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March 30, 2021

Mr. Andy Jassy
Chief Executive Officer
Amazon Services, Inc.
410 Terry Avenue North
Seattle, WA 98109-5210

Dear Mr. Jassy:

I write regarding an investigation by my staff revealing that Amazon search and sponsorship algorithms may be misleading consumers who are seeking masks authorized by the U.S. Food and Drug Administration (FDA) and other personal protective equipment during the COVID-19 pandemic. This problem is exacerbated by the fact that the information consumers need to verify whether a product has received an FDA emergency use authorization (EUA) is often either incorrect or not easily discernable on Amazon.com, and that Amazon's quality control methods do not appear to be sufficient to prevent customers from receiving counterfeit items. I am concerned that Amazon's policies and procedures appear to be increasing risks for many individuals that are purchasing COVID-19 masks and other protective gear to protect themselves and their communities, and I urge you to immediately fix these dangerous problems.

The nation is making extraordinary progress with COVID-19 vaccinations, but millions of Americans have still not been vaccinated, many more indicate they will not ever be vaccinated, and, regardless of vaccination status, the Centers for Disease Control and Prevention (CDC) still recommends mask-wearing.¹ Dr. Anthony Fauci predicts Americans may need to continue to wear masks in 2022.² This means that the ability to procure effective masks to protect against COVID-19 will remain critical in the fight to save lives during the pandemic. In fact, earlier last month, the CDC updated its "Guidance for Wearing Masks"³ in the wake of new research and in response to the presence of increasingly infectious strains of COVID-19 in the United States.⁴ The CDC now recommends KN95 masks, "a type of filtering facepiece respirator that are commonly made and used in China," in certain situations, such as "situations that require

¹ Pew Research Center, "Growing Share of Americans Say They Plan to Get a COVID-19 Vaccine – or Already Have," Cary Funk and Alec Tyson, March 5, 2021, <https://www.pewresearch.org/science/2021/03/05/growing-share-of-americans-say-they-plan-to-get-a-covid-19-vaccine-or-already-have/>; Centers for Disease Control and Prevention, "Guidance for Fully Vaccinated People," Updated March 8, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>.

² Washington Post, "When will we return to normal? The question looms as Fauci says mask-wearing may continue in 2022." Reis Thebault, February 21, 2021, <https://www.washingtonpost.com/health/2021/02/21/covid-fauci-masks-2022/>.

³ Centers for Disease Control and Prevention, "Guidance for Wearing Masks," February 11, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>.

⁴ CBS News, "CDC recommends double masks to help protect against COVID-19," Alexander Tin, February 11, 2021, <https://www.cbsnews.com/news/double-face-mask-covid-19-cdc/>.

prolonged close contact with people who do not live in the same household, or for people who are at increased risk for severe illness from COVID-19.”⁵ Millions of Americans are reliant on Amazon for their purchases of KN95 masks and other personal protective equipment (PPE). But the investigation by my staff revealed that, when consumers search for these items on your website, they may be misled by Amazon’s search algorithms and lack of quality control standards.

Amazon is promoting products not authorized by the FDA, even when customers are specifically searching for FDA-authorized masks.

On March 4, 2021, my staff conducted a sample search of the term “KN95 Face Mask FDA Approved.” This search produced 436 results, with 22 on the first page of results. But two of the masks that appeared in the first page have not, in fact, received an approval or emergency use authorization from the FDA.⁶ Even more concerning, one of these products appeared near the top of the search results as a “sponsored product,” even though it did not advertise itself as “FDA-approved,” —presumably because sellers were paying Amazon to promote their product. (Figure 1). Because sponsored products appear alongside search results specifically responsive to the query, with only a small notation that they are sponsored, customers may be unwittingly directed to non-FDA authorized masks.

