UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA

- against -

KING YEAR PRINTING AND PACKAGING CO., LTD.,

Defendant.

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COMPLAINT AND AFFIDAVIT IN SUPPORT OF APPLICATION FOR SUMMONS

(T. 21 U.S.C. §§ 331(a), 333(a)(2), and 18 U.S.C. §§ 1001(a), 2)

No. 20-MJ-416

EASTERN DISTRICT OF NEW YORK, SS:

DONALD PEARLMAN, being duly sworn, deposes and says that he is a Special Agent with the U.S. Food and Drug Administration, Office of Criminal Investigations ("FDA-OCI"), duly appointed according to law and acting as such.

Counts One Through Three: Introduction of Misbranded Devices into Interstate Commerce

1. On or about the dates set forth below, in the Eastern District of New York and elsewhere, the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. (hereinafter also referred to as "KING YEAR"), with intent to defraud and mislead, did introduce and deliver for introduction, and cause to be introduced and delivered for introduction into interstate commerce devices that were misbranded within the meaning of Title 21, United States Code, Section 352(a)(1), specifically self-breathing filtration particle-preventive respirators whose labeling falsely included the NIOSH logo despite the respirators not being NIOSH approved, and "N95" markings and a test report showing compliance with the N95 standard despite the respirators not meeting the minimum standard for N95 respirators, in the approximate quantities set forth below.

Count	Approximate Date	Approximate Quantity of Respirators
1	4/6/20	95,200
2	4/18/20	300,000
3	4/21/20	100,000

(Title 21, United States Code, Sections 331(a) and 333(a)(2), and Title 18, United States Code, Sections 2 and 3551 et seq.)

Count Four: False Statements

2. On or about April 10, 2020, in the District of Maryland and elsewhere, the defendant, KING YEAR PRINTING AND PACKAGING CO., LTD., by and through the acts of its agents and employees who were acting within the scope of their agency and employment and with intent to benefit KING YEAR, in a matter within the jurisdiction of the executive branch of the United States, namely, the U.S. Food and Drug Administration, did knowingly and willfully (a) falsify, conceal, and cover up by trick, scheme, and device, certain material facts; (b) make materially false, fictitious, and fraudulent statements and representations; and (c) make and use false writings and documents knowing them to contain materially false, fictitious, and fraudulent statements and entries.

(Title 18, United States Code, Sections 1001(a), 2, and 3551 et seq.)

3. The source of your deponent's information and the grounds for his belief are as follows:

4. I am a Special Agent with FDA-OCI. I am aware of the facts contained herein based upon my own investigation and based upon interviews and briefings with other law enforcement officers who have participated in this investigation. I also have participated in

witness interviews and reviewed other evidence, including email and text message communications, telephone toll records, and publicly-available reports. Because this affidavit is being submitted for the limited purpose of establishing probable cause, I have not included each and every fact known to me concerning this investigation. I have set forth only the facts which I believe are necessary to establish probable cause. Unless specifically indicated, all conversations and statements described in this affidavit are related in substance and in part.

Relevant Entities and Individuals

5. Defendant KING YEAR PRINTING AND PACKAGING CO., LTD. was a company located in Guangdong province in the People's Republic of China ("PRC") that was engaged in the business of manufacturing, exporting, and distributing products, including personal protective equipment ("PPE"), to the United States and throughout the world.

6. Individual-1 was a U.S. citizen residing in the PRC who brokered deals for pharmaceutical and medical products from companies located in the PRC. As COVID-19 spread in the PRC and throughout the world, Individual-1 entered the business of buying, selling, and importing PPE into the United States. Individual-1 held himself out to buyers in the United States as having connections to Chinese pharmaceutical companies, medical equipment manufacturers, provincial governmental leaders, and central government ministry leaders, including the Ministry of Health.

7. Individual-2 was a relative of Individual-1. Individual-2 was a U.S. citizen who resided in Salt Lake City, Utah. Individual-2 was a licensed acupuncturist and the owner and operator of Company-1.

8. Company-1 was a Utah corporation located in West Valley City, Utah. Its primary business involved the import and export of supplements and raw materials from the PRC.

9. Individual-3 was a U.S. citizen who resided in Lincoln University, Pennsylvania. Individual-3 owned and operated Company-2.

