



April 14, 2021

The Honorable Elizabeth Warren
United States Senate
309 Hart Senate Office Building
Washington, DC 20510

Dear Senator Warren,

Thank you for your letter dated March 30, 2021. Amazon is committed to keeping our store safe and providing accurate and transparent information to our customers for all products, including personal protective equipment (PPE) such as KN95 masks.

From the start of the COVID-19 pandemic, Amazon has served the needs of our wide range of customers, including healthcare providers and businesses. On March 31, 2020, Amazon launched COVID-19 Supplies, a supply hub offering medical PPE and other products exclusively to healthcare professionals and other frontline workers. Using the online supply hub, PPE manufacturers were able to provide items to more than half of the top 100 hospital systems in the country and 44 of the 50 state governments. Amazon has delivered more than 200 million essential health and safety products to more than 13,000 healthcare and 7,000 government organizations in tens of thousands of locations across the U.S. As the pandemic continued, and consistent with guidance from the Centers for Disease Control and Prevention (CDC), we broadened access to masks and other PPE to consumers for non-medical use, and improved the customer experience for those searching for COVID-19 related products. For example, at the top of the search results page for COVID-19 related queries, we direct customers to official, authoritative sources like the CDC for the latest guidance on masks and vaccines.

Due to the shortage of PPE in the U.S. at the start of the pandemic, the CDC authorized the use of KN95 masks as a suitable alternative for N95 masks. N95s are the U.S. standard, while KN95s are the Chinese standard for these close-fitting filtration masks; both are rated to filter out 95 percent of very small particulate matter. Our selection of KN95 masks features high quality, highly-rated products that have passed a rigorous review process. Further, we require sellers to prominently display clear and accurate product images and information, and we include the following message on KN95 mask detail pages: *"This KN95 mask is NOT an N95 mask. For more information about KN95 masks, please see the following before you purchase: [amazon.com/AboutKN95s](https://www.amazon.com/AboutKN95s)."* This disclosure directs customers to additional resources from the Food and Drug Administration (FDA) and CDC on KN95 masks.

Amazon strictly prohibits the sale of counterfeit products, and we invest heavily to ensure our policy is followed. We continuously monitor our store and take swift action on bad actors that attempt to evade our systems, including removing the item, terminating the seller's account or related accounts, withholding funds, pursuing legal action, or referring them to law enforcement.

The answers to your questions are as follows:

1. How does Amazon choose the items that appear as “sponsored products” and “similar products” in response to a consumers’ search?

Amazon designs the shopping and discovery experience to present customers with the products we think they will want to purchase. We consider many factors when choosing the search results to feature for customers, including purchase frequency, item information, availability, and delivery speed.

“Similar products” are a collection of product recommendations that are based on the context of the customer’s current shopping preferences, aspects of the customer’s shopping history, or elements of both. We select offers to display in product discovery features, including “similar products” widgets, based upon a number of factors, including a customer’s search, browsing, or purchase history, or the product views of other customers. Sponsored Products are ads that enable eligible selling partners to promote offers responsive to customers’ shopping queries in our store. When choosing offers to appear as Sponsored Products, Amazon considers many factors, including customers’ expected interest in the eligible offers based on the query, keywords a selling partner has bid on, and the amount of the bid. When shoppers search Amazon for products, we run a real-time auction to decide which Sponsored Products offers, if any, will be most helpful for our customers when as they shop in our store.

2. What standards does Amazon have regarding these “sponsored products” and “similar products” with regard to promoting medical products that have not received an EUA from the FDA?

According to the FDA, an Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, the FDA may allow the use of unapproved medical products, or unapproved uses of approved medical products in an emergency to diagnose, treat, or prevent serious or life-threatening diseases. Because KN95 masks are not required to be on the FDA’s EUA list to be sold in the U.S., and FDA authorization for KN95 masks is only required for medical use, Amazon does not limit the sale of KN95 masks to only those on the EUA list. The scope of the FDA’s EUA for KN95 masks is limited to the use of the masks by healthcare workers in a healthcare setting, and the FDA stopped adding new KN95 masks to the EUA in October 2020 due to expanded mask availability in the broader market. Amazon continues to invest heavily in tools and processes that enable customers to shop with confidence for the full range of products in our store. In this case, in addition to the other measures we describe in this letter, those tools and processes include extensive supplier and product vetting, as well as policies and enforcement mechanisms that prohibit unsubstantiated claims or improper use of the term “FDA approved” or the FDA logo. We also provide our customers with additional disclosures on CDC resources and guidance that includes a link to the EUA list.

- a. **Specifically, if a customer searches for a product that has an FDA approval or EUA, is there any mechanism that prevents products that do not have an FDA approval or EUA from appearing as “sponsored” or “similar” products?**

No, Amazon’s search feature attempts to provide customers with a wide range of products in response to their search. We give customers a variety of options to make the right choice for their shopping needs. Offers presented on a search results page, including Sponsored Products and “similar products,” include a link to the offer’s product detail page, alongside a summary of product information, such as the product title, picture and average ratings. A customer who wishes to engage with those offers, including to make a purchase, must navigate to the product detail page, where they will find the most comprehensive set of information about the product to make an informed purchase decision.