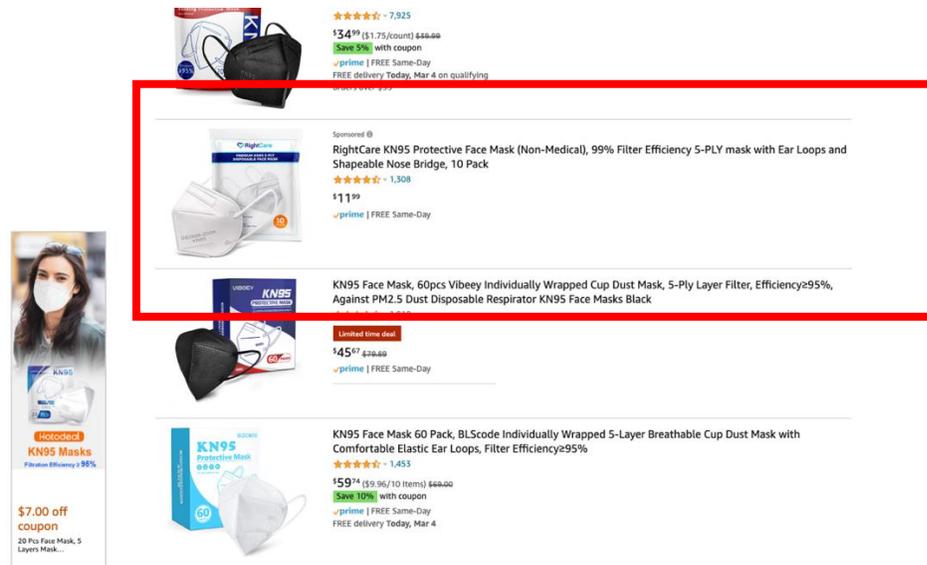


Figure 1. Sponsored product, "RightCare KN95 Protective Face Mask," has not received an approval or EUA from the FDA, but appears within the top 10 Amazon search results.

⁵ Centers for Disease Control and Prevention, “Improve the Fit and Filtration of Your Mask to Reduce the Spread of COVID-19,” Updated February 13, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/mask-fit-and-filtration.html>.

⁶ Amazon.com, “RightCare KN95 Protective Face Mask (Non-Medical), 99% Efficiency 5-PLY mask with Ear Loops and Shapeable Nose Bridge, 10 Pack,” March 4, 2021, https://www.amazon.com/RightCare-Protective-Non-Medical-Efficiency-Shapeable/dp/B08FXZD8BC/ref=sr_1_7_sspa; Amazon.com, “Kingfa KN95 Face Mask 50 Pcs Disposable Respirator 5-Ply Layer | GB2626-2006 Compliant,” March 4, 2021, https://www.amazon.com/Kingfa-Non-NIOSH-Respirator-GB2626-2006-Compliant/dp/B0882TV6JM/ref=sr_1_19.

Amazon’s sponsorship algorithms appear to be facilitating the spread of misinformation: according to Amazon Advertising services, the company “will match [an advertiser’s] ads to shopping queries and products,” in this case potentially misleading consumers about whether masks sold and sponsored by Amazon meet appropriate FDA standards.⁷

Amazon may also be misleading customers through its use of “tag-along algorithms,” which direct consumers to “similar” products listed on items’ landing pages. In one instance, an Amazon landing page for an FDA-authorized mask listed as a similar product a mask that was not FDA-authorized (Figure 2),⁸ and in another instance, Amazon recommended a product with conflicting information about the manufacturer (Figure 3). In this instance, the seller advertised that the mask was made by two different manufacturers—one of which made FDA-authorized masks, and one of which did not.⁹

Figure 2



Figure 3



⁷ Amazon Advertising, “Sponsored Products,” <https://advertising.amazon.com/solutions/products/sponsored-products>.

⁸ Amazon.com, “SupplyAID RRS-KN95-5PK KN95 Protective Mask, Protection Against PM2.5 Dust, Pollen and Haze-Proof, 5 Pack,” March 4, 2021, https://www.amazon.com/SuppyAID-RRS-KN95-5PK-Protective-Protection-Haze-Proof/dp/B086JD7TKZ/ref=pd_lpo_328_t_1/131-2555357-5711158.

⁹ Amazon.com, “KN95 Face Mask included on FDA EUA white list, Pack of 20,” March 4, 2021, https://www.amazon.com/dp/B087RJ9JCF/ref=sspa_dk_detail_0.

Amazon does not provide enough information for consumers to determine whether a product has received an EUA from the FDA

Amazon’s unclear presentation of information or lack of information for consumers makes it difficult for customers to verify whether a mask is in fact authorized by the FDA. Only seven of the top 22 KN95 search results specifically and clearly denote that they have received an EUA either in the title or the description of the product; an additional 12 of the 22 top results indicate that the mask had received an EUA only in the Customer Question & Answer section—meaning Amazon customers, not necessarily Amazon or the sellers, were sometimes having to provide this information after they had purchased the product (Figure 4). Three of the results—including the two that appeared as sponsored results—provided no indication that the mask was authorized by the FDA.

Customer questions & answers

Q fda

All Product Information Customer Q&A's Customer Reviews

Customer questions & answers

Q: Are these masks FDA certified?

A: Yes, the KN95 face mask has been approved by the FDA and included in the FDA EUA Emergency Use Authorization List and manufactured by certificated manufacturer Sengtor Ltd.