10. Company-2 was a Delaware limited liability company located in Lincoln University, Pennsylvania, with warehouse space in Newark, Delaware. Prior to the COVID-19 pandemic, Company-2 imported and distributed hazmat protective suits from a manufacturer in Italy. As COVID-19 spread in the United States, Individual-3 used Company-2 to accumulate large quantities of PPE, including facemasks and respirators, and resell them to private brokers and various governmental entities, medical providers, and first responders, often at substantial mark-ups over the prices he paid to acquire the PPE.

11. Company-3 was a Chinese medicine manufacturer, importer, and distributor located in Guangdong province in the PRC.

12. Company-4 was a Chinese import and export broker located in Jiangsu province in the PRC.

Overview

13. Between on or about April 6, 2020 and on or about April 21, 2020, in the midst of the COVID-19 pandemic, defendant KING YEAR PRINTING AND PACKAGING CO. LTD. exported approximately 495,200 defective and misbranded "N95" respirators (the "Subject Respirators") from the PRC to the United States. The defendant KING YEAR falsely labeled the Subject Respirators with the intent to defraud U.S. consumers, including medical providers and state and local governments, into believing they were buying N95 respirators approved, cleared, or otherwise authorized by the U.S. Food and Drug Administration ("FDA") and National Institute for Occupational Safety and Health ("NIOSH") of the Centers for Disease Control and Prevention ("CDC"). In fact, the Subject Respirators were neither FDA-approved, cleared, nor

authorized nor NIOSH-approved. And the Subject Respirators did not perform at the promised minimum 95% filtration efficiency level. Nevertheless, the defendant KING YEAR attempted to cover up the poor quality of the Subject Respirators in various ways – by stamping FDA and NIOSH logos on its packaging, by embroidering each Subject Respirator with the label, "N95," by procuring and disseminating false documents attesting to the authenticity of the Subject Respirators, by filing a false registration document claiming the masks were NIOSH-approved, and by using a fictitious corporation as its U.S. agent in registration documents filed with the FDA.

The Global COVID-19 Pandemic

14. In December 2019, a novel coronavirus, SARS-CoV-2, was first detected in Wuhan Province of the PRC, causing outbreaks of the coronavirus disease 2019 ("COVID-19") that have since spread globally. On January 31, 2020, the Secretary of Health and Human Services declared a national public health emergency under 42 U.S.C. § 247d as a result of the spread of COVID-19 to and within the United States. On March 11, 2020, the Director-General of the World Health Organization characterized COVID-19 as a pandemic. On March 13, 2020, the President of the United States issued Proclamation 9994 declaring a national emergency as a result of the rapid spread of COVID-19 within the United States.

15. According to the CDC, the virus that causes COVID-19 spreads through respiratory droplets produced when an infected person coughs or sneezes. Droplets can land in the mouths, noses, or eyes of people who are nearby or possibly be inhaled into the lungs of those within close proximity.

16. Accordingly, the CDC has issued guidance to health care providers recommending that they wear PPE, such as N95 respirators, to prevent the coronavirus from

being transmitted by infected patients to healthcare providers. The CDC also has encouraged the public to use face coverings to prevent the spread of the virus. To that end, on or about April 15, 2020, New York Governor Andrew M. Cuomo issued an executive order requiring all people in New York to wear face coverings in public.

The Surge in Demand for N95 Respirators

17. According to CDC guidance, face masks are used by the general public and by healthcare professionals as source control, which refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19. Face masks sometimes contain ear loops, which are not designed to form a seal around the nose and mouth.

