IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PLYMOUTH DIRECT, INC. and NATURES PILLOWS, INC., Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION and UNITED STATES OF AMERICA, Defendants.	)	C.A. No. _____

DECLARATION OF THOMAS C. KNOTT

I, Thomas C. Knott, hereby declare as follows:

1. I am a Senior Regulatory Advisor with Benjamin L. England & Associates, LLC, which represents the Plaintiffs as co-counsel in this case. I previously worked for the U.S. Food and Drug Administration for more than 30 years, serving in a wide range of capacities, with special emphasis on regulatory compliance issues related to medical devices.

2. I am familiar with the details of the regulatory issues involved with the current import-related dispute between Plaintiffs and FDA. I also am familiar with the history of that dispute as it has evolved over the past two months. I have been

contemporaneously updated on that dispute among other things through the business records of Plaintiffs. The history set forth below is based on my knowledge of the facts gained through contemporaneous communications and the Plaintiffs' business records.

Releases With Comment

3. On September 27, 2014, an import shipment of Be Active Braces arrived at the Dallas-Fort Worth airport. Two weeks later, FDA detained that shipment, alleging that the Braces required (and lacked) section 510(k) premarket clearance. An FDA official in Dallas indicated that the Braces were being detained because of labeling claims concerning the relief of back pain caused by two particular conditions (pregnancy and pirifomis syndrome). On October 8, Counsel for Plaintiffs disputed FDA's suggestion that these labeling claims converted the device into one that required section 510(k) premarket clearance. Counsel also notified FDA that, as an accommodation, Plaintiffs would immediately remove the labeling claims that FDA expressed concerns about. The Dallas FDA official nonetheless indicated that the matter would be referred to FDA headquarters (the Centers for Devices and Radiological Health) for further review.

4. Between September 27, 2014 and October 20, 2014, six more import shipments of Be Active Braces arrived at the Dallas-Fort Worth airport. FDA also detained these shipments based on the same allegation regarding section 510(k) premarket clearance.

5. Following these detentions, FDA released all seven shipments; FDA released three of them "with comment." Release "with comment" is a procedure whereby FDA releases imported merchandise into domestic commerce, even though the

agency believes it appears to violate regulatory requirements, because the regulatory violations at issue are considered to be minor. FDA's Regulatory Procedures Manual, which sets forth FDA's internal procedures governing imports, defines "release with comment" as a means of "handling minor violations." FDA Regulatory Procedures Manual 9-5. Exhibit A. The Regulatory Procedures Manual further states that when FDA applies this procedure, "[t]he violation(s) must be minor, since a shipment with serious infraction(s) should be detained." *Id.*

6. I am attaching as Exhibit B to this Declaration the FDA release "with comment" notices applicable to all three shipments. The specific comments relate to the absence of section 510(k) premarket clearance. Plaintiffs' business records indicate that the three shipments that FDA released "with comment" collectively contained 845 cartons of Braces, and that each carton contained 288 Braces, such that FDA released a total of 243,360 Braces "with comment."

Detentions Without Physical Examination

7. On October 24, 2014, an FDA official in Dallas informed counsel for Plaintiffs that it was likely that FDA headquarters (the Center for Devices and Radiological Health) would determine that future shipments of Be Active Braces should be detained for failure to have section 510(k) premarket clearance. The same official informed counsel that the prior release "with comment" procedure would be discontinued for future shipments that had not yet arrived in the United States. The same official informed counsel that FDA's original April 2014 classification determination was apparently wrong but did not give any rationale explaining why.

8. On October 26, 2014, two more import shipments of Be Active Braces arrived at Dallas-Fort Worth airport. On October 28, 2014, FDA detained both shipments without first conducting any physical examination. FDA issued notices to the customs broker stating that FDA was detaining these shipments without physical examination because the devices were "in the process of being posted" to Import Alert 89-08. Exhibits C and D. Import Alert 89-08 is a public listing of the firms and products subject to Detention Without Physical Examination on the ground that a medical device is required to have, but does not have, section 510(k) premarket clearance. Exhibit E. FDA's notices to the customs broker attached information about how the specifics of the Import Alerts and Detention Without Physical Examination work. Exhibits C and D. Among other things, the information stated that "if the appearance of the violation is not overcome, or the violation is not otherwise fixed, that the product is normally refused entry into US commerce by the FDA." Exhibits C and D.

9. In connection with detaining the two October 26 shipments described in the paragraph above, FDA also issued an email containing the conclusion from FDA headquarters (Center for Devices and Radiological Health) specifically stating that the Be Active Brace "does need a 510(k) clearance order in order to be legally marketed." Exhibit F. The FDA headquarters determination further indicated that the Brace "may have" a new intended use based on acupressure and stated that labeling for the Brace included certain claims regarding pain relief that would need clinical data in order to substantiate. *Id.*

10. According to Plaintiffs' business records, FDA has detained without physical examination every import shipment that has arrived in the United States since the two October 26 shipments described above. As of November 1, FDA has detained a total of seven consecutive shipments collectively comprising 260,412 braces.

Plaintiffs' Efforts to Reach Accommodation With FDA

11. Plaintiffs have undertaken a number of efforts to accommodate FDA's stated concerns about the labeling for the Brace. As indicated in paragraph 3 above, Plaintiffs first attempted to accommodate FDA in early October, immediately upon hearing the agency's concerns. More recently, beginning on October 24, 2014 and continuing through October 31, 2014, Plaintiffs have attempted to accommodate the agency in three different ways. *First*, Plaintiffs submitted proposed new boxes for devices sold through retail; the new boxes remove the verbiage that FDA found questionable. *See* Exhibit G. *Second*, Plaintiffs submitted to FDA instructions for use inserts, which is the only labeling that accompanies devices sold through mail order. These instructions for use do not (and never have) made the claims that FDA has found objectionable, and they are the only labeling associated with mail order devices, which are shipped in unmarked plastic bags or boxes. *See* Exhibit H. *Finally*, Plaintiffs verified to FDA that it has discontinued making claims of concern to FDA in advertising (whether on the internet or otherwise).

12. Plaintiffs also informed FDA that they would be willing to file a 510(k) premarket clearance application even though they do not believe one is required. However, given the length of time that agency review of the application would take,

Plaintiffs have requested FDA not to apply Detention Without Physical Examination to the Braces during the period that the application is completed and filed by Plaintiffs and reviewed by FDA.

13. To the best of my knowledge, as of the time I am signing this Declaration FDA has not responded to any of the requests for accommodation submitted by Plaintiffs.

14. On October 30, 2014, I participated in a conference call that included representatives of Plaintiffs and numerous representatives from FDA, including top officials from the FDA headquarters Division of Import Operations and Center for Devices and Radiological Health and FDA's Dallas Southwest Import District. During that call, FDA representatives suggested that the FDA was not changing its position from April 2014, when FDA headquarters (Center for Devices and Radiological Health) had reviewed a submission by Plaintiffs' customs broker and indicated that the Be Active Brace fell within the classification regulation for limb orthosis (21 C.F.R. § 890.3475). The FDA representatives indicated that the agency's current view that the Be Active Brace exceeded the limit for of the exemption for submitting a 510 (k) (21 C.F.R. § 890.9) – and therefore requires a section 510(k) clearance – was based on a change in the device's labeling since the April 2014 determination. One FDA representative characterized the situation as one in which the classification result had changed because facts had changed since April 2014. The same FDA representative further stated that FDA was not giving a different answer to the same classification question, emphasizing again that the facts had changed. When pressed to confirm that they believed FDA's original April 2014 determination was correct, the FDA officials would not give a

definitive answer, with one official indicating that the prior determination was probably correct but that they did not have all of the pertinent information before them. In response to a question, none of the FDA officials would state that the April 2014 determination was incorrect.

I swear under penalty of perjury that the foregoing is true and correct.

Thomas C. Knott

Dated this 2nd day of November 2014.

EXHIBIT A

Inspections, Compliance, Enforcement, and Criminal Investigations

9-5 - Release Notices

9-5 - Release Notices

9-5 - Release Notices

PURPOSE

To provide the field with procedural guidelines in releasing imported lots for which a Notice of Sampling has been issued.

BACKGROUND

The Federal Food, Drug, and Cosmetic Act, and it's regulations directs that a notice (Notice of Sampling) shall be given to the owner or consignee of imported merchandise sampled or intended to be sampled under the authority of the Act. The regulations also require the issuance of a further notice to advise the owner or consignee of the result of examination of the sample, for which a Notice of Sampling has been issued [21 CFR and 1.90]. The Release Notice advises the owner or consignee that the merchandise need not be further held insofar as the FDA is concerned.

