

Daniel Cannistra (202) 624-2902 DCannistra@crowell.com

April 8, 2020

PUBLIC DOCUMENT

VIA ELECTRONIC FILING

The Honorable Robert E. Lighthizer Docket No.: USTR-2020-0014
United States Trade Representative
Office of the United States Trade Representative

600 17th St. NW Washington, DC 20508

Re: Request for Exclusion from Section 301 Tariffs of Medical Exam and

<u>Laboratory Supplies Classified Under HTS Codes 4819.20.0040;</u> 4819.50.4060; 4821.90.2000; 4911.99.8000; 5601.21.0090; 5601.22.0090; 7017.10.6000; 8510.20.9000; 8510.90.4000; 9017.80.0000; 9019.10.2090;

9619.00.1510 (COVID-19)

Dear Ambassador Lighthizer:

On behalf of our client, Cardinal Health ("Cardinal"), we hereby respectfully submit our exclusion request for medical exam and laboratory supplies from the Section 301 tariffs enacted against products from the People's Republic of China ("China"). This request is submitted pursuant to the United States Trade Representative's request for public comments on possible further modifications to remove duties from additional medical-care products, particularly those used to treat or reduce the spread of COVID-19. These products are in short supply as a result of the severe strain placed upon the U.S. healthcare system and are urgently needed to support the treatment and reduce transmission of COVID-19. Current sourcing options for these products outside of China are limited and imposition of additional duties on these products would significantly impact U.S. interests. Additionally, the realized impact of the global COVID-19 pandemic necessitates tariff exclusions on these products to support the ongoing treatment of patients. As a result, Cardinal respectfully requests that these products are excluded from Section 301 tariffs.

I. Background

-

¹ See 85 Fed. Reg. 16987 (March 25, 2020).

Cardinal Health is a global, integrated healthcare services and products company, providing solutions for hospitals, health systems, pharmacies, ambulatory surgery centers, clinical laboratories and physician offices worldwide. Cardinal delivers products and solutions to improve the lives of people every day by providing clinically-proven medical products and cost-effective solutions that enhance supply chain efficiency from hospital to home. Cardinal connects patients, providers, payers, pharmacists and manufacturers for integrated care coordination and better patient management. Backed by nearly 100 years of experience, we have a team of 50,000 employees in 46 countries (including more than 30,000 in the U.S.).

While Section 301 tariffs harm Cardinal, our customers, and patients, they provide no benefits to the U.S. economy and hinder the access to critical supplies by healthcare workers in the midst of a global pandemic. The World Customs Organization has stressed the importance of freely flowing goods across the globe to facilitate the movement of relief goods needed for the treatment of COVID-19. As the Secretary General of the World Customs Organization has emphasized, the transfer of relief supplies around the world is necessary to mitigate the effects of the COVID-19 pandemic on society. G20 Trade and Investment Ministers have further emphasized their commitment to the continued flow of vital medical supplies and equipment to fight the pandemic. Open trade and global value chains are fundamental drivers to treat and begin to recover from this global crisis. A reduction in tariffs and non-tariff barriers is an effective tool in stimulating the economy, and Cardinal urges the U.S. to use these tools as part of a holistic economic policy response.

The products at issue are essential medical products which are in short supply as a result of the COVID-19 pandemic. See Exhibit A. These products have historically been manufactured in China due to the manufacturing expertise and capacity which exists there, local concentration of raw materials, as well as limited supply from other countries. These products are needed more than ever as they are in short supply as a result of COVID-19 and are adding additional stress to the U.S. healthcare system at a time when healthcare providers desperately need access to critical supplies. The imposition of tariffs on these products puts the health and safety of the American people at risk by reducing easy access to a steady supply of needed medical products.

II. Medical Exam and Laboratory Supplies Are In Short Supply Due To COVID-19

The medical exam and laboratory supplies subject to this request include but are not limited to consumable products used in a medical exam or laboratory, such as cotton tipped applicators,

https://g20.org/en/media/Documents/G20_Trade%20&%20Investment_Ministerial_Statement_E N.pdf.

² http://www.wcoomd.org/-/media/wco/public/global/pdf/topics/facilitation/activities-and-programmes/natural-disaster/reliefconsignments.pdf?db=web._See, also, Exhibit B.