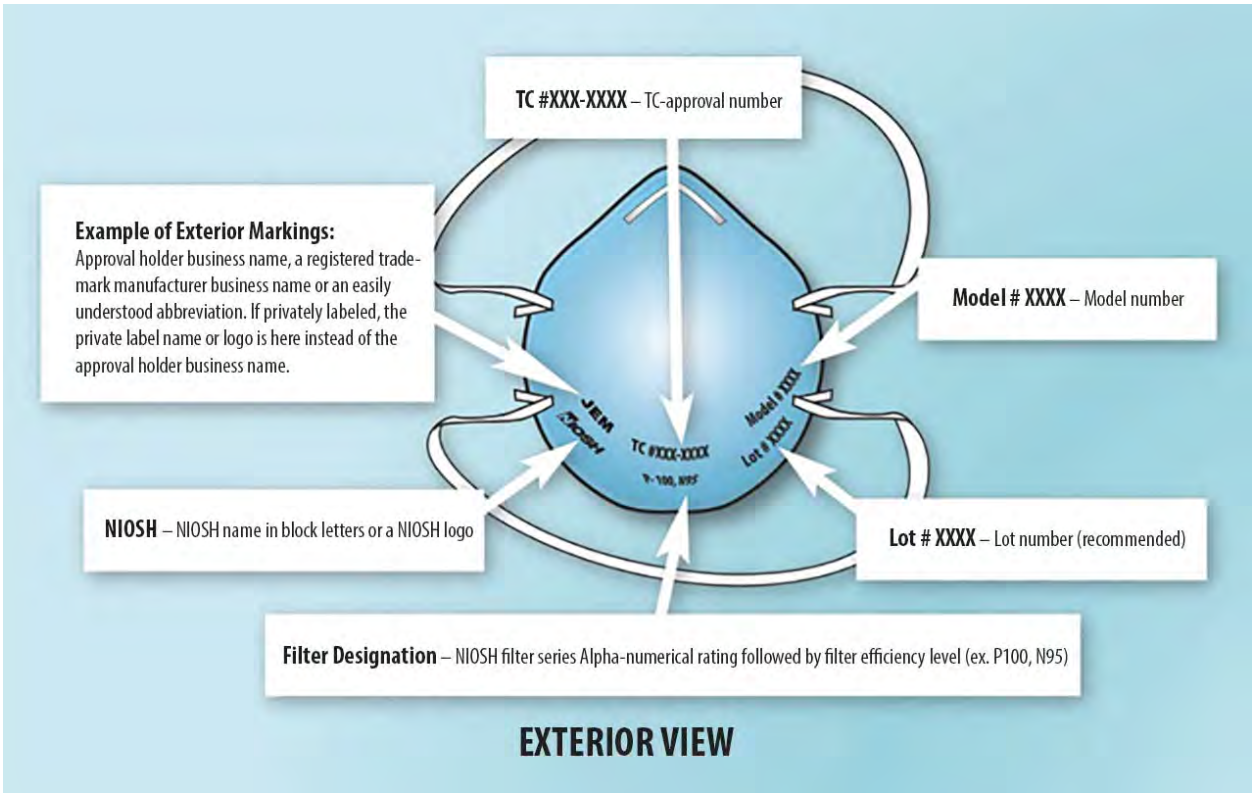
18. A surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. Surgical masks are not designed to form a seal around the nose and mouth. A picture of a surgical mask is attached below:

19. An N95 respirator is a disposable half-mask filtering facepiece respirator that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.170. N95 respirators are worn by both the patient and the healthcare personnel to protect from the transfer of microorganisms, body fluids,

and particulate material. An N95 respirator has headbands and is designed to achieve a very close facial fit and very efficient filtration of airborne particles. If properly fitted, the filtration capabilities of N95 respirators far exceed those of face masks and surgical masks. A picture of an N95 respirator is attached below:

20. A NIOSH-approved N95 respirator is an N95 respirator approved by NIOSH that meets the filtration efficiency level per 42 CFR 84.170. The NIOSH stamp of approval is sought after by manufacturers and healthcare personnel alike as an indication of safety, reliability, and performance.

21. NIOSH-approved respirators are required to have certain markings, including the business name of the approval holder/manufacturer; NIOSH in block letters or the NIOSH logo; the NIOSH testing and certification approval number, e.g., TC-84A-XXXX; NIOSH filter series and filter efficiency level, e.g., N95; and the approval holder's respirator model number or part number, represented by a series of numbers or alphanumeric markings, e.g., 8577 or 8577A. Below is a picture published by the CDC of a generic facepiece respirator with appropriate NIOSH markings:



22. The CDC does not recommend that the general public wear N95 respirators to protect themselves from respiratory diseases, including COVID-19, as those are critical supplies that must be reserved for health care workers and other medical first responders.

23. Due to the unprecedented demand for emergency medical services to treat patients presenting with COVID-19 symptoms, hospitals and medical professionals have experienced critical shortages of N95 respirators and other one-time usage face masks.

The Statutory Framework

24. The FDA is responsible for protecting the health of the American public by ensuring, among other things, that medical devices are safe and effective for their intended uses and bear labeling that contains true and accurate information. The FDA, among other things, regulates the manufacture, labeling, and distribution of medical devices shipped or received in

interstate commerce and enforces the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "FDCA"), and other pertinent laws and regulations.

25. The FDCA prohibits, among other things, the introduction, delivery for introduction, or causing the introduction or delivery for introduction into interstate commerce of a misbranded device. 21 U.S.C. § 331(a).