GENERAL COMMENTS

Release Notice Form, or computer generated notice from OASIS, is issued by FDA under the signature of the field compliance officer or designated individual authorized by the district to sign the notice, whenever FDA has no further interest in a lot for which a Notice of Sampling (or computer generated notice from OASIS) has been issued.

The Release Notice is routinely issued to the importer of record with a copy to CBP and the FDA district fiscal office and file. In accordance with local practices, copies may also be sent to the customhouse broker and the consignee when either is not named as the importer of record. In any case, all persons who are issued a Notice of Sampling should also be sent the Release Notice.

To meet the various circumstances surrounding a release, the following variations of the Release Notice are currently used:

1. "Straight" Release
2. Release without Examination
3. Release with Comment
4. Release after Detention

"STRAIGHT" RELEASE

This release form (or the computer generated notice from OASIS) is issued whenever it appears, from sample examination or otherwise, that merchandise, for which a Notice of Sampling has been issued, is in compliance with the law.

Examples of OASIS Release Notices will be provided at a later date.

RELEASE WITHOUT EXAMINATION

Whenever a sample cannot be examined, for which a Notice of FDA Action/Sampling has been issued; a Notice of FDA Action/Release Notice form as identified in Exhibit 9-6, "Straight Release" or the computer generated notice from OASIS is issued amended as follows:

"RELEASED WITHOUT EXAMINATION MAY PROCEED WITHOUT FDA EXAMINATION ON THE RESPONSIBILITY OF THE IMPORTER"

This statement is typed in caps following the blocked information on the notice. An example of the OASIS form will be provided at a later date.

RELEASE WITH COMMENT

Background

It had been the practice when an importation was encountered which did not fully comply with the requirements of the Act, but the violation was not of sufficient importance to warrant detention of the initial importation, to release the shipment with a "Release with Warning" that future similar violative importations might be denied entry. Although these "Releases with Warning" did not necessarily mean that the correction had to be made before the next importation, that frequently was the intent. The brevity of the warning often gave such notices an unintentional air of curtness.

Therefore, the "RELEASE WITH WARNING" and "RELEASE WITHOUT PREJUDICE" has been replaced with a "RELEASE WITH COMMENT" as a more flexible means of handling minor violations.

Approach

When an importation is encountered which does not fully comply with the requirements of the Acts which we enforce, but the violation(s) is (are) not sufficient to warrant detention on a first encountered basis, it may be "Released With Comment." The violation(s) must be minor, since a shipment with serious infraction (s) should be detained. For example, if an FPLA violation which is not considered subject to NLEA concerns is encountered in a product this shipment may be "Released With Comment." However, if the importer or country of origin has already received "notice" of our FPLA labeling requirements, the shipment may be *detained*.

A standard Release Notice is used with a notation "Release With Comment" prominently shown immediately following the blocked information on the notice. The comments may be placed directly on the Release Notice if sufficient space is available or, on an attached letter. If a letter is used, it should be stapled to the Release Notice and referred to in the body of the Form, i.e. "Release With Comment, See Attached Letter of (date)." An example of a "Release With Comment" is shown as Exhibit 9-6[1] (examples of OASIS Release With Comment notices will be provided at a later date.)

The violations on which the comments are based should be clearly covered by the Acts or regulations which we enforce. The comments should be stated in nonlegal language with reference to the specific sections of the Acts or regulations involved.

Generally, the Release With Comment should not be used if the problem is one commonly existing in domestic commerce and against which no FDA objection has been made. Center non-concurrence of detention recommendations that indicate non-agency support of similar domestic violation and past policy guidance with both domestic and imported products will serve as guide.

If the violation is clearly absent from similar domestic products, prompt correction should be requested by including the statement "Future shipments may be detained unless (nature of violation, i.e. misbranding) is corrected." By omitting this statement, the comments would serve as an information guide to provide a better understanding of the requirements of the law.

Before issuing a Release With Comment that includes a statement that future shipments may be detained we must be in a position to take action. However, other shipments that may be enroute at the time the comment issues or within a time frame established for correction to be completed may be allowed to proceed if otherwise in compliance.

A statement on the Release Notice should be included directing the importer to advise the foreign manufacturer/shipper of our comments when applicable. A copy of this letter should be requested for the FDA file.

RELEASE AFTER DETENTION

Release after detention is issued in the following situations:

1. After the issuance of the Notice of Detention and Hearing (or computer generated notice from OASIS) the importer of record or other designated agent may present testimony which shows that the merchandise is in compliance.
2. In response to the Notice of Detention and Hearing, the importer of record reconditions the merchandise to FDA's satisfaction pursuant to the terms of the Application for Authorization to Relabel or to Perform Other Action (Form FD-766), or else causes it to be brought outside the jurisdiction of the Act. The latter situation can occur, for example, when an importer diverts insect-adulterated, food-grade starch to industrial uses (paper manufacturing, etc.).

Under these situations, a Release Notice is issued with a notation "ORIGINALLY DETAINED AND NOW RELEASED" prominently shown following the blocked information or as appropriately set from the computer

generated notice. If the merchandise has been reconditioned, the fact of this reconditioning should also be shown on the notice including the loss (if any) during reconditioning, reject material, the disposition of reject material, and amount of acceptable material. If supervisory charges are also involved, the notice should also bear the statement "Subject to bond liability for charges in connection with reconditioning."

Page Last Updated: 04/30/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. /downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM179503.pdf

EXHIBIT B

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number: AZX-1006975-8

Notice Number: 2
October 8, 2014

Importer:
Base 4 Group Inc
2611 WESTGROVE DR
STE 109
CARROLLTON, TX 75006-2349

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Port of Entry: 5501, Dallas/Ft Worth, TX
Carrier: AMERICAN AIRLINES;
Date Received: September 29, 2014
Arrival Date: September 27, 2014

Filer of Record: KRAUS INTERNATIONAL SHIPPING CO, Baltimore, MD 21230
Consignee: Base 4 Group Inc, CARROLLTON, TX 75006-3322

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	KNEE BRACE	149 CT	Released with comment 10-08-2014

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry AZX-1006975-8. Any status changes are reflected in the Line summary and line detail sections.

LINE RELEASED WITH COMMENT

The following products are released with comment since they appear to be in violation as indicated below. If problems described are not corrected, future shipments may be detained.

Line ACS/FDA	Product Description
001/001	KNEE BRACE

FD&CA Section 801(a)(3); 502(o) Misbranding
It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device. Pending label

review by CDRH.

Stephanie Pogue, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

(214) 253-5287
(214) 253-5316 (FAX)
STEPHANIE.POGUE@FDA.HHS.GOV

This notice does not constitute assurance that the product released complies with all other provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: ARM

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number: AZX-1007042-6

Notice Number: 2
October 9, 2014

Importer:
Base 4 Group Inc
2611 WESTGROVE DR
STE 109
CARROLLTON, TX 75006-2349

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Port of Entry: 5501, Dallas/Ft Worth, TX
Carrier: AMERICAN AIRLINES;
Date Received: October 6, 2014
Arrival Date: October 4, 2014

Filer of Record: KRAUS INTERNATIONAL SHIPPING CO, Baltimore, MD 21230
Consignee: Base 4 Group Inc, CARROLLTON, TX 75006-3322

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	KNEE BRACE	261 CT	Released with comment 10-09-2014

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry AZX-1007042-6. Any status changes are reflected in the Line summary and line detail sections.

LINE RELEASED WITH COMMENT

The following products are released with comment since they appear to be in violation as indicated below. If problems described are not corrected, future shipments may be detained.

Line ACS/FDA	Product Description
001/001	KNEE BRACE

FD&CA Section 801(a)(3); 502(o) Misbranding
It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device. Pending

review by CDRH.

Stephanie Pogue, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

(214) 253-5287
(214) 253-5316 (FAX)
STEPHANIE.POGUE@FDA.HHS.GOV

This notice does not constitute assurance that the product released complies with all other provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: SP

United States Food and Drug Administration

Southwest Import District

Notice of FDA Action

Entry Number: AZX-1007110-1

Notice Number: 1
October 16, 2014

Importer:
Base 4 Group Inc
2611 WESTGROVE DR
STE 109
CARROLLTON, TX 75006-2349

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Port of Entry: 5501, Dallas/Ft Worth, TX
Carrier: AMERICAN AIRLINES;
Date Received: October 13, 2014
Arrival Date: October 12, 2014

Filer of Record: KRAUS INTERNATIONAL SHIPPING CO, Baltimore, MD 21230
Consignee: Base 4 Group Inc, CARROLLTON, TX 75006-3322

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	KNEE BRACE	435 CT	Released with comment 10-16-2014

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry AZX-1007110-1. Any status changes are reflected in the Line summary and line detail sections.

