April 26, 2021

Dr. Theresa Michele
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Nonprescription Drugs
10903 New Hampshire Avenue WO22 Stop 5411
Silver Spring, MD 20993

Dr. Rima Khabbaz
Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
1600 Clifton Road
Atlanta, GA 30329-4027

RE: Enforcement of Hand Sanitizer Manufacturing and Distribution

Dear Dr. Michele and Dr. Khabbaz,

For more than 120 years, the National Consumers League has fought for access to quality products, honest labeling, and safe, effective medicines for American consumers and workers. We are writing to bring your attention to an ongoing issue related to the COVID-19 epidemic: the manufacturing and distribution of hand sanitizers that do not meet industry standards.

During the initial surge in demand, the federal government relaxed certain regulations in order to get over-the-counter products into consumers' hands. The combination of a need for an immediate ramp-up of hand sanitizer distribution and reduced oversight led to a concerning trend of what we believe is a case of mislabeling — and unfortunately misleading — information regarding hand hygiene products.

While local and small businesses stepping up to produce products for their communities is admirable, hastily manufactured hand sanitizer operations have resulted in lower efficacy rates, with even some reports of products being made with dangerous ingredients. As a result, the Food and Drug Administration (FDA) has currently identified 230 hand sanitizer products that were marketed in 2020 as unsafe or ineffective.

We commend the FDA and the Centers for Disease Control and Prevention (CDC) for their ongoing efforts to keep the American people safe. But as you know, the fight against this virus is far from over, and under-regulated hand sanitizer production and distribution will only prolong this public health crisis.

The CDC requires hand sanitizer to have at least 60 percent ethanol (ethyl alcohol). At the same time, the FDA has observed a sharp increase in those that also contain methanol – an ingredient that can be toxic when absorbed through the skin and can be fatal when ingested. Sadly, four people in Arizona died due to ingesting hand sanitizer containing methanol.

Businesses also began buying hand sanitizer in "bulk" packaging (*e.g.,* gallon bottles) and pouring it into dispensers for consumer use. Mixing differently manufactured products poses a safety issue because it means consumers are being exposed to products that don't meet FDA safety and effectiveness standards. Indeed, refilling a branded hand sanitizer container with a product that is not the original product is a violation of FDA regulations and is false advertising.

As the country starts to reopen, it's critical businesses, schools, and workplaces provide only the highest quality of hand sanitizer products. They must also ensure proper restocking of their supplies, rather than

simply refilling them with lower quality, mislabeled products, and ultimately providing consumers with a faulty product.

We urge the FDA and the CDC to enforce the law and hold accountable those businesses engaged in the production and distribution of poorly manufactured and dangerous hand sanitizer products. Thank you for your attention to our concerns.

Sincerely,

Sally Greenberg
Executive Director
National Consumers League