26. Under the FDCA, a medical device is misbranded if, among other things, the labeling on the device "is false or misleading in any particular." 21 U.S.C. § 352(a)(1).

27. Under the FDCA, a "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). "Labeling" is defined as "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." 21 U.S.C. § 321(m).

28. Under the FDCA, "interstate commerce" is defined in part as "commerce between any State or Territory and any place outside thereof." 21 U.S.C. § 321(b).

29. Under the FDCA, a "device" is defined, in pertinent part, as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man . . . , and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h).

30. Face masks, face shields, and respirators are "devices" subject to FDA regulation when they are intended for a medical purpose, such as prevention of infectious disease

transmission (including uses related to COVID-19). Face masks, face shields, and respirators are not devices when they are intended for a non-medical purpose, such as for use in construction.

31. Under the FDCA, every person who owns or operates any establishment within any foreign country engaged in the manufacture of a device that is imported or offered for import into the United States shall, upon first engaging in such activity, immediately submit a registration to FDA that includes, among other things, the name and place of business of the establishment, the name of the United States agent for the establishment, and the name of each importer of such device in the United States that is known to the establishment. 21 U.S.C. § 360(i)(1)(ii).

Individual-3 Agreed to Purchase N95 Respirators in the PRC from Individual-1

32. In or around March 2020, Individual-1, the American broker living in the PRC, began sourcing PPE, including N95 respirators and COVID-19 test kits, for Individual-3, the individual living in Pennsylvania and the owner of Company-2, from sources in the PRC. Individual-3 intended to import and sell the products procured by Individual-1 to his customers in the United States, including medical providers and first responders.

33. Individual-1 and Individual-3 agreed that they would use Individual-2's company, Company-1, to wire money to sources in the PRC and to help import the products into the United States. Prior to the pandemic, neither Individual-2, the Utah-based acupuncturist, nor Company-1 had experience in the PPE business.

34. From on or about March 18, 2020 to on or about March 27, 2020, Individual-3 wired approximately $3.07 million to Company-1 for the purpose of purchasing 1 million N95 respirators. Individual-1 caused Company-1 to enter into separate agreements with

two Chinese companies in the PRC, Company-3 and Company-4, to purchase a total of approximately 800,000 NIOSH-certified N95 masks for Individual-3 in the United States.

Individual-1 Procured the Subject Respirators from KING YEAR for Individual-3 in the United States

35. On or about March 28, 2020, via text message, Individual-1 reported to Individual-3 that he had obtained approximately 10,000 masks for Individual-3 and expected to obtain an additional 20,000 to 50,000 masks the following day, which he intended to start shipping to Individual-3 in the United States. Individual-1 sent Individual-3 pictures of the packaging for each box of masks which listed the manufacturer as the defendant KING YEAR PRINTING AND PACKAGING CO., LTD.

36. Individual-1 provided Individual-3 with a certificate of registration document from East Notice Certification ("ENC") service, dated March 20, 2020, and signed by a purported Chief Engineer at ENC. Even though ENC was purportedly a Chinese inspection company, the document had an FDA logo, an American eagle, and purported to state that the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. was "registered with the U.S. Food and Drug Administration pursuant to voluntary cosmetic registration program." A picture of the certification document prepared for KING YEAR is attached below:

Fiscal Year 2020-2022

CERTIFICATION OF REGISTRATION

This certifies that:

King Year Printing and Packaging Company Limited
No.30 LongHua Branch RD, Wentang Industry Zone, Dongcheng District, Dongguan

is registered with the U.S. Food and Drug Administration pursuant to voluntary cosmetic registration program, such registration having been verified as currently effective on the date hereof by East Notice Certification Service Co., Ltd.

Establishment ID. : E2003166
Business Type : N95 Face Masks

FDA

ENC will confirm that such registration remains effective upon request and presentation of this certificate until the of end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. ENC makes no other presentations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. ENC assume no liability to any person or entity in connection with the foregoing. The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. ENC is not affiliated with the U.S. Food and Drug Administration.

ENC
Chief engineer

Issued: Mar. 20, 2020
Expiration Date: Mar. 19, 2023

37. In fact, according to FDA records, the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. did not attempt to register with the FDA as a manufacturer of N95 respirators until on or about April 10, 2020, not the March 20, 2020 date this certificate bears. Therefore, this certificate prepared for KING YEAR by ENC and disseminated to Individual-1 and others as a marketing tool for U.S. buyers, such as Individual-3, provided a false impression that KING YEAR had registered with the FDA as a foreign manufacturer of N95 masks, when it had not.