LINE RELEASED WITH COMMENT

The following products are released with comment since they appear to be in violation as indicated below. If problems described are not corrected, future shipments may be detained.

Line ACS/FDA	Product Description
001/001	KNEE BRACE

FD&CA Section 801(a)(3); 502(o) Misbranding
It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510(k) and the device was not found to be substantially equivalent to a predicate device. Pending label

review by CDRH.

Stephanie Pogue, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
4040 N. Central Expressway Suite 300
Dallas, TX 75204

(214) 253-5287
(214) 253-5316 (FAX)
STEPHANIE.POGUE@FDA.HHS.GOV

This notice does not constitute assurance that the product released complies with all other provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: ARM

EXHIBIT C

From: Pogue, Stephanie [mailto:Stephanie.Pogue@fda.hhs.gov]
Sent: Tuesday, October 28, 2014 12:23 PM
To: Shawn Cardwell
Subject: FDA Detention of 9YR-2007235-6

Dear Filer:

This email is intended to assist the importer; please forward a copy of this email to the importer for his/her reference. This email might

also assist the consignee and/or the foreign source firm; consider forwarding to those firms. This email is in addition to the legal notice

called 'Notice of FDA Action' which is provided to filer, importer and consignee.

Entry Numbers: 9YR-2007235-6

Product: BeActive Leg Brace

The time period to provide testimony expires on: 11/18/2014

If an importer does not wish to pursue a release of this line and instead wants an early refusal to expedite destruction or exportation,

please let me know.

The products referenced in the subject line above have been detained by the FDA. This means that the FDA has made an initial

determination that the products violate one or more FDA requirements. This email is designed to help you to understand why your

products are detained and to learn about the relevant FDA requirements and the detention process.

Reason for Detention:

This source/product combination is in the process of being posted to Import Alert:

Import Alert: 89-08 :

Detention Without Physical Examination of Class III Devices Without Approved PMA's Or IDE's and Other Devices Not Equivalent or No

510k

http://www.accessdata.fda.gov/cms_ia/ialist.html

This is based on the information filed with the entry. If you believe this detention is in error, please let me know.

The purpose of an Import Alert is to identify and disseminate import information (such as problems and violative trends) to FDA personnel,

thus providing more uniform and effective import coverage. Import Alerts identify problem commodities and/or shippers and provide

guidance to FDA personnel regarding the importation of the products and/or firms covered in the alert. They may also concern products or

manufacturers that have met the criteria for detention without physical examination.

***Note: If the importer chooses to pursue release of the detained entries listed in this email through private lab analysis, please be

aware that the district would expect to see, at a minimum, a separate private lab package for each line in a given entry. Additionally, if there

are multiple lot codes contained within a single line, then a separate private lab package would be would be expected for each lot code. If

you have any questions, you may wish to contact me in advance of private sample collection and analysis.

Resources to Assist You:

Please review the attached Frequently Asked Questions document that covers detention, testimony, private lab analysis, reconditioning,

refusal, redelivery and more. Please also review the attached document that discusses the DWPE exemption process. The below links

are to FDA webpages which will help you to understand the relevant FDA requirements.

Resources for Import Alert 89-08:

Medical Device Regulation Overview

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm

Div. of Small Mfr Int'l & Consumer Assistance

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ucm142656.htm

Guidance on IDE Polices and Procedures - Devices Main Page

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm

FAQs about IDE - Medical Devices Main Page

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/uc

m051480.htm

Device Advice: Investigational Device Exemption (IDE

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/def

ault.htm

Products that are offered for import should be compliant with our regulations at the time of import. Below is the FDA's main webpage for

industry, the Good Importer Practices, and the search page for 21 CFR:

http://www.fda.gov/ForIndustry/default.htm

http://www.fda.gov/RegulatoryInformation/Guidances/ucm125805

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

Sincerely,

Stephanie Pogue

Compliance Officer, SWID

Southwest Import District

Food and Drug Administration

Office: 214-253-5287

FAX: 214-253-5216

Stephanie.Pogue@fda.hhs.gov

Import Detention Communication: Frequently Asked Questions*

1) My product is detained, what does that mean? What does detention without physical examination mean? What does detained under an Import Alert mean?

When FDA detains a product it means that FDA has made an initial determination that the product appears to violate FDA's requirements and is subject to refusal of admission. If FDA detains your product you may request FDA's permission to correct the violation (see Question #5), or you may offer evidence to overcome the appearance of a violation (see Question #3). If the product is not corrected or the evidence you have offered is not adequate to show that the product complies with FDA's standards, FDA would then refuse admission (see Question #9) of your product into the United States.

When a product is detained the status of the entry line on the Automated Broker Interface (for entries filed electronically, which is almost all entries) shows 'detained'. . Also, the Notice of FDA Action communicating the detention and the legal charge are provided to the broker, consignee and importer of record.

Detention Without Physical Examination, abbreviated DWPE, was first used by FDA in 1974. DWPE is appropriate when there is a history of the importation of violative products, or products appear violative, or when other information indicates that future entries may appear violative. DWPE has the effect of reminding the importing community that FDA is a regulatory agency, not a quality control laboratory. DWPE properly places the responsibility for ensuring compliance with the law on the importer.

Import Alerts identify problem commodities and/or shippers and/or importers and provide guidance for import coverage. Import Alerts will identify those products or shippers that have met the criteria for DWPE.

For example, the normal application of the DWPE process is that if an entry of lettuce from a particular source is found to have an illegal pesticide residue, then the next entry of lettuce from that same source would be subject to DWPE. The lettuce from that source would also be added to the appropriate Import Alert (in this case, Import Alert 99-05). See Question #11 to learn about how products come off of an Import Alert or become exempt from DWPE.

In summary, the significance of detention is that if the appearance of the violation is not overcome, or the violation is not otherwise fixed, that the product is normally refused entry into US commerce by the FDA.

When FDA detains a product it means that FDA has made an initial determination that the product appears to violate FDA's requirements and is subject to refusal of admission. If FDA detains your product you may request FDA's permission to correct the violation (see Question #5), or you may offer evidence to overcome the appearance of a violation (see Question #3). If the product is not corrected or the

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In summary, the significance of detention is that if the appearance of the violation is not overcome, or the violation is not otherwise fixed, that the product is normally refused entry into US commerce by the FDA.

2) Am I obligated under the entry bond to hold this product intact or am I free to distribute it? Can I move my product? Must I get permission first to move my product? Can I repackage it or otherwise process it before it is released?

In general, when an FDA regulated product is offered for import, CBP conditionally releases the product which means that CBP has conditionally released it under a bond agreement with the importer of record. This allows the importer to take possession of the products. However, a condition of the bond agreement is that products are held intact unless and until FDA releases the product.

Under the bond agreement, you do not have to store the goods in any particular location. However, the bond agreement obligates you to return the goods to the port of entry if so ordered by CBP. For that reason it is in your best interest to keep the goods in the port area until you know FDA and CBP have completed any and all physical examinations or samplings of the product. If you choose to move the goods, you may have to bring them back.

If the products are repackaged or otherwise processed, then CBP and FDA may not be able to recognize the goods. It is in the importer's best interest, as well as a condition of the bond agreement, to hold the goods intact. Holding intact means keep the products as they were when they were imported. If you have an unusual situation (for example, fresh product that must be processed soon after importation to avoid loss of the product), contact the FDA District office. One possibility is that you request FDA authorization to process before release via a form 766. If it is something more simple such as the cardboard boxes the goods were shipped in become wet or damaged, it may be possible for FDA to witness the repackaging or to instruct you how to repackage in a way that maintains the ability of FDA and CBP to recognize the goods. You should not repackage or process goods held by FDA or CBP without authorization to do so.
See Question #10 for more information about the financial penalties associated with distributing imported products without an FDA release.

In general, when an FDA regulated product is offered for import, CBP conditionally releases the product which means that CBP has conditionally released it under a bond agreement with the importer of record. This allows the importer to take possession of the products. However, a condition of the bond agreement is that products are held intact unless and until FDA releases the product.

Under the bond agreement, you do not have to store the goods in any particular location. However, the bond agreement obligates you to return the goods to the port of entry if so ordered by CBP. For that reason it is in your best interest to keep the goods in the port area until you know FDA and CBP have completed any and all physical examinations or samplings of the product. If you choose to move the goods, you may have to bring them back.