3. **Specifically, with regard to KN95 or other FDA-approved masks (or those that receive FDA EUAs), how much does Amazon charge manufacturers to appear as a “sponsored” or “similar” product?**

Eligible sellers of lawful products in the Amazon store, including sellers of KN95 masks, are able to participate in Sponsored Products advertising. Advertisers are charged for Sponsored Products when a customer clicks on the advertiser’s ad, and the price per click is set in an auction based on advertisers’ bids, how relevant the advertised product is in the context of the customers search intent, the likelihood of the ad being clicked on in that context, and other similar factors. Many of our product discovery features, including “similar products” widgets, are simply additional ways to provide valuable information to customers based on that intent and Amazon does not charge for placement in these widgets.

4. **How, if at all, does Amazon verify the quality of KN95 masks sold on its site that are advertised as being FDA-approved or as having received an FDA EUA?**

Amazon requires that all products in our store comply with applicable laws, regulations, and Amazon policies, and we continuously scan numerous data points related to sellers, products, brands, and offers to detect activity that may indicate a potential concern. When we find such concerns, we act quickly to protect our customers and our store from these bad actors. For KN95 masks, we review filtration lab testing results from accredited labs, verify manufacturer information (including a review of invoices to trace the inventory from the supplier to the manufacturer), review product packaging and the product detail page for unverified or unapproved claims, check the product against the CDC’s counterfeit list, and confirm that any KN95 masks claiming to be on the FDA’s EUA list are in fact on the list. Further, Amazon expressly prohibits sellers from claiming their KN95 masks are “FDA approved” given that the FDA does not “approve” KN95 masks, and we automatically scan product details to identify and remove products making this claim.

5. What standards does Amazon have in place to assure the quality of other personal protective equipment, and other COVID-19 related products sold on its site?

Before making key COVID-19 supplies available, we verify the seller and perform product-specific compliance reviews. These reviews, which vary by product type, include evaluation of registration requirements with applicable authorities and package labeling. We also closely monitor the evolving guidance from federal agencies, including the FDA and CDC, and audit this range of selection to ensure that it is not on the CDC's counterfeit list.

6. What activities has the Counterfeit Crimes Unit undertaken since its creation last year? Please provide information on the number of investigations the Unit has undertaken, data on how these investigations have been resolved, and information on the processes the Unit takes to decide to undertake an investigation and complete it.

On June 24, 2020, Amazon launched its Counterfeit Crimes Unit (CCU), a global team dedicated to pursuing bad actors and holding them accountable to the fullest extent of the law, including working with law enforcement. Examples of actions Amazon has taken against counterfeiters include a lawsuit against individuals using social media to promote and facilitate the sale of counterfeits, joint lawsuits with Italian luxury fashion house Valentino, cosmetics brand KF Beauty, family travel accessory brand JL Childress, and global outdoor products designer and retailer Yeti, and numerous law enforcement referrals and prosecutions.

Amazon's first objective remains protecting customers, its store, and brands by blocking counterfeits before they enter the store. The CCU investigates the bad actors or counterfeiters and the illicit networks that support them in order to hold them accountable through civil litigation and working with law enforcement for criminal prosecution. The CCU has a strong track record of partnering with both large brands and small businesses to bring counterfeiters to justice, and welcomes the support of law enforcement authorities in the fight against counterfeiters.

Since its launch, the CCU has investigated thousands of sellers and their networks and co-conspirators suspected of selling counterfeit goods in the Amazon store. As a result of these investigations, Amazon has filed lawsuits or submitted criminal referrals to law enforcement against more than 275 individuals and entities. These civil and criminal actions have also resulted in the removal of millions of dollars of counterfeit goods from the stream of commerce. The CCU continues to actively pursue multiple criminal and civil actions in order to disrupt criminal networks.

The CCU has accomplished these results by conducting deep dive investigations of bad actors. The CCU utilizes Amazon data as well as external resources to identify these actors who use sophisticated schemes to try and hide their true identities and locations. The CCU has developed strategic relationships with law enforcement agencies and law firms around the world to pursue these actors wherever they are. According to the Department of Justice's

most recently available data, only 0.1 percent of filed federal criminal cases led to charges for trafficking in counterfeit goods, and in more than half of the cases where a defendant was found guilty, they received no jail time at all. As a result, there is too little disincentive for bad actors committing IP crimes. We ask Congress to increase resources for law enforcement to investigate and prosecute these crimes and for more severe penalties for convictions. Both are essential to winning the fight against bad actors, and we welcome the opportunity to work with you on this critical issue.

Thank you for your attention to this important topic. We will continue to ensure that quality masks and other PPE are available to all of our customers.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian Huseman". The signature is fluid and cursive, with a large initial "B" and "H".

Brian Huseman
Vice President, Public Policy

CC:

Acting Commissioner of Food and Drugs, Janet Woodcock, M.D.
Acting Federal Trade Commission Chair, Rebecca Kelly Slaughter
Attorney General Merrick Garland