April 12, 2016

Secretary Sylvia Mathews Burwell
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dr. Robert M. Califf, MD, Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: FDA 4/1/2016 Safety Alert: Urogynecologic Surgical Mesh Implants by Boston Scientific: Notification – **Potential for Counterfeit Raw Material**

Dear Secretary Burwell and Commissioner Califf:

We are in receipt of the FDA's April 1, 2016 safety alert in which the FDA stated:

> The FDA is aware of allegations that Boston Scientific's urogynecologic surgical mesh may contain **counterfeit** raw material. We are examining these allegations to determine any necessary and appropriate next steps.
>
> * * * * *
>
> However, in light of the allegations, Boston Scientific will conduct additional testing relevant to the safety and effectiveness of the finished product.
>
> * * * * *
>
> The additional testing should be sufficient for the FDA to determine whether or not the urogynecologic surgical mesh manufactured from the alleged counterfeit raw material are *equivalent* to the urogynecologic surgical mesh manufactured from the original raw material supplier. We expect that this testing will take several months to complete.[1]

These statements strongly imply that the FDA believes it is sufficient and proper to allow Boston Scientific Corporation ("BSC") to test its own mesh products for equivalency to mesh made from genuine, authentic Phillips Sumika Polypropylene Company ("Phillips") Marlex HGX-030-01. This is alarming and leads to the following fundamental question:

> **Does the FDA believe equivalence is a defense to trafficking of counterfeit raw material in violation of 18 U.S.C. § 2320 (Trademark Counterfeiting Act)?**

If this is the position of the FDA, it is flawed and demonstrates a fundamental lack of understanding of Congress' anti-counterfeiting laws. This position also contradicts BSC's own prior process of verifying lot numbers with the manufacturer. If the lot number is invalid, the product is counterfeit.

[1] *See Exhibit 1*, attached hereto.

The FDA's investigation should not be into the ***quality*** of the raw material, but rather the ***source*** of the raw material. Allowing a defense of equivalence undermines the public policy positions articulated in the very statutes Congress passed to prevent this type of criminal conduct.

The Trademark Counterfeiting Act, 18 U.S.C. § 2320(a), states:

(a) Offenses.— Whoever intentionally—

(1) traffics in goods or services and knowingly[2] uses a counterfeit mark on or in connection with such goods or services,

(2) traffics in labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging of any type or nature, knowing that a counterfeit mark has been applies thereto, the use of which is likely to cause confusion, to cause mistake, or to deceive,

(3) traffics in goods or services knowing that such good or service is a counterfeit military good or service the use, malfunction, or failure of which is likely to cause serious bodily injury or death, the disclosure of classified information, impairment of combat operations, or other significant harm to a combat operation, a member of the Armed Forces, or to national security, or

(4) traffics in a counterfeit drug,

or attempts or conspires to violate any of paragraphs (1) through (4) shall be punished as provided in subsection (b).

Recognizing the continued threat to public health and wellness, and to the intellectual property rights of manufacturers, Congress amended the Trademark Counterfeiting Act by enacting The Stop Counterfeiting in Manufactured Goods Act (2006), The Prioritizing Resources and Organization for Intellectual Property Act (2009), and the National Defense Authorization Act (2011). Most recently, Congress passed the **Food and Drug Administration Safety and Innovation Act** (2012), which created a specific criminal section for trafficking in counterfeit drugs and included new, enhanced penalties for this offense.

The FDA itself has likewise acknowledged the dangers of counterfeit medical products. Immediate past FDA Commissioner Hamburg stated that a fake medical product poses a threat to public health:

[2] "To prove this element, the government must present evidence that the defendant had 'an awareness or a firm belief' that the mark used was counterfeit. *See Joint Statement*, 130 Cong. Rec. 31,674 (1984). Knowledge can also be proved with evidence that the defendant acted with willful blindness, conscious avoidance, or deliberate ignorance, which means the defendant 'deliberately closed his eyes to what otherwise would have been obvious to him concerning the fact in question.' *See United States v. Brodie*, 403 F.3d 123, 132 (3d Cir. 2005) (quotation and citation omitted). "[I]f the prosecution proves that the defendant was 'willfully blind' to the counterfeit nature of the mark, it will have met its burden of showing 'knowledge.'" *Joint Statement*, 130 Cong. Rec. 31,674 (1984) (citing *United States v. Jewell*, 532 F.2d 697 (9th Cir. 1976) (other citations omitted)); *see also United States v. Hiltz*, 14 Fed. Appx. 17, 19 (1st Cir. 2001); *United States v. Hamamoto*, No. 99-10019, 2000 WL 1036199, *2 (9th Cir. July 27, 2000); *cf.* Tal S. Benschar et al., *Proving Willfulness in Trademark Counterfeiting Cases*, 27 Colum. J.L. & Arts 121, 125 (2003)." *See Prosecuting Intellectual Property Crimes, Fourth Edition*