By Amazon Customer on January 12, 2021

[See other answers](#)

Q: Are these masks FDA certified?

A: I came with a piece of paper that said Pass Certification. I am not sure if it is FDA approved. But the product is good.

By Oyumaa on January 23, 2021

[See other answers](#)

[See 2 matching Q&A >](#)

Figure 4

Even when a mask is authorized by the FDA, the information needed to verify this authorization may be incomplete or wrong, or missing important facts. The manufacturer and model number of a mask are the two criteria necessary to determine whether a product is listed on FDA’s official list of “Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China.”¹⁰ But only nine of the top 22 search results for KN95 masks had clear and/or accurate information regarding the manufacturer and the model of the mask. For seven items, the sellers did not provide the name of the manufacturer.¹¹ For example the seller, Hotodeal, claims to sell FDA-approved masks, but does not provide information on the manufacturer, and a review of photos of the product provided by customers indicates that

¹⁰ U.S. Food and Drug Administration, “Personal Protective Equipment,” <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>.

¹¹ *Id.*

Hotodeal may use different manufacturers—one of which is FDA approved and one which is not (Figure 5, 6, 7).¹²

Product Specifications	
Color	01.white
Item Weight	1.76 ounces
Material	cotton
Model Number	tool-95-100
Part Number	tool-95-100
Specification Met	
UNSPSC Code	46182008

Specification for this product family	
Brand Name	Hotodeal
Size	Medium
UNSPSC Code	46182001

Figure 5: Manufacturer is not noted in product specifications.



Figure 6 on left is from FDA Approved Manufacturer, Figure 7 on right is not.

¹² Amazon.com, “Hotodeal KN95 Mask Safety Mask Breathable Mask (20 pcs),” March 4, 2021, https://www.amazon.com/Protection-Breathable-Against-Pollution-Outdoor/dp/B087LR59CF/ref=sr_1_5.

For six of the top 22 KN95 search results, the seller appears to be providing incorrect information about the manufacturer all together, as evidenced by the photos customers provided in their review.¹³ (Figure 8 and 9).

Product details

Color: **Black-30pcs**

Package Dimensions : 6.34 x 5.12 x 4.8 inches; 8 Ounces

Date First Available : February 9, 2021

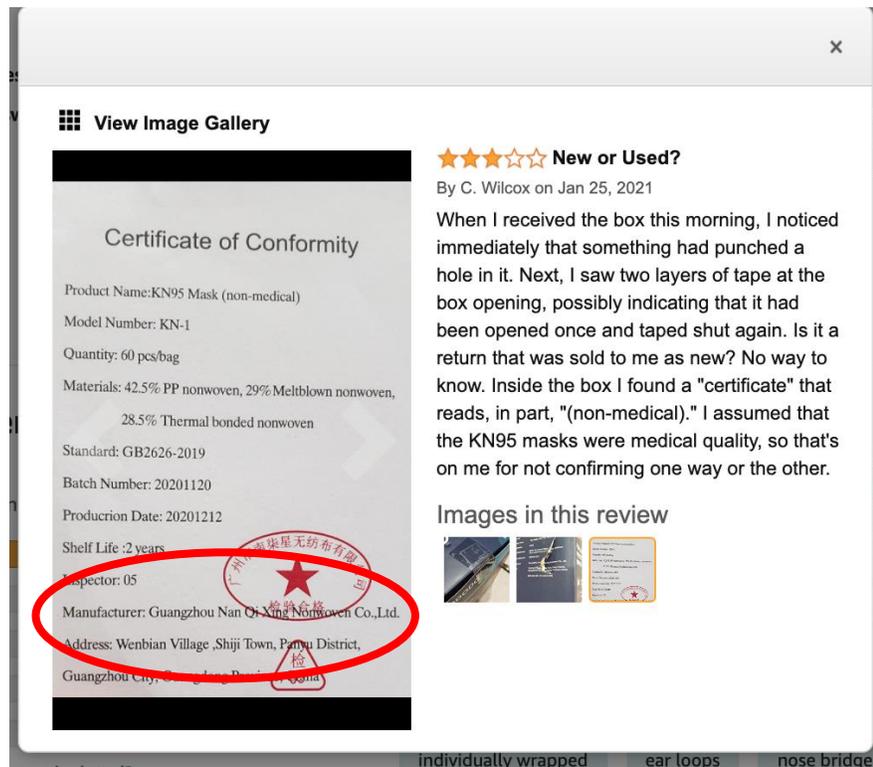
Manufacturer : HALIDODO

ASIN : B08NWRJ89B

Customer Reviews:

★★★★☆ 447 ratings

Figure 8 (above) lists manufacturer as HALIDODO, but a photo from a customer provided in a review in Figure 9 (to the right) lists Guangzhou Nan Qi Xing Nonwoven Co., Ltd, which is an FDA-approved manufacturer. Halidodo is the brand name.