³ See

self-seal sterilization pouches, trays for blood, urine, and other patient specimens, test tubes, test tube labels, and general purpose surgical blades. These products are essential to providing ongoing, high-quality care throughout the healthcare system and the imposition of Section 301 tariffs on these products will hinder, rather than facilitate, the movement of these essential goods. As the COVID-19 healthcare crisis continues to unfold across the globe, Cardinal Health is focused on the communities impacted by the pandemic and how to help. Cardinal Health is an essential link in the healthcare supply chain, and now our mission is more important than ever. Our paramount focus is on getting essential medicines and supplies into the hands of our healthcare provider customers who need them. For all products that move through our channels, we are working around the clock. We are engaging with customers, leading experts, and officials to ensure products are going where they are needed; we are actively collaborating with suppliers to understand impacts of the coronavirus on product supply.

These products are essential to protect the American people and to prevent infection as medical professionals respond to infectious diseases in thousands of medical procedures every day. More than 210,000 physician offices, 6,500 hospitals, and 44,000 nursing homes and extended care facilities nationwide depend on these products, and they are limited to no viable alternative sources. Now, they are needed more than ever to protect health care workers on the front lines in the fight against the pandemic and to maintain a high level of care in response to the spread of COVID-19. As current demand is skyrocketing, the only way to ensure adequate supply of these essential goods is to reduce barriers to trade. The imposition of Section 301 tariffs on the products outlined in this request would further hinder Cardinal's ability to supply health care workers with essential medical supplies, putting the health and safety of the American public at risk.

American hospitals are under severe strain as a result of the COVID-19 pandemic. Hospitals are operating at or above capacity, temporary hospitals are being deployed, and our healthcare system is coming under increasing strain as it treats the rising influx of patients. The U.S. must remain capable of protecting Americans from COVID-19 and other deadly infectious diseases and these tariffs will put that capability at risk. With that urgent product need in the healthcare ecosystem in mind, it is imperative to consider tariff exclusions on critical medical products. The added costs associated with applying a tariff to healthcare products increases cost throughout the supply chain, which ultimately may fall on the patient. This is counter to our shared goal of lowering the cost of healthcare and quickly and efficiently getting needed medical supplies to the health care providers who urgently need them. In some instances, these added costs will result in disruption of supply availability. Patients should always have access to life-enhancing and lifesaving technologies, especially during a global public health emergency.

As we have seen in previous infectious outbreaks, including the 2014 Ebola outbreak and the 2009 HIN1 epidemic, we are seeing a significant increase in demand for medical supplies. The U.S. must remain capable of protecting Americans from deadly infectious diseases and these tariffs will put that capability at risk. Such an unprecedented increase in demand is already

causing depletion of inventory and requires multiple months to recover from back orders. While we work through this crisis, there are no available resources to dedicate to the 12-24 month process that is required to establish new sources.

However, it is important to note that extreme demand surges are not limited solely to medical products used to treat COVID-19; as patient census and healthcare consumption increases, so too does the need for all items required to deliver care at the highest standards. For example, in accordance with CDC guidelines, vital sign monitoring products like thermometry devices are required to measure patient and provider temperature to identify and limit exposure risks. Supply chain disruptions for these and other medical products will only exacerbate the COVID-19 challenges.

In closing, to successfully combat COVID-19 in the U.S. and ensure healthcare worker protection and patient safety, it is essential to exclude tariffs on critical medical products. Because these consumables are low-margin commodity products, the added tariff expense cannot be absorbed by manufacturers. Faced with operating at a financial loss, a reinstatement of tariffs could force some manufacturers to exit certain product categories, which would create additional product shortages and other unforeseeable and unintended consequences. These consequences would severely hinder the ability of the U.S. healthcare system to adequately treat COVID-19 patients and further reduce its spread by causing essential supplies to be unavailable to those who need them most

III. Additional Section 301 Tariff Could Impact Costs and Harm U.S. Interests

Tariffs on essential medical products will lead to reduced access and availability to products needed in the fight against COVID-19. The additional costs associated with applying a tariff to these products would cause an increase in cost throughout the supply chain. At a time of increasing economic strain for so many Americans, this runs counter to our shared goal of providing affordable access to needed medical supplies.