> Passing off a fake medical product or stealing it for re-distribution on a gray market is a direct and indirect threat to public health. Fake medical products may contain too much, too little or the wrong active ingredient, and could contain toxic ingredients. They can also increase the likelihood of drug resistance and they may prevent patients from getting the real medical products that they need to alleviate suffering and save lives.[3]
>
> * * * * *
>
> We have seen that the threat from economically motivated adulteration, counterfeiting, and cargo theft is real. And, unfortunately, we know that the results can be tragic.[4]

Teresa Stevens submitted a Citizen Petition to the FDA the day before the FDA issued its safety alert. She clearly laid out a *prima facia* case of counterfeiting in violation of 18 U.S.C. § 2320, with supporting evidence including:

(1) BSC lacked any of the normal documentation that would accompany raw material purchased from a legitimate source;[5]
(2) BSC lacked any import documentation for the raw material to show it was originally imported to China;[6]
(3) Internal BSC documents claim different manufacturing sources. For example, BSCM13500000465 lists the manufacturer of the raw material as Dongguan Sunmei Plastic Raw Material Co., Ltd. and BSCM13500000446 lists the manufacturer of the raw material as EMAI Plastic Raw Material (Dongguan) Co., Ltd. (both companies are located in China);[7]
(4) BSC purchased and used the product from a questionable supplier – a company that BSC already knew counterfeited material;[8]
(5) BSC purchased the product for an unusually low price compared to the then-current market price;
(6) BSC "over-bagged" the counterfeit bags to smuggle the counterfeit product out of China, and split shipments of the products for import to multiple ports;[9]
(7) BSC had confirmation from Phillips on multiple occasions that the lot number (used to prevent counterfeiting of Phillips products) on the bags of raw material purchased by BSC was invalid;[10] and
(8) BSC's own process to determine authenticity is to check lot numbers, not test for equivalency. The same distributor which sold the raw material to BSC attempted to

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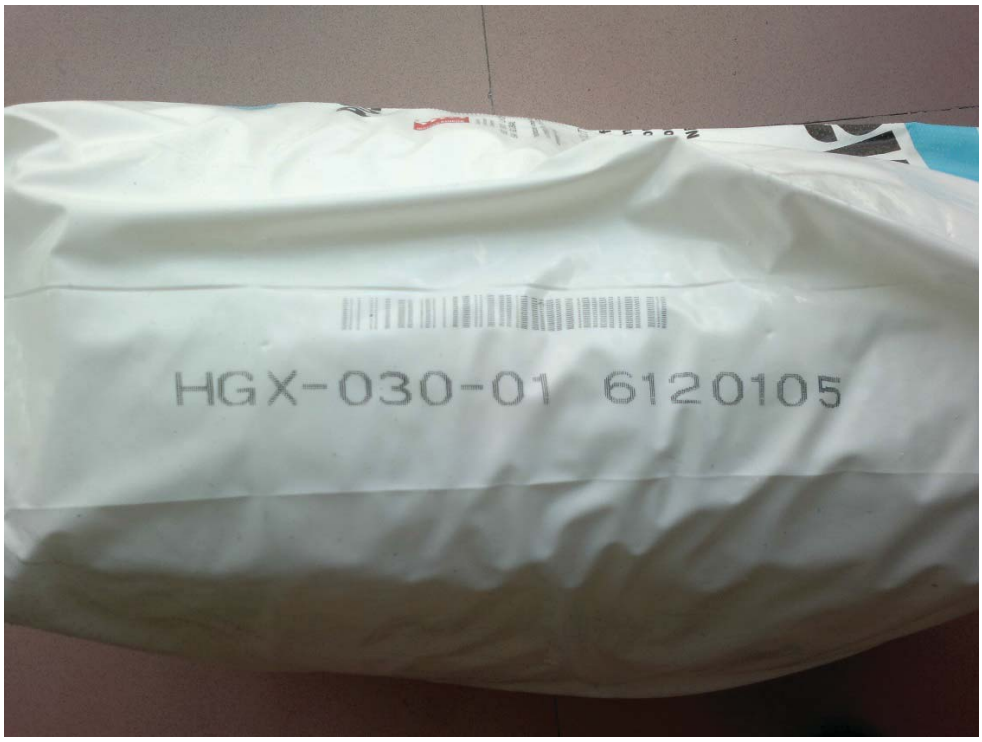
[3] Excerpt of Remarks of Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, *Partnership for Safe Medicines Interchange 2010*, October 8, 2010, available at: http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/CounterfeitMedicine/UCM235240.pdf
[4] *Id.*
[5] *See* Stevens' 3/31/16 Citizen's Petition at page 8, 9, 12, 13, 14, 15, 31.
[6] *Id.; see also Exhibit 2* attached hereto, an email from Robert Mullally, BSC's Import/Export Coordinator, asking "How did all of this resin end up in China if it was made in Texas?" BSCM13500000937.
[7] *Id.* at page 17; *see also Exhibits 3 and 4*, attached hereto.
[8] *Id.*
[9] *Id.* at page 18.
[10] *Id.* at pages 14-15; *see also Exhibit 5*, attached hereto.