¹³ See Amazon.com, "KN95 Face Mask, 30 Packs Included on FDA EUA List 5-Ply Breathable & Comfortable Filter Safety Mask with Elastic Ear loop and Nose Bridge Clip, Protective Face Cover Mask," March 4, 2021, https://www.amazon.com/Included-Breathable-Comfortable-Elastic-Protective/dp/B08NWRJ89B/ref=sr_1_17_sspa.

Amazon’s quality control standards result in consumers obtaining masks that are not authorized by the FDA

In addition to the misleading search results and inaccurate or incomplete information, a staff assessment of customer reviews for KN95 products found cases where customers indicated that the quality of the product received may not have matched the product that was advertised and that the customer had ordered. One review of a mask that claimed to be authorized by the FDA stated:

Bought the product because it claimed that it is on FDA EUA list and mentions FFP2 certification. The packaging box I received has no mention of either. I checked the CDC website for test results of international respirators and found the test results displayed on Amazon by seller. However, the packaging picture included on CDC website [sic] (see attached photo) has FFP2 certification and FDA no 10062960 clearly marked (bottom right) while the box I received looks identical but without the certifications text. What looks disconcerting is that two shipping labels were positioned exactly to mask where the certifications appear on two sides of the packaging box pictured on CDC website. I peeled the shipping labels, only to find out that the certifications text is not on my box. The filters are paper thin unlike certified N95 filters I have seen. Hope the seller would explain the absence of any certification claims on the packaging they sell on Amazon and can convincingly confirm it is genuine certified product.¹⁴

Another product claiming to be FDA-authorized had reviews from July 2020 stating that the mask was a “scam,” but Amazon algorithms were still referring customers to this page. The reviewer stated:

I did not receive the KN95 face masks pictured, I received masks from an entirely different manufacturer. The masks I received are so thin and flimsy, they are hardly more than the disposable paper masks given out at hospitals. The picture I am posting shows a quality KN95 I already owned (right) vs. a smaller and flimsier mask from this seller (left). I don't want to take them out of sealed packaging until time to use, but even through the package you can tell there is a difference.

I paid \$52 for 20 masks, I received two boxes stating each contained 12 masks but there were only 10 per box...something is strange. According to other buyers the price went way up, appears to be price gouging due to rising Covid numbers. Now the price is over \$70? I mention the price because these are in NO WAY worth \$52 or \$70 dollars! Buyer beware!¹⁵

¹⁴ See Amazon.com, “KN95 Advanced Filtration Respirator Face Masks (50 Pack) | On FDA EUA list | > 95% Filtration | Type FFP2 - CE Certified to EN149,” March 4, 2021, <https://www.amazon.com/KN95-Advanced-Filtration-Respirator-Masks/dp/B087996M76>.

¹⁵ Amazon.com, “KN95 Face Mask included on FDA EUA white list, Pack of 20,” March 4, 2021, <https://www.amazon.com/KN95-Face-Mask-Pack-20/dp/B087RJ9JCF>.

Earlier in the pandemic, in response to high customer demand and the subsequent proliferation of counterfeit COVID-19 related products being sold on its platform, Amazon implemented “anti-counterfeiting” programs¹⁶ and established a Counterfeit Crimes Unit, “dedicated to bringing counterfeiters attempting to list counterfeit products in its store to justice.”¹⁷ But the continued reports of fraudulent or counterfeit items raise questions about the effectiveness of these programs.

Questions

Given the significant public health concerns facing consumers who may be receiving misleading information from Amazon about the masks that they seek for protection from COVID-19, I urge you to immediately modify your policies and procedures to prevent consumers from receiving misleading information. I also request answers to the following questions by no later than April 13, 2021:

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

¹⁶ Business Insider, “Sold-out Amazon sellers warn shoppers about counterfeit face masks as demand soars amid coronavirus fears,” Bethany Biron, January 28, 2020, <https://www.businessinsider.com/amazon-sold-out-sellers-warn-counterfeit-masks-coronavirus-2020-1>.

¹⁷ Amazon, “Amazon establishes new Counterfeit Crimes Unit,” Amazon, June 24, 2020, <https://www.aboutamazon.com/news/company-news/amazon-establishes-new-counterfeit-crimes-unit>.

Thank you for your attention to this matter.

Sincerely,


Elizabeth Warren
United States Senator

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