38. Individual-1 also sent Individual-3, by text message, a test report prepared for the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. by ENC that purportedly certified that the masks manufactured by KING YEAR met the NIOSH standard for particulate filtration efficiency. The test report was from a non-accredited laboratory and appears to have been false. The report did not include a model number or brand name for the masks tested, rendering it impossible to verify whether the masks allegedly tested were the Subject

Respirators sold to Individual-3. Additionally, the pictures of the masks depicted in the report were generic and appeared to be different from the Subject Respirators later imported by Individual-3 into the United States. For example, unlike the Subject Respirators, the masks depicted in the ENC report were not stamped with any marks or logos, were not embroidered with "N95," and had ear loops that visibly appeared to be made of different material.

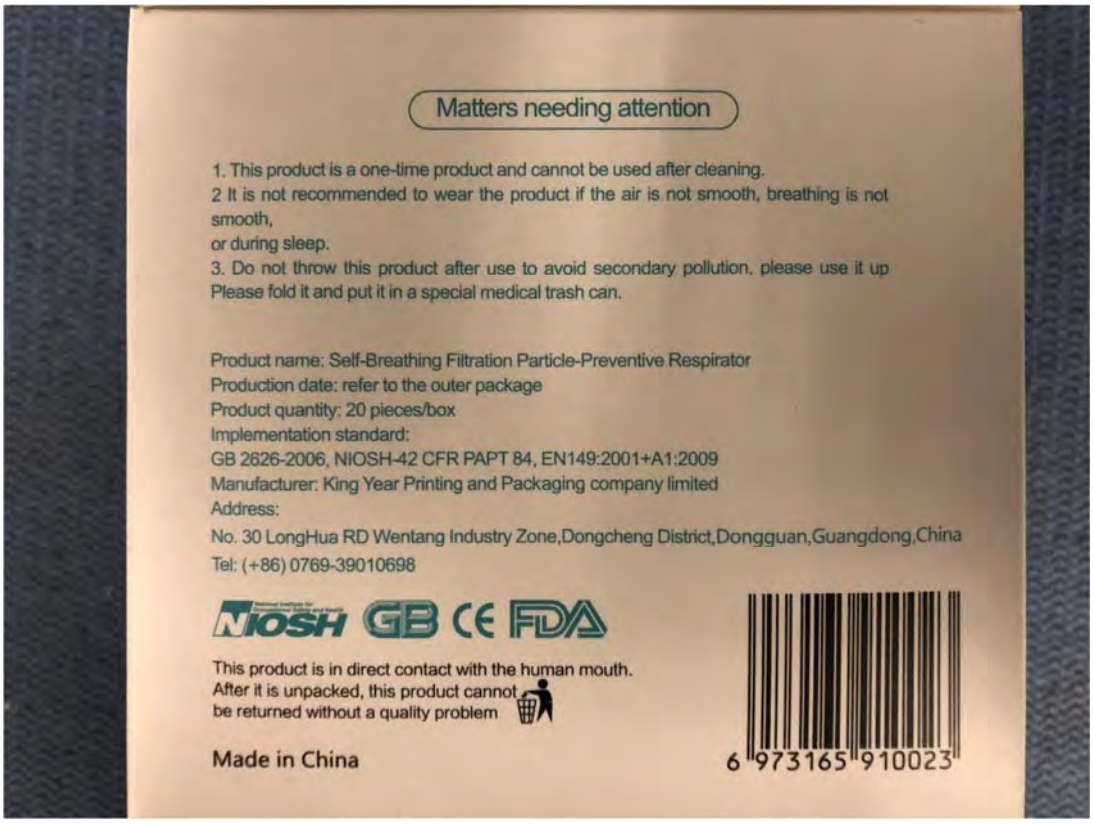
KING YEAR Put False and Misleading Claims on the Labeling of the Subject Respirators