sell counterfeit plastic to another BSC division. The other BSC division promptly concluded that the plastic was counterfeit because the lot number on the bag was invalid as confirmed by the manufacturer. The other BSC division informed all divisions of BSC.[11]

The picture below is of a bag trafficked by BSC. It contains virtually identical, substantially indistinguishable markings from genuine, authentic Marlex. However, to a trained eye, the bags demonstrate subtle differences in the markings. The red circles on the photograph below indicate copies of trademarks registered at the United States Patent and Trademark Office for companies such as Phillips and the International Organization for Standardization ("ISO").

[11] *Id.* at pages 12-13; *see also Exhibit 6*, attached hereto.

These spurious markings coupled with BSC's knowledge that the bag contained an invalid lot number (pictured below) are direct evidence of trafficking in counterfeit goods by BSC. But notwithstanding this direct evidence, any of the facts listed above amount to circumstantial evidence of trafficking in counterfeit goods, which has been held sufficient to impute knowledge to BSC that the goods are counterfeit.[12]



Mrs. Stevens' clear analysis in her Citizen Petition shows that BSC knew the marks on the bag shown above were not authentic because BSC had verification from Phillips that the lot number on the bags was invalid. Yet these counterfeit marks are still being used by BSC on or in connection with the surgical mesh sold by BSC in a manner that is likely to deceive the general public, or cause the general public to be confused to mistake this product for Phillips' Marlex. Therefore, the FDA's investigation should not be into the ***quality*** of the raw material. Rather, the FDA's investigation should be into the ***source*** of the raw material.

The FDA's proposed investigation requires waiting months for the results of an equivalency test when product equivalency has no bearing on whether the raw material used by BSC in its surgical mesh is counterfeit. We strongly urge the FDA to contact the **Department of Justice** for guidance on this issue. The Department of Justice issued a publication entitled *Prosecuting Intellectual Property Crimes*, which contains the following instructions directly on point:

[12] *See Prosecuting Intellectual Property Crimes, Fourth Edition* at pages 122-23 (citing *Cf.* Tal S. Benschar et al., *Proving Willfulness in Trademark Counterfeiting Cases*, 27 Colum. J.L. & Arts 121, 130-35 (2003) (discussing civil cases)), available online at https://www.justice.gov/ sites/default/files/criminal-ccips/legacy/2015/03/26/prosecuting_ip_crimes_manual_2013.pdf

1. High-Quality and Low-Quality Counterfeits

Defense counsel often argue that it is inappropriate to charge a § 2320 offense if the counterfeit goods are of very low or, conversely, very high quality, arguing that nobody is fooled by low-quality counterfeits and **that nobody is harmed or deceived by high-quality counterfeits**.[13] Both arguments are misguided. *See, e.g.*, *United States v. Farmer*, 370 F.3d 435 (4th Cir. 2004) (affirming conviction under § 2320 for irregular garments purchased from factories **that manufactured garments to trademark holder's specifications**);[14] *United States v. Gonzalez*, 630 F. Supp. 894, 896 (S.D. Fla.1986) (denying motion to dismiss § 2320 indictment because the counterfeits' low price did not preclude finding that they could cause confusion, mistake or deception).