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4) What is a testimony due date or a "Respond By" date and what does it mean?
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When a product is detained the usual testimony time period of 14 working days is provided (10 days plus two on either side to allow time for mailing for a total of 14 working days). This due date is found on your Notice of FDA Action next to the words "Respond By". The significance of this date is that your product becomes subject to immediate refusal of admission (see Question #9) after this date unless: (1) You have submitted testimony and the monitoring Compliance Officer is still evaluating it; (2) You have submitted a request for relabeling/reconditioning and the monitoring Compliance Officer is still evaluating it (see Question #5); Or, (3) An extension has been granted or you have requested one and the monitoring Compliance Officer is still considering it. You have the right to request an extension, but you do not have a right to an extension itself. If you are granted an extension you will be assigned a new testimony due date.

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5))What is a reconditioning or relabeling proposal? What is a form 766?

Some violations may be corrected through conditioning, for example: (1) An entry of raw shrimp is found by FDA to be contaminated by salmonella and the importer proposes to properly cook the shrimp in order to kill the salmonella and bring the product into compliance; (2) An entry of dried fruit was found by FDA to contain sulfites but sulfites are not declared on the product's label and the importer proposes to relabel the product so that the sulfites are properly declared.

If you wish to propose reconditioning of a product, you need to submit to you FDA contact (usually the Compliance Officer) a form 766, found here: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072766.pdf

You need to fill out the form with the details of the process you are proposing. If you are proposing relabeling, then a copy of the proposed corrected labeling must be provided with the form 766. This means a COMPLETE label as it would appear after correction. It is not acceptable to provide merely labels that you will 'stick over' parts of the existing label because that makes it very difficult to evaluate placement or whether any existing labeling information would be covered.

Please note that no reconditioning or relabeling should occur until the form 766 has been approved by FDA.

Our Regulatory Procedures Manual contains the policy that requests for a third attempt at reconditioning generally should not be granted. See this link: http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179472.htm. The practical effect of this policy is that if you submit a 766 and it is denied, you generally only get one more chance.

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6) ***What is a private lab analysis? Do I have to have a private lab analyze my product? What standards should a private lab packet meet? Can I ask FDA to analyze it instead?***

As part of testimony introduction you may choose to hire a private laboratory to test your product. You are not obligated to do this. There are some situations where it will be very difficult to overcome the appearance of the violation with a private laboratory test. Examples of situations where private laboratory analysis is commonly done include: (1) Lettuce listed on Import Alert 99-05 (violative pesticide residue) is offered for import and the importer has it tested by a private lab to show that the residue is not present; (2) Cherry soda listed on Import Alert 45-02 (violative color additives) is offered for import and the importer has it tested by a private lab to show that the illegal color additive is not present

Manufacturer's certificates and/or expressions of confidence are not adequate substitutes for a private laboratory analysis. Here is a link to private laboratory analysis guidance to assist you: http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM092191.pdf

A complete lab packet includes a sample collection report and other supporting documents reflecting a representative sample from the actual goods offered for import. If you choose to work with a private lab that has little to no experience with offering analytical testimony to FDA, it is in your best interest to ensure that the private lab uses this link to read and understand the breadth and depth of documentation needed. The FDA will not analyze your product for you to help you avoid the time, trouble and expense of a private laboratory analysis.

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7) How do I find a private lab to perform the analysis?

Listed below are two organizations that maintain lists of private laboratories. The lists are not intended to be used as lists of FDA 'approved' or 'certified' laboratories. It is up to each interested party to call and discuss their particular needs with the laboratory they employ.

Council of Independent Laboratories, Inc. 1629 K Street
Washington, D. C. 20006
Phone: (202) 887-5872; Fax: (202) 887-0021
www.acil.org

Directory of Testing Laboratories 1916 Pace Street
Philadelphia, PA 19103-1187
Phone: (215) 977-9679; Fax: (215) 977-9679
www.astm.org

8) If a Private lab has technical questions, who in FDA can they contact?

Questions regarding analytical method, sample size, compositing, etc. may be addressed to the Division of Field Science (DFS) personnel listed in the Import Alert as a contact. If no specific DFS contact is listed in the Import Alert, here is the main DFS contact number: 301-796-5992

9) What does an FDA Refusal mean?

An FDA Refusal means the goods have been rejected by FDA and are not allowed to be entered into US commerce. Refusal is a final decision made by FDA. Refusal triggers a demand for redelivery by CBP (see Question #10).

The FDA's Regulatory Procedures Manual contains the FDA policy on rescission (reversal) of refusals. The policy is that unless the refusal was erroneously issued by FDA, we do not normally consider rescinding (reversing) the refusal in order to provide more time for testimony or submission of a reconditioning proposal (form 766).

Here is a link to the webpage that contains that policy:
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179470.htm

10) What is Redelivery? What is a form 4647?

CBP form 4647 communicates a demand for redelivery per the bond agreement you have entered into with CBP. Redelivery means that you either destroy the goods or export the goods, per the CBP described process.

The bond that covers your product is a contract between you and CBP which states, among other things, that you are liable for monetary damages under the bond if you do not redeliver the product to CBP when so ordered. CBP can order redelivery under your bond if you fail to make an FDA regulated product available for FDA to examine or sample, or if FDA refuses admission of your product.

CBP can seek damages equal to three (3) times the value of the merchandise that is not redelivered. Also, you may have additional legal liability for distributing violative goods into US commerce.

The form 4647 normally references a due date that is 90 days after the FDA refusal. If you need more than 90 days to export or destroy a refused shipment, please contact CBP. The redelivery process is a CBP process and the FDA cannot grant such extensions.

11) How does a product get off of an Import Alert? How can a product become exempt from an Import Alert? Can I continue to offer goods for import while my exemption request is being considered?

To lean about how to qualify for exemption from an Import Alert, first you must review the specific Import Alert your entry is subject to and see if there are any specific instructions or requirements contained within regarding qualification for exemption. The Import Alerts are found here:
http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm
Removal or exemption from Import Alerts (Detention Without Physical Examination) is handled by the FDA's Division of Import Operations and Policy (DIOP), 12420 Parklawn Drive, Rockville, MD 20857, importalerts2@fda.hhs.gov (this email address is specific to the topic of exemptions).

The exemption process is covered in the Regulatory Procedures Manual, Chapter 9, Subchapter titled Detention Without Physical Examination), heading of Removal from Detention Without Physical Examination:
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179271.htm
Requests for removal provided to the FDA's DIOP should include a written explanation of the investigational steps taken to identify how the problem came about and a description of corrective actions taken. Additionally, you should submit the entry documents for all of the entries cited as evidence that the problem has been corrected. You do not normally need to submit copies of any private laboratory testing which was performed.
For fresh produce subject to DWPE for pesticide residues only, contact your monitoring FDA Compliance Officer to see if he or she can evaluate your exemption packet instead of DIOP.
After you have submitted an exemption packet and are waiting for the outcome of the review, you may choose to stop importing new entries of the product or while you wait; or offer new entries for import and have them tested by the private laboratory also or otherwise overcome the appearance of the violation.
It is important to include in your request for exemption a statement that you request exemption for any entries offered for import after you submit the packet. You should also state that the entries offered for import after you submitted the packet are compliant with all applicable FDA requirements.

12) Where can I learn more about the importation process and my rights and responsibilities as an importer?

Here is a link to the main Imports page of the FDA website:
http://www.fda.gov/ForIndustry/ImportProgram/default.htm
Here is a link to the entire Regulatory Procedures Manual:
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm. You may wish to review Chapter 9, Importer Operations for more details to understand detentions, notices, refusals, the rights of an importer to submit testimony, etc.

* The information in this document was believed to be correct at the time it was developed. However, laws and regulations are subject to change. Always check for the most current information before proceeding on the basis of the information contained herein. This document does not convey any waive of responsibility to the firm, nor impart any immunity to the firm for violations that may occur, even if you implement our recommendations as per 21 CFR 10.85(k).

EXHIBIT D

From: Pogue, Stephanie [mailto:Stephanie.Pogue@fda.hhs.gov]
Sent: Tuesday, October 28, 2014 2:08 PM
To: lisaryan@krausintl.com
Subject: FDA Detention of AZX-1007236-4

Dear Filer:

This email is intended to assist the importer; please forward a copy of this email to the importer for his/her reference. This email might

also assist the consignee and/or the foreign source firm; consider forwarding to those firms. This email is in addition to the legal notice

called 'Notice of FDA Action' which is provided to filer, importer and consignee.

Entry Numbers: AZX-1007236-4

Product: KNEE BRACE

The time period to provide testimony expires on: 11/18/2014

If an importer does not wish to pursue a release of this line and instead wants an early refusal to expedite destruction or exportation,

please let me know.

The products referenced in the subject line above have been detained by the FDA. This means that the FDA has made an initial

determination that the products violate one or more FDA requirements. This email is designed to help you to understand why your

products are detained and to learn about the relevant FDA requirements and the detention process.

Reason for Detention: Lacks a 510(k).