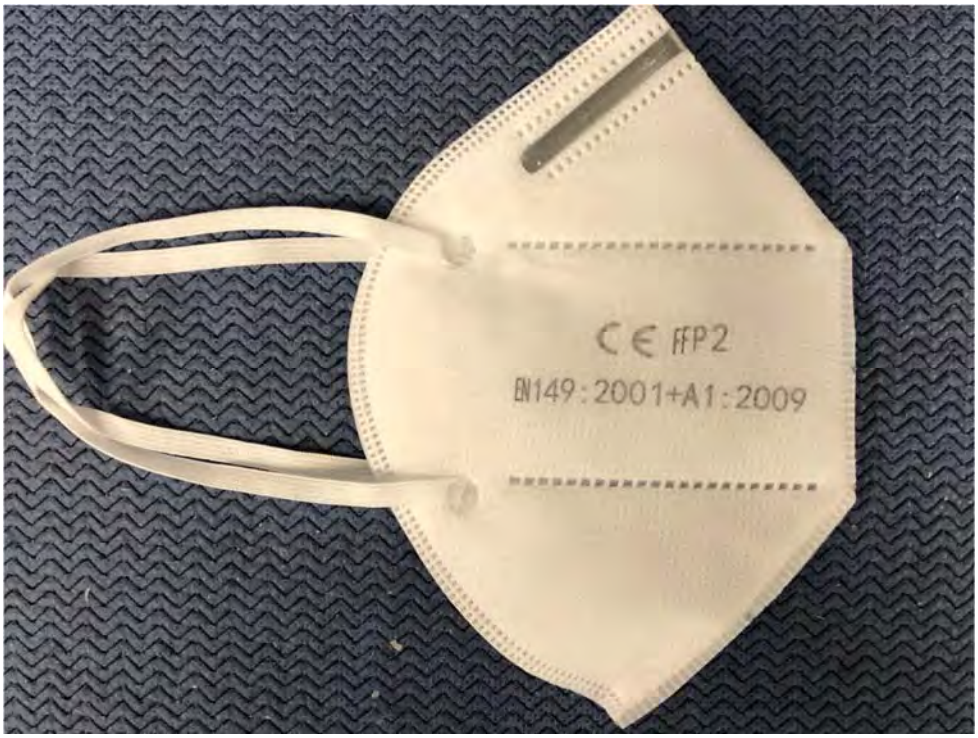
39. On or about April 6, 2020, the U.S. Customs and Border Protection ("CBP") intercepted and detained a shipment of approximately 95,200 Subject Respirators at the John F. Kennedy Airport ("JFK") that were inbound from the PRC and destined for Individual-3's warehouse in Newark, Delaware ("Shipment 1"). Shipment 1 consisted of approximately 4,760 identical boxes of masks, with each box containing approximately twenty masks.

40. Law enforcement reviewed pictures of the Subject Respirators and the labeling on the packaging for the Subject Respirators. The labeling on one face of each box stated "N95," contained the logos of FDA and NIOSH, and claimed to meet the NIOSH filtration standard. Another face of the box contained a warning label, listed the manufacturer as the defendant KING YEAR PRINTING AND PACKAGING CO., LTD., and again prominently displayed the NIOSH and FDA logos. The packaging also included the logos suggesting it complied with European Union health laws and regulations (CE) and Chinese laws and regulations (GB).

41. Each respirator had ear loops. One side of each respirator was embroidered with "N95." The other side was embroidered with "CE FFP2, EN149:2001+A1:2009," which refers to European Union filtration standards for respirators. Below are pictures of the labeling on the Subject Respirators:


FFP2•N95
20 pieces/box
Exquisite single-box package
3D breathable structure
GB NIOSH EN standard
4-ply class A material
NIOSH GB CE FDA
4-PLY SOLIDPROTECTIVE MASK
GB 2626-2006 NIOSH-42 CFR PAPT 84 EN 149:2001+A1:2009


Matters needing attention
1. This product is a one-time product and cannot be used after cleaning.
2 It is not recommended to wear the product if the air is not smooth, breathing is not smooth,
or during sleep.
3. Do not throw this product after use to avoid secondary pollution. please use it up
Please fold it and put it in a special medical trash can.
Product name: Self-Breathing Filtration Particle-Preventive Respirator
Production date: refer to the outer package
Product quantity: 20 pieces/box
Implementation standard:
GB 2626-2006, NIOSH-42 CFR PAPT 84, EN149:2001+A1:2009
Manufacturer: King Year Printing and Packaging company limited
Address:
No. 30 LongHua RD Wentang Industry Zone,Dongcheng District,Dongguan,Guangdong,China
Tel: (+86) 0769-39010698
NIOSH GB CE FDA
This product is in direct contact with the human mouth.
After it is unpacked, this product cannot be returned without a quality problem
Made in China
6 973165 910023



42. The labeling on the Subject Respirators manufactured by KING YEAR was false and misleading because, among other things: (i) the packaging for the Subject Respirators displayed the NIOSH logo prominently in two places, falsely implying the Subject

Respirators were NIOSH-approved (they were not); (ii) the labeling on the Subject Respirators included the FDA logo, implying the Subject Respirators were FDA-approved, cleared, or authorized (they were not); and (iii) the Subject Mask were embroidered with "N95" in their fabric (they did not meet the N95 standard).