The government's response lies in the plain language of the statute. Subsections 2320(a) and (f) focus on whether the counterfeit mark is likely to cause confusion, cause mistake, or to deceive and make no mention of the counterfeit item's quality. *See United States v. Foote*, 413 F.3d 1240, 1246 (10th Cir. 2005) ("[T]he correct test is whether the defendant's use of the mark was likely to cause confusion, mistake or deception in the public in general."). As discussed in Section B.4.g. of this Chapter, § 2320 was "not just designed for the protection of consumers," but also for "the protection of trademarks themselves and for the prevention of the cheapening and dilution of the genuine product." *United States v. Hon*, 904 F.2d 803, 806 (2d Cir. 1990) (internal quotation marks and citations omitted). In this vein, "[o]ne of the rights that a trademark confers upon its owner is the 'right to control the quality of the goods manufactured and sold' under that trademark**.** ***For this purpose the actual quality of the goods is irrelevant; it is the control of quality that a trademark holder is entitled to maintain.****"* *Farmer*, 370 F.3d at 441 (internal quotation marks and citations omitted) (emphasis added).[15,16]

Similarly here, **the actual quality of the raw material BSC is using is irrelevant.** Ironically, testing for equivalence will only ***help prove*** the case for counterfeiting – specifically, that the counterfeit raw material BSC is using and passing off as Phillips' Marlex is substantially indistinguishable from Phillips' genuine, authentic Marlex.

Setting aside the overwhelming evidence we have already uncovered that the raw material BSC is using to manufacture its mesh products is counterfeit, the FDA's proposal to allow BSC to test its own product for equivalency is flawed at its core and stands in stark contrast to statements by the FDA, statutes enacted by Congress, and the public policies behind them. The FDA's initial inquiry should be whether the raw material being used by BSC is counterfeit in violation of the Trademark Counterfeiting Act. ***If it is, the product should be recalled immediately.***

[13] Emphasis added.
[14] Emphasis added.
[15] Emphasis included in original.
[16] *See Prosecuting Intellectual Property Crimes, Fourth Edition*, available online at https://www.justice.gov/sites/default/files/criminal-ccips/legacy/2015/03/26/prosecuting_ip_crimes_manual_2013.pdf

Again, we respectfully request that the FDA to answer this fundamental, initial inquiry:

Does the FDA believe equivalence is a defense to trafficking of counterfeit raw material in violation of 18 U.S.C. § 2320 (Trademark Counterfeiting Act)?

As this product is permanently implanted in thousands of women each year, we look forward to a prompt response from the FDA and the FDA's appropriate action to protect the women affected by BSC's illegal actions.

Respectfully submitted,

Amber Anderson Mostyn
Mostyn Law Firm
3810 West Alabama Street
Houston, Texas 77027
(713) 861-6616 (Office)
(713) 861-8084 (Facsimile)

Mike Hull
Hull Henricks
3616 Far West Blvd.
117-421
Austin, Texas 78731
(512) 472-4554

Attorneys on behalf of Teresa Stevens

cc:

Senator Joe Manchin
900 Pennsylvania Avenue, Suite 629
Charleston, WV 25302

Senator Shelley Moore Capito
500 Virginia Street East, Suite 950
Charleston, WV 25301

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Urogynecologic Surgical Mesh Implants by Boston Scientific: Notification – Potential for Counterfeit Raw Material

[Posted 04/01/2016]

AUDIENCE: Surgery, OB/GYN, Risk Manager

ISSUE: The FDA is aware of allegations that Boston Scientific's urogynecologic surgical mesh may contain counterfeit raw material. We are examining these allegations to determine any necessary and appropriate next steps. FDA is not currently aware that the alleged counterfeit raw material contributes to adverse events associated with these products.

It is not uncommon for a firm, based on its own appropriate evaluation of potential suppliers and raw material, to change the source of a raw material after the device has been cleared by the FDA, and such a change often does not require FDA premarket review. However, in light of the allegations, Boston Scientific will conduct additional testing relevant to the safety and effectiveness of the finished product.

The additional testing should be sufficient for the FDA to determine whether or not the urogynecologic surgical mesh manufactured from the alleged counterfeit raw material are equivalent to the urogynecologic surgical mesh manufactured from the original raw material supplier. We expect that this testing will take several months to complete.

In the interim, the FDA believes that health care professionals and their patients should be aware of this investigation and the plan for FDA to review additional data from Boston Scientific so that they can make the most informed health care decisions.

FDA will continue to update this webpage as additional information becomes available.