This source/product combination is in the process of being posted to Import Alert:

Import Alert: 89-08 : Detention Without Physical Examination of Class III Devices Without Approved PMA's Or IDE's and Other Devices Not Equivalent or No 510k

http://www.accessdata.fda.gov/cms_ia/ialist.html

This is based on the information filed with the entry. If you believe this detention is in error, please let me know.

The purpose of an Import Alert is to identify and disseminate import information (such as problems and violative trends) to FDA personnel,

thus providing more uniform and effective import coverage. Import Alerts identify problem commodities and/or shippers and provide

guidance to FDA personnel regarding the importation of the products and/or firms covered in the alert. They may also concern products or

manufacturers that have met the criteria for detention without physical examination.

Resources to Assist You:

Please review the attached Frequently Asked Questions document that covers detention, testimony, private lab analysis, reconditioning,

refusal, redelivery and more. Please also review the attached document that discusses the DWPE exemption process. The below links

are to FDA webpages which will help you to understand the relevant FDA requirements.

Resources for Import Alert 89-08:

Medical Device Regulation Overview

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm

Div. of Small Mfr Int'l & Consumer Assistance

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ucm142656.htm

Guidance on IDE Policies and Procedures - Devices Main Page

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080202.htm

FAQs about IDE - Medical Devices Main Page

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/uc

m051480.htm

Device Advice: Investigational Device Exemption (IDE

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/def

ault.htm

Products that are offered for import should be compliant with our regulations at the time of import. Below is the FDA's main webpage for

industry, the Good Importer Practices, and the search page for 21 CFR:

http://www.fda.gov/ForIndustry/default.htm

http://www.fda.gov/RegulatoryInformation/Guidances/ucm125805

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm

Sincerely,

Stephanie Pogue

Compliance Officer, SWID

Southwest Import District

Food and Drug Administration

Office: 214-253-5287

FAX: 214-253-5216

Stephanie.Pogue@fda.hhs.gov

Important Email Information

The information in this email is confidential and may be legally privileged. It is intended solely for the addressee. Access to this email by anyone else is unauthorized. If you are not the intended recipient, any disclosure, copying, distribution or any action taken or omitted to be taken in reliance on it, is prohibited and may be unlawful. If you are not the intended addressee please contact the sender and dispose of this e-mail.

Import Detention Communication: Frequently Asked Questions*

1) My product is detained, what does that mean? What does detention without physical examination mean? What does detained under an Import Alert mean?

When FDA detains a product it means that FDA has made an initial determination that the product appears to violate FDA's requirements and is subject to refusal of admission. If FDA detains your product you may request FDA's permission to correct the violation (see Question #5), or you may offer evidence to overcome the appearance of a violation (see Question #3). If the product is not corrected or the evidence you have offered is not adequate to show that the product complies with FDA's standards, FDA would then refuse admission (see Question #9) of your product into the United States.

When a product is detained the status of the entry line on the Automated Broker Interface (for entries filed electronically, which is almost all entries) shows 'detained'. . Also, the Notice of FDA Action communicating the detention and the legal charge are provided to the broker, consignee and importer of record.

Detention Without Physical Examination, abbreviated DWPE, was first used by FDA in 1974. DWPE is appropriate when there is a history of the importation of violative products, or products appear violative, or when other information indicates that future entries may appear violative. DWPE has the effect of reminding the importing community that FDA is a regulatory agency, not a quality control laboratory. DWPE properly places the responsibility for ensuring compliance with the law on the importer.

Import Alerts identify problem commodities and/or shippers and/or importers and provide guidance for import coverage. Import Alerts will identify those products or shippers that have met the criteria for DWPE.

For example, the normal application of the DWPE process is that if an entry of lettuce from a particular source is found to have an illegal pesticide residue, then the next entry of lettuce from that same source would be subject to DWPE. The lettuce from that source would also be added to the appropriate Import Alert (in this case, Import Alert 99-05). See Question #11 to learn about how products come off of an Import Alert or become exempt from DWPE.

In summary, the significance of detention is that if the appearance of the violation is not overcome, or the violation is not otherwise fixed, that the product is normally refused entry into US commerce by the FDA.

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2) Am I obligated under the entry bond to hold this product intact or am I free to distribute it? Can I move my product? Must I get permission first to move my product? Can I repackage it or otherwise process it before it is released?

In general, when an FDA regulated product is offered for import, CBP conditionally releases the product which means that CBP has conditionally released it under a bond agreement with the importer of record. This allows the importer to take possession of the products. However, a condition of the bond agreement is that products are held intact unless and until FDA releases the product.

Under the bond agreement, you do not have to store the goods in any particular location. However, the bond agreement obligates you to return the goods to the port of entry if so ordered by CBP. For that reason it is in your best interest to keep the goods in the port area until you know FDA and CBP have completed any and all physical examinations or samplings of the product. If you choose to move the goods, you may have to bring them back.

If the products are repackaged or otherwise processed, then CBP and FDA may not be able to recognize the goods. It is in the importer's best interest, as well as a condition of the bond agreement, to hold the goods intact. Holding intact means keep the products as they were when they were imported. If you have an unusual situation (for example, fresh product that must be processed soon after importation to avoid loss of the product), contact the FDA District office. One possibility is that you request FDA authorization to process before release via a form 766. If it is something more simple such as the cardboard boxes the goods were shipped in become wet or damaged, it may be possible for FDA to witness the repackaging or to instruct you how to repackage in a way that maintains the ability of FDA and CBP to recognize the goods. You should not repackage or process goods held by FDA or CBP without authorization to do so.
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When a product is detained the usual testimony time period of 14 working days is provided (10 days plus two on either side to allow time for mailing for a total of 14 working days). This due date is found on your Notice of FDA Action next to the words "Respond By". The significance of this date is that your product becomes subject to immediate refusal of admission (see Question #9) after this date unless: (1) You have submitted testimony and the monitoring Compliance Officer is still evaluating it; (2) You have submitted a request for relabeling/reconditioning and the monitoring Compliance Officer is still evaluating it (see Question #5); Or, (3) An extension has been granted or you have requested one and the monitoring Compliance Officer is still considering it. You have the right to request an extension, but you do not have a right to an extension itself. If you are granted an extension you will be assigned a new testimony due date.

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5))What is a reconditioning or relabeling proposal? What is a form 766?

Some violations may be corrected through conditioning, for example: (1) An entry of raw shrimp is found by FDA to be contaminated by salmonella and the importer proposes to properly cook the shrimp in order to kill the salmonella and bring the product into compliance; (2) An entry of dried fruit was found by FDA to contain sulfites but sulfites are not declared on the product's label and the importer proposes to relabel the product so that the sulfites are properly declared.

If you wish to propose reconditioning of a product, you need to submit to you FDA contact (usually the Compliance Officer) a form 766, found here: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072766.pdf

You need to fill out the form with the details of the process you are proposing. If you are proposing relabeling, then a copy of the proposed corrected labeling must be provided with the form 766. This means a COMPLETE label as it would appear after correction. It is not acceptable to provide merely labels that you will 'stick over' parts of the existing label because that makes it very difficult to evaluate placement or whether any existing labeling information would be covered.

Please note that no reconditioning or relabeling should occur until the form 766 has been approved by FDA.

Our Regulatory Procedures Manual contains the policy that requests for a third attempt at reconditioning generally should not be granted. See this link: http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179472.htm. The practical effect of this policy is that if you submit a 766 and it is denied, you generally only get one more chance.

Some violations may be corrected through conditioning, for example: (1) An entry of raw shrimp is found by FDA to be contaminated by salmonella and the importer proposes to properly cook the shrimp in order to kill the salmonella and bring the product into compliance; (2) An entry of dried fruit was found by FDA to contain sulfites but sulfites are not declared on the product's label and the importer proposes to relabel the product so that the sulfites are properly declared.

If you wish to propose reconditioning of a product, you need to submit to you FDA contact (usually the Compliance Officer) a form 766, found here: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072766.pdf

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6) ***What is a private lab analysis? Do I have to have a private lab analyze my product? What standards should a private lab packet meet? Can I ask FDA to analyze it instead?***

As part of testimony introduction you may choose to hire a private laboratory to test your product. You are not obligated to do this. There are some situations where it will be very difficult to overcome the appearance of the violation with a private laboratory test. Examples of situations where private laboratory analysis is commonly done include: (1) Lettuce listed on Import Alert 99-05 (violative pesticide residue) is offered for import and the importer has it tested by a private lab to show that the residue is not present; (2) Cherry soda listed on Import Alert 45-02 (violative color additives) is offered for import and the importer has it tested by a private lab to show that the illegal color additive is not present

Manufacturer's certificates and/or expressions of confidence are not adequate substitutes for a private laboratory analysis. Here is a link to private laboratory analysis guidance to assist you: http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM092191.pdf

A complete lab packet includes a sample collection report and other supporting documents reflecting a representative sample from the actual goods offered for import. If you choose to work with a private lab that has little to no experience with offering analytical testimony to FDA, it is in your best interest to ensure that the private lab uses this link to read and understand the breadth and depth of documentation needed. The FDA will not analyze your product for you to help you avoid the time, trouble and expense of a private laboratory analysis.