43. In addition, certifications prepared for the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. and disseminated to brokers, such as Individual-1, falsely implied that KING YEAR was registered with the FDA as a manufacturer of N95 masks (it was not registered until April 10, 2020, and the registration documents filed were misleading), and that the Subject Respirators met the NIOSH filtration standard for N95s pursuant to a purported lab test report prepared by ENC (ENC is not an accredited laboratory, and the CDC later concluded that a sample of the Subject Respirators failed to meet the N95 filtration standard).

Individual-3 Sold the Subject Respirators to First Responders and Medical Providers

44. Individual-3 marketed, priced, and sold the Subject Respirators as FDA-approved, NIOSH-approved, N95 respirators. In marketing materials sent to potential customers, including healthcare providers, Individual-3 appended pictures of the false and misleading packaging for the Subject Respirators containing the NIOSH and FDA logos, the false and misleading ENC certification, and the false and misleading ENC test report.

45. Individual-3 then attempted to sell the Subject Respirators at prices ranging from $4.85 to $5.85 per mask, to various entities, including, hospitals, pilots associations, medical centers, and governments.

46. On or about April 6, 2020, a customs broker hired by Individual-3 to clear Shipment 1 through U.S. customs raised questions concerning the intended use of the Subject

Respirators and whether they should include FDA and CBP authorization codes for importation. Individual-3 relayed these questions over text message to Individual-1 in the PRC.

47. On or about April 8, 2020, Individual-1 advised Individual-3 in a text message to disclaim the Subject Respirators as being for medical use because the masks were "civilian use N95 masks." Individual 3 then instructed the customs broker to disclaim the Subject Respirators as intended for a medical use, notwithstanding the fact that Individual-3 intended to sell the Subject Respirators to first responders and medical providers. As a result of this false information, FDA did not perform an initial inspection of the Subject Respirators upon arrival at JFK.

KING YEAR Filed False Registration Documents with the FDA

48. On or about April 10, 2020, the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. filed documents with the FDA to register as a foreign exporter and manufacturer of "[f]ace Masks, KN95, N95, N95 respirator[s] with antimicrobial/antiviral agent[s]." This was the first time KING YEAR filed a registration document with the FDA concerning the Subject Respirators, notwithstanding that KING YEAR manufactured and offered the Subject Masks for import into the United States as early as in or around March 2020.

49. The defendant KING YEAR PRINTING AND PACKAGING CO., LTD. coded its products in the registration documents as Class II medical devices and "single use, disposable, NIOSH-approved N95 respirator[s]." KING YEAR's registration submission further designated its respirators as "intended for use by the general public in public health medical emergencies to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological particulates and has an added antimicrobial and/or antiviral agent which kills specified pathogens under specified contact conditions." This was false. First, KING YEAR

did not obtain NIOSH approval for the Subject Respirators. Instead, KING YEAR obtained a test report from ENC, a non-accredited Chinese laboratory, falsely claiming that the Subject Respirators satisfied the N95 standard. Second, the Subject Respirators were not intended to be used by the general public. KING YEAR knew or consciously avoided knowing that any respirators sold in the United States were going to be used first and foremost by healthcare personnel on the frontlines of the COVID-19 health emergency given the widely reported shortages of respirators in the national stockpile and in the U.S. market generally, and the CDC's guidance that all respirators should be reserved for healthcare personnel. By embroidering "N95" on each individual mask and falsely marking the packages with the NIOSH logo on the packaging, KING YEAR was actively causing the respirators to be most marketable to healthcare personnel in the United States.

50. In the false registration documents filed by the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. with the FDA, it nominated CCTC Service, Inc. ("CCTC") as its U.S. agent, and listed an address for CCTC in Wilmington, Delaware, a phone number, and an email address.

51. The responsibilities of the United States agent, include: assisting the FDA in communications with the foreign establishment; responding to questions concerning the foreign establishment's devices that are imported or offered for import into the United States; and assisting the FDA in scheduling inspections of the foreign establishment. 21 CFR 807.40(b)(2). If the FDA is unable to contact the foreign establishment directly or expeditiously, the FDA may provide information or documents to the U.S. agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment. *Id.* In addition, the United States agent cannot be a mailbox, answering machine or service, or any other

place where an individual acting as the foreign establishment's agent is not physically present. 21 CFR 807.3.

