RE: Status – Advoque Safeguard N95 Particulate Filtering Respirator – NIOSH TC-84A-PH02

We are distributing this notice to update you with regard to the Advoque Safeguard N95 Particulate Filtering Respirator, model number ADV001.

We have been informed by NIOSH that effective September 10, 2020, the Advoque Safeguard N95 Particulate Filtering Respirator, model number ADV001 cannot be considered NIOSH-Approved. Revocation also means that respirators bearing NIOSH approval number TC-84A-PH02 can no longer be manufactured, assembled, labeled, sold, or distributed as NIOSH approved product.

Fortunately, we have already submitted our application package for full NIOSH approval and, as per NIOSH’s time estimate, expect to receive NIOSH review within 2-3 weeks, and hope to achieve conventional approval within that time frame as well, at which time we can commence production of products bearing a new NIOSH approval number. We continue to actively coordinate with NIOSH to resolve this situation and resume operations as soon as our conventional approval is granted.

As you know, we have always taken our product quality seriously, have implemented and maintained a full internal testing equipment department and engaged regular testing protocols which have continually demonstrated that the units we have produced have met the standards under which NIOSH approves products, and had previously granted our temporary approval.

We look forward to receiving the conventional approval which has more systems in place that also allow for further product development, additional SKUs, and the ability to work with NIOSH to establish remediation and retesting procedures in the future. It is our expectation that this interruption in our ability to deliver NIOSH certified N95 respirators will be limited to NIOSH’s estimate to be no longer than 30-45 days, and that we will therefore open production under a conventional approval as soon as possible.

Please reach out to us with any questions you may have. We will be keeping you informed on the revised process for approval of conventional NIOSH certification.

Sincerely,

Jason Azevedo
Co-founder & Chief Technical Officer
Advoque Safeguard LLC