As part of testimony introduction you may choose to hire a private laboratory to test your product. You are not obligated to do this. There are some situations where it will be very difficult to overcome the appearance of the violation with a private laboratory test. Examples of situations where private laboratory analysis is commonly done include: (1) Lettuce listed on Import Alert 99-05 (violative pesticide residue) is offered for import and the importer has it tested by a private lab to show that the residue is not present; (2) Cherry soda listed on Import Alert 45-02 (violative color additives) is offered for import and the importer has it tested by a private lab to show that the illegal color additive is not present

Manufacturer's certificates and/or expressions of confidence are not adequate substitutes for a private laboratory analysis. Here is a link to private laboratory analysis guidance to assist you: http://www.fda.gov/downloads/ScienceResearch/FieldScience/UCM092191.pdf

A complete lab packet includes a sample collection report and other supporting documents reflecting a representative sample from the actual goods offered for import. If you choose to work with a private lab that has little to no experience with offering analytical testimony to FDA, it is in your best interest to ensure that the private lab uses this link to read and understand the breadth and depth of documentation needed. The FDA will not analyze your product for you to help you avoid the time, trouble and expense of a private laboratory analysis.

7) How do I find a private lab to perform the analysis?

Listed below are two organizations that maintain lists of private laboratories. The lists are not intended to be used as lists of FDA 'approved' or 'certified' laboratories. It is up to each interested party to call and discuss their particular needs with the laboratory they employ.

Council of Independent Laboratories, Inc. 1629 K Street
Washington, D. C. 20006
Phone: (202) 887-5872; Fax: (202) 887-0021
www.acil.org

Directory of Testing Laboratories 1916 Pace Street
Philadelphia, PA 19103-1187
Phone: (215) 977-9679; Fax: (215) 977-9679
www.astm.org

8) If a Private lab has technical questions, who in FDA can they contact?

Questions regarding analytical method, sample size, compositing, etc. may be addressed to the Division of Field Science (DFS) personnel listed in the Import Alert as a contact. If no specific DFS contact is listed in the Import Alert, here is the main DFS contact number: 301-796-5992

9) What does an FDA Refusal mean?

An FDA Refusal means the goods have been rejected by FDA and are not allowed to be entered into US commerce. Refusal is a final decision made by FDA. Refusal triggers a demand for redelivery by CBP (see Question #10).

The FDA's Regulatory Procedures Manual contains the FDA policy on rescission (reversal) of refusals. The policy is that unless the refusal was erroneously issued by FDA, we do not normally consider rescinding (reversing) the refusal in order to provide more time for testimony or submission of a reconditioning proposal (form 766).

Here is a link to the webpage that contains that policy:
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179470.htm

10) What is Redelivery? What is a form 4647?

CBP form 4647 communicates a demand for redelivery per the bond agreement you have entered into with CBP. Redelivery means that you either destroy the goods or export the goods, per the CBP described process.

The bond that covers your product is a contract between you and CBP which states, among other things, that you are liable for monetary damages under the bond if you do not redeliver the product to CBP when so ordered. CBP can order redelivery under your bond if you fail to make an FDA regulated product available for FDA to examine or sample, or if FDA refuses admission of your product.

CBP can seek damages equal to three (3) times the value of the merchandise that is not redelivered. Also, you may have additional legal liability for distributing violative goods into US commerce.

The form 4647 normally references a due date that is 90 days after the FDA refusal. If you need more than 90 days to export or destroy a refused shipment, please contact CBP. The redelivery process is a CBP process and the FDA cannot grant such extensions.

11) How does a product get off of an Import Alert? How can a product become exempt from an Import Alert? Can I continue to offer goods for import while my exemption request is being considered?

To lean about how to qualify for exemption from an Import Alert, first you must review the specific Import Alert your entry is subject to and see if there are any specific instructions or requirements contained within regarding qualification for exemption. The Import Alerts are found here:
http://www.fda.gov/ForIndustry/ImportProgram/ImportAlerts/default.htm
Removal or exemption from Import Alerts (Detention Without Physical Examination) is handled by the FDA's Division of Import Operations and Policy (DIOP), 12420 Parklawn Drive, Rockville, MD 20857, importalerts2@fda.hhs.gov (this email address is specific to the topic of exemptions).

The exemption process is covered in the Regulatory Procedures Manual, Chapter 9, Subchapter titled Detention Without Physical Examination), heading of Removal from Detention Without Physical Examination:
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179271.htm
Requests for removal provided to the FDA's DIOP should include a written explanation of the investigational steps taken to identify how the problem came about and a description of corrective actions taken. Additionally, you should submit the entry documents for all of the entries cited as evidence that the problem has been corrected. You do not normally need to submit copies of any private laboratory testing which was performed.
For fresh produce subject to DWPE for pesticide residues only, contact your monitoring FDA Compliance Officer to see if he or she can evaluate your exemption packet instead of DIOP.
After you have submitted an exemption packet and are waiting for the outcome of the review, you may choose to stop importing new entries of the product or while you wait; or offer new entries for import and have them tested by the private laboratory also or otherwise overcome the appearance of the violation.
It is important to include in your request for exemption a statement that you request exemption for any entries offered for import after you submit the packet. You should also state that the entries offered for import after you submitted the packet are compliant with all applicable FDA requirements.

12) Where can I learn more about the importation process and my rights and responsibilities as an importer?

Here is a link to the main Imports page of the FDA website:
http://www.fda.gov/ForIndustry/ImportProgram/default.htm
Here is a link to the entire Regulatory Procedures Manual:
http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm. You may wish to review Chapter 9, Importer Operations for more details to understand detentions, notices, refusals, the rights of an importer to submit testimony, etc.

* The information in this document was believed to be correct at the time it was developed. However, laws and regulations are subject to change. Always check for the most current information before proceeding on the basis of the information contained herein. This document does not convey any waive of responsibility to the firm, nor impart any immunity to the firm for violations that may occur, even if you implement our recommendations as per 21 CFR 10.85(k).

EXHIBIT E

U.S. Food & Drug Administration

Import Alert 89-08

FDA Home[3] Import Program[4] Import Alerts Imports Alerts by Number Import Alert

(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer (s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 89-08
Published Date: 10/23/2014
Type: DWPE
Import Alert Name:
"Detention Without Physical Examination of Class III Devices Without Approved PMA's Or IDE's and Other Devices Not Equivalent or No 510k"

Reason for Alert:
NOTE: The revisions to this import alert dated 10/14/2014 replaces DIOP with DIO, updates the CDRH Import Branch name and contact information, updates contact information for the Office of Regulatory Science and provides additional information on the removal process. Changes are bracketed by asterisks (***).

Note:
Foreign firms previously subject to detention without physical examination under Import Alert #73-03 are now listed on this alert. FDA believes these devices are Class 3 and need a PMA. Please verify when products make entry.

Devices listed in the attachment for this alert have not been determined substantially equivalent or lack either a 510(k) or a Pre-Market Approval (PMA) for commercial distribution or, alternately, lack an Investigational Device Exemption (IDE).

Guidance:
*** Districts may detain, without physical sampling and analysis, products from the manufacturers identified in the Red List for this import alert.

A recommendation for detention without physical examination and background information, including analytical worksheets, should be forwarded to DIO, Import Operations and Maintenance Branch, HFC-172.

For questions or issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology, contact the Office of Regulatory Science at 301-796-6600.

For questions concerning these types of products or other compliance issues, contact CDRH/OC Imports Branch, 301-796-5500, or email: cdrhocimport@fda.hhs.gov.

For questions or issues involving import operations, contact the Division of Import Operations at (301) 796-0356, or email fdaimportsinquiry@fda.hhs.gov.

For guidance on removal from detention without physical examination, refer to FDA's Regulatory Procedures Manual, Chapter 9, "Detention Without Physical Examination (DWPE)."

If a firm, shipper or importer wishes to request removal from detention without physical examination, they should forward information supporting their request to FDA at the following address:

Food and Drug Administration
Division of Import Operations
12420 Parklawn Drive, ELEM-3109
Rockville, MD 20857

Or via email: Importalerts2@fda.hhs.gov ***

Product Description:
Medical devices (see attachment)

Charge:
For Class III device:

The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the device appears to be a Class III device and does not appear to have in effect an approved application for premarket approval pursuant to Section 515 of the Act, or an exemption pursuant to Section 520(g)(1) [Adulteration, Section 501(f)(1)(B)]."