Placing tariffs on medical products is troubling from a public health perspective. The added costs associated with applying a tariff to healthcare products will cause a rise in cost throughout the supply chain. This extra cost may ultimately fall on the patient, which is counter to our shared goal of lowering the cost of healthcare. In some instances, these added costs will result in disruption of supply availability. Patients should have access to life-enhancing and lifesaving technologies, not least when the U.S. health system is under added stress due to a public health emergency as it currently is due to COVID-19. As the Secretary General of the World Customs Organization has emphasized, the transfer of relief supplies around the world is necessary to mitigate the effects of the COVID-19 pandemic on society.

We believe Section 301 tariffs on all of these products should be removed without a fixed termination date or, of that is not possible, at least until one year after the World Health

Organization declares the end of the coronavirus pandemic. When foreign suppliers have a choice of where to ship, the cost of sending such products to U.S. patients should be competitive with other countries that do not impose Section 301 tariffs. Inventories will need time to rebuild after COVID-19 has ended.

We also request the suspension of MFN tariffs for this group of products, as allowed under Section 318 (a) of the Tariff Act of 1930 (as amended). Specifically the text says:

(a) Whenever the President shall by proclamation declare an emergency to exist by reason of a state of war, or otherwise, he may authorize the Secretary of the Treasury to extend during the continuance of such emergency the time herein prescribed for the performance of any act, and may authorize the Secretary of the Treasury to permit, under such regulations as the Secretary of the Treasury may prescribe, the importation free of duty of food, clothing, and medical, surgical, and other supplies for use in emergency relief work. The Secretary of the Treasury shall report to the Congress any action taken under the provisions of this section.

President Trump has declared an emergency for coronavirus, so the conditions for applying section 318 have been fulfilled. We request that you take this action for the same duration as requested for the Section 301 tariffs (noted above). In addition, for any product in which the MFN duty is tied to a price cap for the specific product, we ask that the price cap be removed to enable the duty to be completely eliminated. We therefore request that USTR remove all tariffs on medical exam and laboratory supplies subject to this request.

Please direct any questions concerning this submission to the undersigned.

Sincerely,

Daniel Cannistra

Partner Crowell and Moring LLP 1001 Pennsylvania Ave.

Parkle

Washington, DC 20006

Exhibit A

Products Subject to Exclusion Request





Exhibit B

World Customs Organization Guidelines



HUMANITARIAN ASSISTANCE

Emergency Measures

In the event of a natural disaster (for example, an earthquake) and similar catastrophes (for example, a burst dam), aid to those affected by such catastrophes obviously needs to be delivered and moved across international boundaries efficiently and expeditiously. The effectiveness of humanitarian assistance is dependent to a large extent on the speed with which it can be furnished. It is therefore imperative that Customs administrations be as facilitative as possible and be prepared to clear goods rapidly that, as a result of catastrophic events, are being forwarded as aid.

General measures

The following provisions apply to the Customs formalities involved in the clearance of relief consignments, at any stage of their transportation, be it at exportation, during transit or at importation:

- Clearance of relief consignments for export, transit, temporary admission and import shall be carried out as a matter of priority;
- Clearance of relief consignments should be granted without regard to the country of origin, the country from which arrived or country of destination;
- ❖ Lodging of a simplified Goods Declaration or of a provisional or incomplete Goods Declaration subject to completion of the declaration within a specified period;
- Clearance outside the designated hours of business or away from Customs offices and the waiver of any charges in this respect;
- If the goods must be inspected by other competent authorities and the Customs also schedules an examination, the Customs shall ensure that the inspections are coordinated and, if possible, carried out at the same time:
- Examination and/or sampling of goods only in exceptional circumstances;
- Generally, when Customs is clearing relief consignments, Customs control should be restricted to the absolute minimum necessary to ensure compliance with the laws and regulations which Customs are responsible for enforcing; and
- In the application of Customs control, Customs shall use risk management.

It is also recommended that Governments sign the United Nations Agreement concerning measures to expedite the import, export and transit of relief consignments and possessions of relief personnel in the event of disasters and emergencies.

