misleading and, as such, are within the EPA’s authority to approve under FIFRA.^{vi}

Following consideration of this issue, we ask your office to instruct the EPA to lift the ban and allow producers, manufacturers, and users of antimicrobial copper to make infection reduction claims that are proven and supported by peer-reviewed research. Your doing so is the right decision, and it will save lives.

We appreciate your prompt attention to this important matter.

Sincerely,

A handwritten signature in black ink that reads "John J. Wasz". The signature is written in a cursive style with a large, stylized "W" and "J".

John J. Wasz
Chief Executive Officer

ⁱ Centers for Disease Control and Prevention, "HAI Data and Statistics," <https://www.cdc.gov/hai/surveillance/>

ⁱⁱ Marchetti A, Rossiter R. Economic burden of healthcare-associated infection in US acute care hospitals: societal perspective. J Med Econ 2013; 16:1399-404

ⁱⁱⁱ Centers for Disease Control and Prevention, "Antibiotic / Antimicrobial Resistance," <https://www.cdc.gov/drugresistance/>

^{iv} Petition to Administrator Scott Pruitt, US Environmental Protection Agency. "Published Research," <https://cuverro.rallycongress.net/ctas/urge-epa-to-take-action>

^v FIFRA §12(a)(1)(E). A pesticide is considered "misbranded", and hence, illegal under FIFRA, if the label bears any claims or other information that is "false or misleading in any particular." (FIFRA §2(q)(1)(A)) EPA regulations further explain that the prohibition includes "false and misleading statements concerning the effectiveness of the product." 40 C.F.R. §156.10(a)(5)) Hence, neither the law nor the text of the EPA's regulations implementing FIFRA explicitly prohibit "infection-related" claims.

^{vi} Similarly, EPA requires claims to focus on control of the "pest" rather than the potential infection or disease that may result from exposure to the pest. Again, however, it is possible to craft claims that address the ability to control bacteria or other "pests," and, in doing so, reduce infection rates.