BACKGROUND: Surgical mesh is a medical device that is used to provide additional support when repairing weakened or damaged tissue.

RECOMMENDATION: For women who already have Boston Scientific urogynecologic surgical mesh implanted, the FDA is not recommending removal of this device since the available data do not suggest any decreased benefit associated with the device. Moreover, based on currently available information, the FDA believes the additional risks associated with mesh removal outweigh any risk that may be associated with the use of mesh manufactured from alleged counterfeit raw material.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

EXHIBIT 1

- Complete and submit the report Online: www.fda.gov/MedWatch/report (http://www.fda.gov/MedWatch/report)
- Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[04/01/2016 - Urogynecologic Surgical Mesh Implants (/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm) - FDA]

More in Safety Alerts for Human Medical Products (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/default.htm)

2016 Safety Alerts for Human Medical Products (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm479348.htm)

2015 Safety Alerts for Human Medical Products (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm428326.htm)

2014 Safety Alerts for Human Medical Products (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm380008.htm)

2013 Safety Alerts for Human Medical Products (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm333878.htm)

2012 Safety Alerts for Human Medical Products (/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm285497.htm)

From:	Smith, Charles
Sent:	04/12/2012 02:28:06 PM
To:	Mullally, Robert; Zhao, Ying
CC:	Kieran, Damian
Subject:	RE: Marlex HGX-030-01 shipments from China to Belgium and USA
Attachments:	Marlex HGX-030-01 Equivalency Testing Rev AB[1].doc

Robert

As just discussed, here is the report we have loaded in PDM that we have shared with the shipper in China as well due to lack of the certification.

Thks

Charlie

-----Original Message-----
From: Mullally, Robert
Sent: Thursday, April 12, 2012 2:08 PM
To: Smith, Charles; Zhao, Ying
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Charlie or Mike,

Please go back to the vendor in China and request the actual manufacturing address. What kind of a statement is the following?

"Vendor we bought form in China doesn't have the certification to prove the traceability."

How did all of this resin end up in China if it was made in Texas?

Thanks,
Rob

-----Original Message-----
From: Smith, Charles
Sent: Thursday, April 12, 2012 10:59 AM
To: Mullally, Robert; Zhao, Ying; Kieran, Damian
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Robert

Yes

Yes, bag has correct packaging and we tested. Vendor we bought form in China doesn't have the certification to prove the traceability.

The address in Texas for the plant made at is:

La Porte, Texas USA

Attached is picture showing example of the bags we have bought, all same lot# with address.

thks

Charlie

-----Original Message-----
From: Mullally, Robert
Sent: Thursday, April 12, 2012 10:50 AM
To: Smith, Charles; Zhao, Ying; Kieran, Damian
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Hi Charlie,

Is this the same material, Polyproylene HGX-030-1 (Marlex Resin)?

Was it manufactured by Phillips in Texas? Please give me the complete manufacturing address, wherever it was made, China, Texas, Brazil, etc.

Thanks,
Rob Mullally
Boston Scientific Corporation
Import Export Compliance Coordinator
U.S. Licensed Customs Broker
Phone: 617-689-7391

-----Original Message-----
From: Smith, Charles
Sent: Thursday, April 12, 2012 9:53 AM
To: Zhao, Ying; Kieran, Damian; Mullally, Robert
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Mike

We worked with Robert on these last shipments. I would suggest once the paperwork is prepared we review with Robert to insure we are all set

Robert

We are having final material (30,000 lbs.) in China forwarded back in three shipments (10,000 Lbs.) to two locations:

1. To Belgium extrusion house we work with

2. &3. To USA, storage facility Gould in Indiana.

I have attached email from back in AUG when we had about 5,000 lbs. shipped here to Marlboro.

Thks

Charlie

-----Original Message-----
From: Smith, Charles
Sent: Thursday, April 12, 2012 7:56 AM
To: Zhao, Ying; Vialle, George

Cc: Kieran, Damian
Subject: RE: Marlex HGX-030-01 shipments

Mike

Last time we had our custom person involved. I assume we should involve them up front and we should be all set. I think they work in Quincy or Natick? George

Do you have info?