Export

It is recommended:

To waive any economic export prohibitions or restrictions, and any export duties or taxes, in respect of goods contained in relief consignments destined to countries having suffered disasters:

- To accept at exportation, as a general rule, the written summary declarations made out by the exporters of relief consignments as evidence of the contents and of the intended use of such consignments;
- To take such steps as may be necessary in order that the Customs authorities of the exporting country may be in a position to:
 - (a) Examine, based on risk analysis, against a detailed list, the contents of relief consignments, and certify the results of this examination on that list; and
 - (b) Where possible place such consignments under Customs seals where such action is likely to avoid delays in the forwarding of the goods at later stages in their journey;
- To permit such consignments to be presented for export clearance at any approved Customs office in advance of the need for actual export.

Transit

It is recommended:

To facilitate as far as possible the carriage of relief consignments in Customs transit, with due regard to any action taken at earlier stages in their journey.

Import

It is recommended:

- To allow admission free of import duties and taxes, or charges having an equivalent effect, and free of economic import prohibitions or restrictions in respect of all relief consignments imported by organizations approved by the competent authorities, for distribution free of charge by such organizations or under their control to the victims of a disaster in their territory, in particular where such consignments consist of foodstuffs, medicaments, clothing, blankets, tents, prefabricated houses, or other goods of prime necessity;
- To facilitate the temporary admission, with conditional relief from import duties and taxes, of any equipment required by the organizations involved in disaster relief and used by them or under their control in action undertaken to alleviate the effects of a disaster; and wherever possible not require security but be content with an undertaking given by the approved organization to reexport such equipment;
- To lodge and register or check the Goods declaration and supporting documents prior to the arrival of the goods, and their release upon arrival.

Sources

- WCO Revised Kyoto Convention, Specific Annex J.5
- WCO Istanbul Convention, Annex B.9
- Recommendation of the Customs Co-operation Council to expedite the forwarding of relief consignments in the event of disaster (8 June 1970)

HS classification reference for Covid-19 medical supplies

Categories	Product names	Brief info	HS Classification
I. COVID-19 Test kits/ Instruments and apparatus used in Diagnostic Test	COVID-19 Test kits	Diagnostic reagents based on polymerase chain reaction (PCR) nucleic acid test.	3822.00
	COVID-19 Test kits	Diagnostic reagents based on immunological reactions	3002.15
	COVID-19 Diagnostic Test instruments and apparatus	Instruments used in clinical laboratories for In Vitro Diagnosis	9027.80
	Face and eye protection		
	Textile face-masks, without a replaceable filter or mechanical parts, including surgical masks and disposable face-masks made of non-woven textiles.		6307.90
	Gas masks with mechanical parts or replaceable filters for protection against biological agents. Also includes such masks incorporating eye protection or facial shields.		9020.00
	Protective spectacles and goggles		9004.90
	Plastic face shields (covering more than the eye area)		3926.20
	Gloves		
	Plastic gloves		3926.20
	Surgical rubber gloves		4015.11
	Other rubber gloves.		4015.19
II. Protective		Knitted or crocheted gloves which have been impregnated or covered with plastics or rubber	
_	Textile gloves that are not knitted or o		6216.00
like	Other		
	Disposable hair ne	ts	6505.00
	Protective garments for surgical/medical use <i>made up of</i>		
	felt or nonwovens whether or not impregnated, coated,		6210.10
	covered or laminated (fabrics of heading 56.02 or 56.03).		
	This includes spun-bonded garments.		
	Other protective garments of textiles of rubberised textile		
	fabrics or woven fabrics that are impregnated, coated,		6210.20
		covered or laminated (fabrics of headings 59.03, 59.06 or	
	*	59.07). Actual classification will depend on type of	
	_	males or females. Example: a unisex	6210.40 6210.50
	•	it impregnated with plastics would be	
		10.50 - Other women's or girls' garments	2025.22
	 Protective garmen 	ts made from plastic sheeting	3926.20

