

Proposed Cover Letter to Potential Copper Clinical Trial Expert Panel Reviewers

January 15, 2018

Dear Reviewers:

In 2008, the U.S. Environmental Protection Agency (EPA) Antimicrobials Division (AD) approved public health registrations for “Antimicrobial Copper Alloys” (EPA Reg. Nos. 82012-1 to -6), which are solid, metallic materials containing 60%-99.9% copper. These engineering materials are used to manufacture a variety of touch surfaces in healthcare facilities, community buildings, and homes.¹ The labeling of Antimicrobial Copper Alloys was carefully crafted to ensure that users were well-informed about the proper role of the product as a supplement to – but not a replacement for – routine cleaning and sanitizing programs.

At the time of registration, EPA approved claims for Antimicrobial Copper Alloys based on laboratory data showing that the materials continuously kill over 99.9% of bacteria, including *E. coli*, MRSA, and VRE, within two hours of contact.² Prior to registration, EPA required the registrant, the Copper Development Association (CDA), to conduct outreach to experts in the infection control community.³ The input received noted that antimicrobial copper could provide a public health benefit as a supplement to existing infection control measures, and included a recommendation to conduct clinical trials to demonstrate the efficacy of the product outside of the laboratory in helping to reduce bioburden and the rate of infection.

Subsequently, the U.S. Department of Defense (DoD) launched an effort to study the antimicrobial properties of copper alloys. DoD funded a multi-site clinical trial of antimicrobial copper use in intensive care units (ICUs) at three facilities: Medical University of South Carolina; Memorial Sloan-Kettering Cancer Center; and Ralph H. Johnson Veterans Administration Medical Center. In conducting the studies, microbial burden was measured on high touch surfaces in patient rooms for 43 months. At month 23, half of the rooms were outfitted with components made from EPA-registered Antimicrobial Copper Alloy materials. After two years of measuring microbial burden on the copper and control surfaces, patient data were collected from July 12, 2010 to June 14, 2011 to investigate the impact on infection rates. During the study period, each facility followed pre-existing infection control measures and cleaning protocols.

Results of the clinical trials were peer-reviewed and published in 2012-2013. The researchers reported a greater than 80% reduction in the level of microbes present on components made from Antimicrobial Copper Alloys (*e.g.*, bedrails, IV poles, *etc.*) deployed in outfitted

¹ A copy of the currently registered label for Antimicrobial Copper Alloys Group I is attached (similar labels are registered for Groups II-VI).

² The currently approved claims are specified on the attached registered label for Antimicrobial Copper Alloys Group I.

³ Outreach was directed to the Association for Professionals in Infection Control and Epidemiology (“APIC”), the American Society for Healthcare Environmental Services (“ASHES”), and a leading expert in the field, Dr. William Rutala from the University of North Carolina-Chapel Hill, among others.

hospital ICU rooms over the study period. The researchers also identified a 58% reduction in the number of infections acquired by patients in these rooms.

In order to assist the agency in reviewing proposed claims for Antimicrobial Copper Alloys based on the DoD clinical trials (a copy of the proposed claims is included in the supporting materials), EPA is seeking expert review of the clinical data. Included in this package are information on the clinical study, the raw data from the study, and other supporting background materials provided by CDA, as well as charge questions designed to help you and EPA develop a complete understanding of the clinical study under review, and how that data relates to the proposed microbial burden and infection reduction claims that EPA will consider for antimicrobial copper products.

Thank you for your assistance in this matter.

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