First shipment goes to Belgium, not US? I assume the BSC customs contact can address this as well.

thks

Charlie

-----Original Message-----
From: Zhao, Ying
Sent: Thursday, April 12, 2012 3:47 AM
To: Smith, Charles; Vialle, George
Subject: RE: Marlex HGX-030-01 shipments

hi, Charlie and George:

OK, 3 shipments, 5 tons each. 1st to Belgium, then 2nd and 3rd to U.S..
I have talked to the shipper more today, I asked them to handle everything if possible, including packaging, all of paperwork needed for custom clearance in China, shipping on land and by sea, a door-to-door solution. They said they can take care of everything, but BSC needs to prepare for custom handling in U.S.. basically when the goods arrive at U.S. custom, we will need to clear the custom. They will handle all of the shipping, but not U.S. custom. Is this what we did previously on those 2 tons? is this new? can we or a 3rd party we use handle this? any question or concern?

Regards,
Michael

From: Smith, Charles
Sent: Wednesday, April 11, 2012 7:45 AM
To: Vialle, George; Zhao, Ying
Subject: RE: lab test report for Marlex HGX-030-01

Mike

Here is report.

Just to confirm per our meeting this AM; plan is for three shipments splitting material into 5tons each as George states below. Look forward to quote.

Thks

Charlie

-----Original Message-----
From: Vialle, George
Sent: Wednesday, April 11, 2012 7:54 AM
To: Zhao, Ying; Smith, Charles
Subject: RE: lab test report for Marlex HGX-030-01

Michael,
Charlie has the test data. Regarding the shipment to Belgium, I thought we were going to ship 5 tons/10,000 lbs. Can we confirm final quantity with Charlie?

Thanks,
George

-----Original Message-----
From: Zhao, Ying
Sent: Tuesday, April 10, 2012 11:35 PM
To: Smith, Charles; Vialle, George
Subject: lab test report for Marlex HGX-030-01

hi, Charlie and George:

I am working on getting the first 1 ton out to Belgium soon. I was told the lab test result you guys did a few months ago will be helpful to deal with custom. Do you have that, can you send me a copy of the report? It is about the material content itself.

I am working with the shipper on quotes and hope to get the 1st ton out by this week. I am checking on options: whether to combine it with other materials in one container or use dedicated container. this one ton is too small for one container, I was told it can take probably 10 of 1 ton box. Anyway, I will let you know the difference on cost and make a decision with you on this.

I will work with them packing it up extrally for sea water and smell concerns.

Thanks,
Michael

From: Mullally, Robert
Sent: 07/20/2012 04:44:27 AM
To: brian.greaney@am.kwe.com; KWECHISF@am.kwe.com
Subject: ISF form for July 25th Departure from China
Attachments: 10+2 (2).xls

Hi Brian,

Attached is the ISF form for our next shipment of resin from China. Please use the following information to clear this entry.

3902.10.0000

Made by:

Dongguan Sunmei Plastic Raw Material Co., Ltd.

No.1, R-Building, New Railway Freight Yard

BaiGuoDong Industrial Zone, Zhangmutou

Dongguan, Guangdong 523000

China

Please contact me if there are any questions.

Thanks,

Rob Mullally

Boston Scientific

Import Export Compliance Coordinator

US Licensed Customs Broker

EXHIBIT 3

617-689-7391

From: Smith, Charles
Sent: Friday, July 20, 2012 7:17 AM
To: Mullally, Robert; Kieran, Damian; Zhao, Ying
Cc: Vialle, George
Subject: FW: ISF form for 2nd 5 tons to U.S.

Mike

Thks

Rob

Attached is ISF form

thks

Charlie

From: Zhao, Ying
Sent: Friday, July 20, 2012 5:43 AM
To: Smith, Charles
Subject: ISF form for 2nd 5 tons to U.S.

Hi, Charlie:

Attached is the doc for our ISF filing of the 2nd 5 tons. Pls forward to the right people who will perform this preparation. We need to get it ready before 7/25.

Thanks,

Michael

NO. OF PACKAGE :
P.O. NO. :
INVOICE NO. :
BOOKING NO.
VESSEL NAME :
VOYAGE NO. :
PORT OF LOADING :
ETD:
CONTAINER NO. :
MASTER B/LADING NO.:
SCAC code:
HOUSE B/LADING NO.: (SAME AS AMS HB NO.)