III.	Liquid filled thermometer for direct reading	Includes standard "Mercury-in-glass" clinical thermometer.	9025.11
Thermometers	Other thermometers	For example, digital thermometers, or infrared thermometers for placing on the forehead.	9025.19
	Alcohol solution	Undenatured, containing by volume 80% or more ethyl alcohol	2207.10
	Alcohol solution	Undenatured, 75% ethyl alcohol	2208.90
	Hand sanitizer	A liquid or gel generally used to decrease infectious agents on the hands, alcohol-based type.	3808.94
	Other disinfectant preparations	Put up in forms or packings for retail sale such as rubs and wipes impregnated with alcohol or other disinfectants.	3808.94
	Medical, surgical or laboratory sterilisers	Function by steam or boiling water	8419.20
IV. Disinfectants/	Hydrogen peroxide in bulk	Bulk H_2O_2 whether or not with solidified with urea.	2847.00
Sterilisation products	Hydrogen peroxide presented as a medicament	H ₂ O ₂ put up for internal or external use as a medicine, including as an antiseptic for the skin. Only covered here if in measured doses or in forms or packings for retail sale (including directly to hospitals) for such use.	3004.90
	Hydrogen peroxide put up in disinfectant preparations for cleaning surfaces	H ₂ O ₂ put up as cleaning solutions for surfaces or apparatus.	3808.94
	Other chemical disinfectants	Put up in forms or packings for retail sale as disinfectants or as disinfectant preparations, containing alcohol, benzalkonium chloride solution or peroxyacids, or other disinfectants.	3808.94
V. Other medical devices	Computed tomography (CT) scanners	Uses a rotating X-ray machine to image thin slices of the body to diagnose diseases such as pneumonia.	9022.12
	Extracorporeal membrane oxygenation (ECMO)	Provides prolonged cardiac and respiratory support by removing blood from the person's body and artificially removing the carbon dioxide and oxygenating red blood cells.	9018.90

	NA died vertiletere	Durantidas usas banisal martilatian la	
	Medical ventilators	Provides mechanical ventilation by	0040 00
	(artificial respiration	moving breathable air into and out of	9019.20
	apparatus)	the lungs.	
	Other oxygen therapy	As well as complete oxygen therapy	
	apparatus including	apparatus, this subheading also covers	9019.20
	oxygen tents	recognisable parts of such systems.	
		Electrical or electronic equipment for the	
		observation of a disease, condition or	
		one or several medical parameters over	
		time. This includes such devices as pulse	
	Patient monitoring	oximeters or bedside monitoring stations	
	devices -	used for continuous monitoring of	
	Electro-diagnostic	various vital signs.	9018.19
	apparatus		
	11	(Note: this does not include devices	
		more specifically covered elsewhere e.g.	
		electro-cardiographs (9018.11) or	
		electronic thermometers (9025.19).)	
	Wadding, gauze,	Impregnated or coated with	
	bandages, cotton	pharmaceutical substances or put up in	3005.90
	sticks and similar	forms or packings for retail sale for	3003.90
	articles	medical use.	
	Syringes, with or		9018.31
VII BAssissi	without needles		9018.31
VI. Medical	Tubular metal needles		
Consumables	and needles for		9018.32
	sutures		
	Needles, catheters,		0010 30
	cannulae and the like		9018.39
	Intubation kits		9018.90
	Paper bed sheets		4818.90

Exhibit C

Representative Product SKUs

Representative SKUs – HTS Codes 4819.20.0040; 4819.50.4060; 4821.90.2000; 4911.99.8000; 5601.21.0090; 5601.22.0090; 7017.10.6000; 8510.20.0000; 8510.00.4000;		
7017.10.6000; 8510.20.9000; 8510.90.4000; 9017.80.0000; 9019.10.2090; 9619.00.1510		
DY31		
DY32		
DY33		
DY34		
90168		
90308		
90408		
90411		
90422		
90515		
90610		
90713		
90810		
91015		
91218		
91315		
91616		
91822		
92028		
92114		
92152		
92308		
92309		
92322		
92510		
92515		
92713		
92923		
1103-001766		
1103-001767		
1103-001768		
1103-001769		
1103-001770		

1103-001771	
1103-001//1	
1103-001773	
1103-001830	
1103-001831	
1103-001881	
1107-003724	
92168	
A5000-1	
A5000-2	
C15053-006	
C15055-006	
CTA3W	
CTA6W	
C15050-003	
C15050-006	
C15050-016	
C15053-003	
C15053-600	
C15055-003	
C15055-600	
A5005-1	
C15052-008	
HD-C112075	
HD-C213100	
HD-C316100	
SP1290-2	
SP1290-3	
SP1290-4	
SP1290-6	
CAH4413	
CAH4403	
CAH4406	
CAH4406D	
CAH4412	
CAH4412D	
1	
CAH4414	

April 8, 2020

A11168	
A11168-SP	
V2022A	