52. The investigation revealed that the address listed by the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. for CCTC in its certification documents was a personal residence with no affiliation to CCTC. Law enforcement interviewed the occupant of the residence, who stated that he was a clinical psychologist who has rented the premises for three years. The occupant had never heard of CCTC or KING YEAR. Law enforcement subsequently interviewed the owners of the residence, both of whom stated that they had not heard of CCTC or KING YEAR, and had never registered any company with the FDA.

53. On or about May 28, 2020, law enforcement attempted to reach out multiple times to the phone number listed by the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. in its registration documents. Each time, law enforcement received a message stating that the number was temporarily unavailable. Subsequent attempts to reach anyone at that number were unsuccessful. CCTC has not responded to emails sent by law enforcement to the email address listed for the company by KING YEAR on its registration documents. Searches of open source records and law enforcement databases revealed no active corporation by the name of CCTC in Delaware or elsewhere. There is, therefore, probable cause to believe CCTC is a fictitious corporation.

54. In my training and experience, foreign manufacturers of counterfeit goods use fictitious corporations as U.S. agents to circumvent regulatory oversight of their products.

The Subject Respirators Did Not Meet the Minimum N95 Standard in Tests Performed by the CDC

55. On or about April 17, 2020, FDA employees reviewed photographs of the first shipment of the Subject Respirators and found that they appeared to be misbranded.

56. On or about April 18, 2020, CBP intercepted a second shipment of the Subject Respirators at JFK intended for delivery to Individual-3's warehouse in Newark, Delaware. This shipment consisted of 300,000 Subject Respirators ("Shipment 2").

57. On or about April 22, 2020, the FDA performed an initial inspection of the Subject Respirators at JFK from Shipments 1 and 2 and confirmed that they were misbranded. On that same day, the FDA sent a sample of 10 masks from each shipment to the CDC for testing.

58. On or about April 22, 2020, a third shipment of the Subject Respirators arrived at JFK inbound from the PRC and was intercepted by CBP ("Shipment 3"). Shipment 3 was also destined for Individual-3's warehouse in Newark, Delaware. Law enforcement confirmed that the packaging for the masks in Shipment 3 appeared to be identical to the Subject Respirators in Shipments 1 and 2.

59. On or about April 24, 2020, the CDC published the results of the tests performed on the Subject Respirators in Shipments 1 and 2. The CDC found that all of the tested samples measured a filter efficiency of less than the minimum 95 percent required for an N95 respirator. The filter efficiency for the masks ranged from 83.4% to 91.12% for the first sample and 82.7% to 90.03% for the second sample. With the exception of two masks, all of the masks tested with a filter efficiency rate of below 90%. The CDC found that despite the packaging having the NIOSH logo and claiming that the product met the NIOSH certification standard, the Subject Respirators were not NIOSH-approved and did not meet the NIOSH certification standard.

60. In addition, the CDC report noted fit difficulties with the ear loop design of the Subject Respirators, stating that "[c]urrently, there are no NIOSH-approved products with ear loops" and that "limited assessment of ear loop designs, indicate difficulty achieving a proper fit."

The fit of a respirator is critical because it is only when an N95 respirator is properly fitted that its filtration capabilities exceed those of face masks and surgical masks, and thereby, provide greater protection from airborne particles and respiratory droplets containing the virus.

61. The FDA Center for Devices and Radiological Health ("CDRH") Inspections and Audits team also reviewed the Subject Respirators from Shipments 1 and 2. In addition to CDC's findings, CDRH concluded that the ENC test report prepared for KING YEAR PRINTING AND PACKAGING CO., LTD. was not from an accredited laboratory.

62. WHEREFORE, your affiant respectfully requests that a summons be issued for the defendant KING YEAR PRINTING AND PACKAGING CO., LTD. so that it may be dealt with according to law.

Dated: Brooklyn, New York
June 5, 2020

/s Donald Pearlman 06/05/2020
Donald Pearlman
Special Agent
FDA Office of Criminal Investigations

Sworn to before me by telephone this
5th day of June, 2020

Steven M. Gold
THE HONORABLE STEVEN M. GOLD
UNITED STATES MAGISTRATE JUDGE
EASTERN DISTRICT OF NEW YORK