OASIS charge code - NO PMA

For other devices:

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a post 1976 device for which a Section 510(k) application has not been determined substantially equivalent or a 510(k) has not been filed [Misbranding, Section 502(o)]."

OASIS charge code - NO 510(K)

Countries

MULTIPLE COUNTRIES (PODS ONLY)

(79 K - - GM) Silicone, Liquid, Injectable

List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

ARGENTINA

Lebian International S R L — **Date Published : 05/16/2014**
La Pax 1071 , Rosario, ARGENTINA

85 H - - -- Portion of device code — Date Published: 05/16/2014
Desc:Gynecological devices (Small #2; Medium #3; Large #4)
Notes:Autoexpandable and Discardable Speculum for Gynecological Use Models

AUSTRALIA

Australian Light Therapy — **Date Published : 09/16/2009**
108 Forrest Street , Cottesloe, WA AUSTRALIA

73 - - - -- Anesthesiology — Date Published: 09/16/2009
Notes:All devices. DE. Seasonal Affective Disorder Devices. (SAD Devices)
74 - - - -- Cardiovascular — Date Published: 09/16/2009
76 - - - -- Dental — Date Published: 09/16/2009
77 - - - -- Ear,Nose And Throat — Date Published: 09/16/2009
78 - - - -- Gastroenterological & Urological — Date Published: 09/16/2009
79 - - - -- General & Plastic Surgery — Date Published: 09/16/2009
80 - - - -- General Hospital/Personal Use — Date Published: 09/16/2009
84 - - - -- Neurological — Date Published: 09/16/2009
85 - - - -- Obstetrical & Gynecological — Date Published: 09/16/2009
86 - - - -- Ophthalmic — Date Published: 09/16/2009
87 - - - -- Orthopedic — Date Published: 09/16/2009
89 - - - -- Physical Medicine — Date Published: 09/16/2009
90 - - - -- Radiological — Date Published: 09/16/2009

Medec Pty Ltd — **Date Published : 09/16/2009**
22 Letchworth Centre Ave , Salter, FN AUSTRALIA

89 I - - SA Massager, Therapeutic, Electric — Date Published: 09/16/2009
Notes:MEDEC BioResonance System

BAHAMAS

IHT Ltd — **Date Published : 09/16/2009**
P.O. Box N4361 , Nassau, BAHAMAS

82 - - - -- Immunology — Date Published: 09/16/2009
Notes:HIV Oral Test (aka 1; 2 and Subtype O Saliva Test). 10/26/1999. Note HIV Diagnostic Kits are Class III devices within the meaning of Section 513(f)(1) of the Act and are regulated by CBER under the current intercenter agreement between CDRH and CBER. The unapproved diagnostic test kits claim to detect HIV antibodies in blood or saliva and provide results in the home in 15 minutes or less. The test kits are imported into the US through the mail and may be entered as Asamples@ or for Apersonal usa@. The contents may be labeled Afor investigational use@ for Aresearch use@ or Afor export only @. The test kits could present a serious hazard to the public health; including possible HIV transmission to partners and delayed access to medical care due to mis-diagnosed false negative tests. If entries are encounted; contact CBER Import/Export team at 301-827- 6201.

Newco Associates Limited — **Date Published : 09/16/2009**
P.O. Box CB12611 , Nassau, BAHAMAS

82 - - - -- Immunology — Date Published: 09/16/2009
Notes:HIV Oral Test (aka 1; 2 and Subtype O Saliva Test). 10/26/1999. HIV Diagnostic Kits are Class III devices within the meaning of Section 513(f)(1) of the Act and are regulated by CBER under the current intercenter agreement between CDRH and CBER. The unapproved diagnostic test kits claim to detect HIV antibodies in blood or saliva and provide results in the home in 15 minutes or less. The test kits are imported into the US through the mail and may be entered as Asamples@ or for Apersonal usa@. The contents may be labeled Afor investigational use@ for Aresearch use@ or Afor export only @. The test kits could present a serious hazard to the public health; including possible HIV transmission to partners and delayed access to medical care due to mis-diagnosed false negative tests. If entries are encounted; contact CBER Import/Export team at 301-827-6201.

BRITISH VIRGIN ISLANDS

(REMAINING LISTINGS OMITTED)

EXHIBIT F

From: **Pogue, Stephanie** <Stephanie.Pogue@fda.hhs.gov>
Date: Tuesday, October 28, 2014
Subject: New Entries of Be Active Braces
To: "Benjamin England (应革难)" <blengland@fdaimports.com>, "Cato, Todd W" <Todd.Cato@fda.hhs.gov>
Cc: "John F. Johnson, III" <jfjohnson@fdaimports.com>, "Hill, Toby" <Toby.Hill@fda.hhs.gov>, William Senior <wjsenior@fdaimports.com>, "Waltrip, Elizabeth" <Elizabeth.Waltrip@fda.hhs.gov>, "Smith, Christopher T" <Christopher.Smith@fda.hhs.gov>

Below is CDRH's review of entry AZX-1006975-8 BeActive™ Knee Brace.

CDRH states: *The labeling includes the following information which indicates the device is intended to be placed over the calf muscle below the knee cap rather than surrounding the knee joint.*

In addition, the mechanism of action of the device is to provide pressure (acupressure specifically) to initiate the relief of back pain:

- *"The brace fits around the calf right below the knee and applies pressure to the soleus muscle in the calf..."*
- *"Slip wrap on the left leg with the (L) on the top, just under the kneecap...Note: If the pressure pad is not on the outside outer edge of the calf muscle, adjust."*
- *"BeActiveTM Brace provides relief with acupressure below the knee"*
- *"...patented pressure pad..."*

The regulation 21 CFR 890.3475 includes examples of a limb orthosis such, "A whole limb and joint brace, a hand splint, an elastic stocking, a knee cage, and a corrective shoe."

This device would better compare to an elastic stocking (Product Code ILG) than a limb or joint brace. However, the subject device may have a new mechanism of action (i.e., applying acupressure to

the calf muscle for low back pain relief) which would be a new intended use for a Limb Orthosis. This device appears more appropriately classified as a Pre-amendment Acupressure Device (Product Code MVV).

Although, the cleared MVV devices have been placed on the wrist, the labeling for the subject device indicates it uses, "acupressure," to produce its intended effect. Therefore, there is a possibility the subject device

could be an Acupressure Device subject to 510(k) clearance. In addition, the labeling includes claims which would need clinical data in order to substantiate. For example, the labeling includes claims for:

- *"The Secret is the acupressure pad, apply to trigger points to relieve tension up your leg and back for instant help with pain relief"*
- *"Helps relieve Lower Back Pain associated with: Chronic Low Back Pain; Sciatica; Piriformis syndrome; and Pregnancy"*
- *"Reduces both short term and chronic sciatic back pain"*

Therefore, ***the device does need a 510(k) clearance in order to be legally marketed****. Additionally, the sponsor would need to submit data (i.e., clinical data) to support the claims noted above.*

At this time, it is unclear if the uses noted above are considered new intended uses, which may require a De Novo submission prior to marketing the device.

Additionally, CDRH recommends that this device be placed on Import Alert 89-08 "Detention Without Physical Examination of Class III Devices Without Approved PMA's Or IDE's and Other Devices Not Equivalent or No 510k" for lack of 510(k).

Based on CDRH's review, entries 9YR-2007235-6 and AZX-1007236-4 will be detained for lack of 510(k). A label review of these entries will determine if they will also be detained for lack of PMA.

Stephanie Pogue
Compliance Officer
US Food and Drug Administration
4040 North Central Expy, Suite 300
Dallas, TX 75204
Phone: 214-253-5287
E-mail: stephanie.pogue@fda.hhs.gov

EXHIBIT G

MBC Be Active v6
Prog#0700023C
10/24/14

Black Cyan Magenta Yellow Water Base

The wrap for back pain relief

BeACTIVE®

Includes 1 Beactive® Wrap
For Use Left or Right Calf

AS SEEN ON TV

Beactive® Wrap Instructions

Apply wrap using these simple steps:

STEP 1. **If Lower Back Pain is on the Left Side**; Slip wrap on the left leg with the **(L)** on the top, **just under the kneecap** (Fig. 1). Center the **(L)** just under the **LEFT** kneecap. The pressure pad should then be on the outside outer edge of the calf muscle as shown below. (Fig 2.) **Note: If the pressure pad is not on the outside outer edge of the calf muscle, adjust accordingly.**

If Lower Back Pain is on the Right Side; Follow Step 1, applying the wrap to the **RIGHT** leg with the **(R)** on the top just under the Right kneecap (Fig. 1). Then follow Step 1.