1	Seller name and address : (賣方公司名稱和地址郵编)
2	Buyer name and address : (買方公司名稱和地址)
3	Importer of Record Number Name and address (进口商的海关登記号/名稱/地址)
4	Consignee number(s) : (收貨人的联邦報稅号碼)
5	Manufacturer ID Name and address (工厂的代碼/公司名稱和地址)
6	'Ship to' name and address : (貨物送達的公司名稱和地址)
7	Country of origin of the goods : (所有貨品的原产地)
8	U.S.A. Harmonized Tariff : (海关关稅編号)
9	Container stuffing location : (貨櫃的裝櫃公司名稱和地址)
10	Consolidator name and address : (拼箱的公司名稱和地址)

EXHIBIT
4

HTS #
3902100090

200 BAGS
ACN0314031
CLEMENTINE MAERSK
US627E
YANTIAN
7/25/2012
SEGU1271710
ANC0314031
ELII
ITL12070145

SHENZHEN YFL INTERNATIONAL LOGISTICS LIMITED
Room 511-512,Building B,Yingdali,Futian,Free Trade Zone,Shenzhen ； Zipcode:518038
BOSTON SCIENTIFIC
500 Commander Shea . Blvd， Quincy, MA 02171, U.S.A.
Attn: Robert Mullally; Tel: 617-689-7391; mail: Robert.Mullally@bsci.com
EIN number: 042695240
Emai Plastic Raw Material(Dongguan)Co., Ltd   ***22 Xianwei Road, Cheung Muk Tau Plastic Market, Dongguan,Guangdong 523000***
Stephen Gould Corp
8351 Northwest Blvd, Indianapolis, IN 46278 ， U.S.A
CHINA
3902100090
Emai Plastic Raw Material(Dongguan)Co., Ltd
22 Xianwei Road, Cheung Muk Tau Plastic Market, Dongguan,Guangdong 523000
Emai Plastic Raw Material(Dongguan)Co., Ltd
22 Xianwei Road, Cheung Muk Tau Plastic Market, Dongguan,Guangdong 523000

From: Puttagunta, Prasad
Sent: 08/31/2011 05:15:38 AM
To: McCaslin, Todd
CC: Charest, Ann
Subject: RE: URGENT: Marlex HGX-030-01

Todd,

We tried two routes to get this information, I called my contacts on the sales side at Sumika and we had our Product manager call the contact on the CofA. Debra Bowen is no longer in that role but we have more recent C of As for material we buy and called the current contact listed on the paperwork, as well as their quality leader. Unfortunately, we received the same answer. The lot number on the bag is not a lot number in their system. My guess is that the material was repackaged in China from a bulk container and given a new lot number that may mean something to the Chinese distributor.

As I mentioned in a separate e-mail, I have been unable to discover who the Chinese distributors are, and Phillips Sumika will not take responsibility for the material sold their.

Prasad

N. Prasad Puttagunta

Phone: 517-223-5136

Cell : [redacted]

npputtagunta@akplastics.com

From: McCaslin, Todd [mailto:Todd.McCaslin@bsci.com]
Sent: Tuesday, August 30, 2011 11:06 AM
To: Puttagunta, Prasad

EXHIBIT
5

Cc: Charest, Ann
Subject: RE: URGENT: Marlex HGX-030-01

Prasad,

I have a question (and maybe a suggestion) for you.

I have attached the "old" C of A from Philips Sumika. There is a contact listed on the bottom "for questions...call Debra Bowen at 832-813-4916"

I was wondering if someone from AK could contact the phone # listed (who knows if it is still accurate or not) and ask about the lot # that we have identified on our bags the were procured from the alternate source (picture attached).

I'm just hoping that someone in the department that prepares C of A's may help.

If you have already taken this route, I apologize for the redundant thought.

Thanks

Todd

Todd McCaslin

Global Sourcing Director

Boston Scientific Corporation

(508) 650-8337

mccaslit@bsci.com

[redacted] (cell)

From: Puttagunta, Prasad [mailto:npputtagunta@akplastics.com]
Sent: Thursday, August 25, 2011 12:10 PM
To: Charest, Ann
Subject: RE: URGENT: Marlex HGX-030-01

Ann,

I met with my contacts this morning at Phillips Sumika in Houston and I was not able to discover who their brokers are in China or Singapore.

From what I gather, they sell excess material to brokers in the USA that off shore the material through their contacts. I believe this material would have been excess material that PS had at one time, or it was near prime or transitional material that they sold to a broker in the Texas area who sent it overseas. PS does not certify any material they release to the "secondary" market.

The lot number is not the PS data base, so it may be a number that was made up by the person that packaged the material.

PS does not have an office in Singapore but their parent company does and they only sell material from the middle east and Asia through that office. The other materials are from these secondary brokers.

I will send the e-mail on the testing we can do separately.