Left Front Calf

Fig. 1

Left Back Calf

Fig. 2

NOTE:
RED ARROW FOR PRESSURE POINT LOCATION

STEP 2. With the wrap in the proper position, pull the strap through the loop fitting, pulling firmly forward across the front of the wrap. Be sure there is firm-strong pressure from the pressure pad on your outside outer edge of the calf muscle. **Note: The wrap should feel tight but not uncomfortably tight. Loosen slightly if uncomfortable, but keeping it firm.**

STEP 3. Adhere the strap to the wrap.

Note: After tightening, if the pressure pad is not on the outside outer edge of the calf muscle, adjust accordingly.

When To Use: The Beactive® wrap should initially be worn for up to 2 hours at a time. If it remains comfortable, the wrap can be worn for longer periods as needed. If your lower back pain occurs in the center of your back, try to determine if the pain is more towards the right or left side and then apply the wrap to that side. If your lower back pain is exactly in the center of your low back, first try the wrap on your right leg and if no relief then switch to your left leg.

Note: Wearing wraps on both legs at the same time is not recommended.

Size: The Beactive® wrap fits calf circumference sizes 12.5 inches to 18 inches measured around the fullest part of your calf. The Beactive wrap is effective when worn on a single leg, on the side of the pain.

Caution: Some individuals may be sensitive to Neoprene. If rash develops, discontinue use and consult a physician.

Caution: If while wearing the wrap discomfort or pain results, persists or increases, discontinue use and consult a physician.

Care Instructions: Hand wash. Hang dry. Do not bleach. Do not iron.

Material Contents: 80% Neoprene / 20% Polyester

Reg. Trademark of
Beactive Technologies, LLC
Baltimore, Maryland

Copyright of
Plymouth Direct, Inc
& Natures Pillows, Inc.

© 2014 ALL RIGHTS RESERVED

Distributed by:
Natures Pillows, Inc.
2607 Interplex Dr.
Trevose, PA 19053.

Customer service or reorders call
(800) 471-6123 (M-F 9 to 5)
www.BeActiveBrace.com

Lower back pain radiates from the lower back to lower extremities.

One Size Fits All Adjustable

Unisex

The Secret is the calf wrap for help with back pain relief.

Helps relieve Lower Back Pain associated with:

- Lower Back Pain
- Sciatica
- One size fits all
- Unisex

Works on Left or Right Leg • Wear Over or Under Clothes

Made in China
Model # NP-BA1000

8 93621 00244 3

Patent No.
US8187212 B2

Includes 1 Beactive® Wrap
For Use Left or Right Calf


The wrap for back pain relief
BeACTIVE®
AS SEEN ON TV
Lower back pain radiates from the lower back to lower extremities.
One Size Fits All
Adjustable
Unisex
The Secret is the calf wrap for help with back pain relief.
Helps relieve Lower Back Pain associated with:
• Lower Back Pain
• Sciatica
• One size fits all
• Unisex
Works on Left or Right Leg • Wear Over or Under Clothes
Beactive®
The wrap for back pain relief
Includes 1 Beactive® Wrap
For Use Left or Right Calf
Made in China
Model # NP-BA1000
8 93621 00244 3
Patent No.
US8187212 B2

AS SEEN ON TV

BeACTIVE®

Beactive® Wrap Instructions

Apply wrap using these simple steps:

STEP 1. **If Lower Back Pain is on the Left Side**; Slip wrap on the left leg with the **(L)** on the top, **just under the kneecap** (Fig. 1). Center the **(L)** just under the **LEFT** kneecap. The pressure pad should then be on the outside outer edge of the calf muscle as shown below. (Fig 2.) **Note: If the pressure pad is not on the outside outer edge of the calf muscle, adjust accordingly.**

If Lower Back Pain is on the Right Side; Follow Step 1, applying the wrap to the **RIGHT** leg with the **(R)** on the top just under the Right kneecap (Fig. 1). Then follow Step 1.

Left Front Calf

Fig. 1

Left Back Calf

Fig. 2

NOTE:
RED ARROW FOR PRESSURE POINT LOCATION

STEP 2. With the wrap in the proper position, pull the strap through the loop fitting, pulling firmly forward across the front of the wrap. Be sure there is firm-strong pressure from the pressure pad on your outside outer edge of the calf muscle**. Note: The wrap should feel tight but not uncomfortably tight. Loosen slightly if uncomfortable, but keeping it firm.**

STEP 3. Adhere the strap to the wrap.

Note: After tightening, if the pressure pad is not on the outside outer edge of the calf muscle, adjust accordingly.

When To Use: The Beactive® wrap should initially be worn for up to 2 hours at a time. If it remains comfortable, the wrap can be worn for longer periods as needed. If your lower back pain occurs in the center of your back, try to determine if the pain is more towards the right or left side and then apply the wrap to that side. If your lower back pain is exactly in the center of your low back, first try the wrap on your right leg and if no relief then switch to your left leg.

Note: Wearing wraps on both legs at the same time is not recommended.

Size: The Beactive® wrap fits calf circumference sizes 12.5 inches to 18 inches measured around the fullest part of your calf. The Beactive wrap is effective when worn on a single leg, on the side of the pain.

Caution: Some individuals may be sensitive to Neoprene. If rash develops, discontinue use and consult a physician.

Caution: If while wearing the wrap discomfort or pain results, persists or increases, discontinue use and consult a physician.

Care Instructions: Hand wash. Hang dry. Do not bleach. Do not iron.

Material Contents: 80% Neoprene / 20% Polyester

EXHIBIT H

Beactive® Wrap Instructions

Apply wrap using these simple steps:

STEP 1. **If Lower Back Pain is on the Left Side**; Slip wrap on the left leg with the **(L)** on the top, **just under the kneecap** (Fig. 1). Center the **(L)** just under the **LEFT** kneecap. The pressure pad should then be on the outside outer edge of the calf muscle as shown below. (Fig 2.) **Note: If the pressure pad is not on the outside outer edge of the calf muscle, adjust accordingly.**

If Lower Back Pain is on the Right Side; Follow Step 1, applying the wrap to the **RIGHT** leg with the **(R)** on the top just under the Right kneecap (Fig. 1). Then follow Step 1.

Left Front Calf

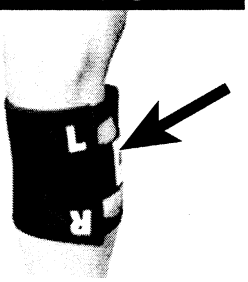


Fig. 1

Left Back Calf

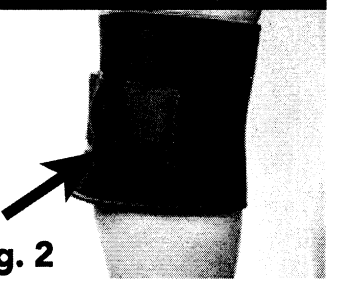


Fig. 2

NOTE:
RED ARROW FOR PRESSURE POINT LOCATION

STEP 2. With the wrap in the proper position, pull the strap through the loop fitting, pulling firmly forward across the front of the wrap. Be sure there is firm-strong pressure from the pressure pad on your outside outer edge of the calf muscle. **Note: The wrap should feel tight but not uncomfortably tight. Loosen slightly if uncomfortable, but keeping it firm.**

STEP 3. Adhere the strap to the wrap.

Note: After tightening, if the pressure pad is not on the outside outer edge of the calf muscle, adjust accordingly.

When To Use: The Beactive® wrap should initially be worn for up to 2 hours at a time. If it remains comfortable, the wrap can be worn for longer periods as needed. If your lower back pain occurs in the center of your back, try to determine if the pain is more towards the right or left side and then apply the wrap to that side. If your lower back pain is exactly in the center of your low back, first try the wrap on your right leg and if no relief then switch to your left leg.

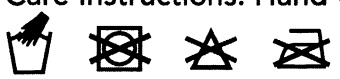
Note: Wearing wraps on both legs at the same time is not recommended.

Size: The Beactive® wrap fits calf circumference sizes 12.5 inches to 18 inches measured around the fullest part of your calf. The Beactive wrap is effective when worn on a single leg, on the side of the pain.

Caution: Some individuals may be sensitive to Neoprene. If rash develops, discontinue use and consult a physician.

Caution: If while wearing the wrap discomfort or pain results, persists or increases, discontinue use and consult a physician.

Care Instructions: Hand wash. Hang dry. Do not bleach. Do not iron.



Material Contents: 80% Neoprene / 20% Polyester