Prasad

N. Prasad Puttagunta

Phone: 517-223-5136

Cell : [redacted]

npputtagunta@akplastics.com

From: Charest, Ann [mailto:Ann.Charest@bsci.com]
Sent: Wednesday, August 24, 2011 12:53 PM
To: Puttagunta, Prasad
Subject: URGENT: Marlex HGX-030-01
Importance: High

Prasad,

1) Is the lot number invalid for the US and Singapore?

2) Would PS be willing to tell us who their Singapore distributors are? Our contact is reluctant to release this information, which of course means it could be counterfeit.

3) When might I expect your e:mail per our discussion last week, regarding what you've been able to find through PS and test services AK might be able to offer BSC?

Thank-you for your continued assistance.

Best Regards, Ann

Ann Charest

Manager, Global Sourcing, Resin

Boston Scientific Inc.

One Scimed Place, A399

Maple Grove, MN

Office: 763-494-1199

Cell: [redacted]

"Defining tomorrow, today."

From: Puttagunta, Prasad [mailto:npputtagunta@akplastics.com]
Sent: Monday, August 15, 2011 4:18 PM
To: Charest, Ann
Subject: RE: Marlex HGX-030-01

Ann –

I have been told by someone in the quality organization at Phillips Sumika that the lot number below is not valid.

Can you send me a picture of the bag and the lot number. I will check again.

Prasad

N. Prasad Puttagunta

Phone: 517-223-5136

Cell : [redacted]

npputtagunta@akplastics.com

From: Charest, Ann [mailto:Ann.Charest@bsci.com]
Sent: Monday, August 15, 2011 10:38 AM
To: Puttagunta, Prasad
Subject: Marlex HGX-030-01
Importance: High

Prasad,

We believe we have located material in China and the lot number is 6120105. The distributor does not have a Certificate of Compliance on file. We've have pictures of the bags, they are unopened and have the LaPorte, TX address on them. Would it be possible to ask you to use your connections at Phillips Sumika to obtain a copy of the CofC for us?

Thank-you again for your assistance in this task.

Best Regards, Ann

Ann Charest

Manager, Global Sourcing, Resin

Boston Scientific Inc.

One Scimed Place, A399

Maple Grove, MN

Office: 763-494-1199

Cell: [redacted]

"Defining tomorrow, today."

From: Smith, Charles
Sent: 06/07/2012 01:49:07 PM
To: Delaney, JP
CC: Kummailil, John; Sammarco, Carmine
Subject: Re: Counterfeit material from a supplier you use - ACTION REQUIRED

Not ours

Sent from my iPhone

On Jun 7, 2012, at 1:48 PM, "Delaney, JP" <JP.Delaney@bsci.com> wrote:

John- Who was this material being shipped to and what PO was this against?

Charlie- Is this your Marlex project?

JP

From: Kummailil, John
Sent: Thursday, June 07, 2012 11:33 AM
To: Smith, Charles; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

We did not run any tests. The lot numbers in the pic were Evonik lot numbers for a different grade, per Evonik's VP.

The hypothesis is that they re-bagged god knows what grade, or even recycled material, in bags that have the grade # we were looking for.

From: Smith, Charles
Sent: Thursday, June 07, 2012 11:14 AM

EXHIBIT 6

To: Kummailil, John; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

How did you determine it was counterfeit? What material tests did you run?

From: Kummailil, John
Sent: Thursday, June 07, 2012 11:10 AM
To: Smith, Charles; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

The resin we found was in sealed bags and looked pristine.

From: Smith, Charles
Sent: Thursday, June 07, 2012 10:48 AM
To: Kummailil, John; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

Thks, we will review. Our material was in sealed bags and we tested as we had no certification (trail back to Marlex on lot #).

From: Kummailil, John
Sent: Thursday, June 07, 2012 10:19 AM
To: Smith, Charles; Delaney, JP
Cc: Sammarco, Carmine
Subject: Counterfeit material from a supplier you use - ACTION REQUIRED

Hello Guys,

We were looking for Nylon 12 in China and came across possibly counterfeit material form a distributor (Emai), who you use for Carbothane(?) or Marlex – not sure which.

I have asked Helge Batz to determine whether we do other business with Emai and to warn affected parties, if any. I took the task of warning you myself.

I completely understand that you have a well-defined process to ensure that your material is good. This is just a data point to take into consideration. Please take any action you see fit, including doing nothing at all.

Thanks,

John