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SUMMARY

Comprehensive inspection of this own label distributor and warehouse was conducted as a Compliance Follow Up inspection to the previous inspection of 12/18-19/14 and per FLA-DO work plan for FY-16 under FACTS assignment ID #11606206 and FACTS OP ID #14036. Inspectional coverage was given in accordance with CP #7329.001, Cosmetics Program: Import and Domestic, PAC 29001. The firm is engaged in the distribution of finished cosmetic products, contracting for the manufacturer of cosmetic ingredients, and purchase and storage of ingredients/components used in the manufacture of the cosmetic products, and final approval of the labeling used upon the finished cosmetic products.

The previous inspection of 12/18-19/14 was classified as No Action Indicated (NAI), and re-classified as Official Action Indicated (OAI) by FLA-DO compliance branch upon their receipt of sample results. No Form FDA 483, Inspectional Observations was issued. Upon receipt of sample results, a Warning Letter (FLA-15-31) dated 9/2/15 was issued to the firm for adulterated cosmetic
and for misbranded cosmetics. No completed corrections were observed during the current inspection. FACTS CARS was not updated.

Current inspection resulted in the issuance of an one (1) item, Form FDA 483, Inspectional Observation to Mr. Ronaldo M. Esteves, Office Manager. The item consists of: the firm cosmetic bears or contains a poisonous or deleterious substance which may render it injurious to users under the conditions prescribed in the labeling or under the conditions of use that are customary or usual. In addition, two (2) items were discussed with Mr. Ronaldo M. Esteves, Office Manager: appropriate labeling of unmarked cosmetic ingredients, e.g. Juvenix, and labeling of UV/UVA labeled finished products. Mr. Ronaldo M. Esteves, Office Manager, committed to make corrections and to send a written response to the Form FDA 483, Inspectional Observation within 15 working days from the close of the inspection. No complete corrections were observed during the inspection. FACTS CARS was not updated. Also, at the beginning of the current inspection, we presented our FDA credentials, issued a Form FDA 482, Notice of Inspection and explained the scope of the inspection to Mr. Ronaldo M. Esteves, Office Manager.

No samples were collected during the inspection. No refusals were encountered during the inspection. No consumer complaints were observed in FACTS.

All marks and highlights made on all collected documents were made by the firm’s management.

Establishment Inspectional Report follows the Routine Surveillance format as stated in Investigations Operational Manual section 5.10.4.3.1 - STANDARD NARRATIVE REPORT located at http://www.fda.gov/ICECI/Inspections/IOM/ucm063172.htm.

**ADMINISTRATIVE DATA**

<table>
<thead>
<tr>
<th>Inspected firm:</th>
<th>Van Tibolli Beauty Corp</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location:</td>
<td>4800 NW 15th Ave Unit E</td>
</tr>
<tr>
<td></td>
<td>Fort Lauderdale, FL 33309-3781</td>
</tr>
<tr>
<td>Phone:</td>
<td>305-390-0044</td>
</tr>
<tr>
<td>FAX:</td>
<td>-</td>
</tr>
<tr>
<td>Mailing address:</td>
<td>4800 NW 15th Ave Unit E</td>
</tr>
<tr>
<td></td>
<td>Fort Lauderdale, FL 33309-3781</td>
</tr>
<tr>
<td>Days in the facility:</td>
<td>5</td>
</tr>
<tr>
<td>Participants:</td>
<td>Karl D Hezel, Investigator</td>
</tr>
<tr>
<td></td>
<td>Gina C Chen, Investigator</td>
</tr>
</tbody>
</table>

**HISTORY**
The firm was incorporated in Florida in 2009 and warehouses and distributes own label cosmetics. A photograph of the firm’s current business license is identified under EXHIBIT #2, page 1. The firm has 19 employees and operates Monday through Friday, 8:30 am to 6 pm. The firm’s total sales, which is listed in FACTS MARCS, is classified as Establishment size “5”. During the inspection, the firm did register under the Voluntary Cosmetic Registration Program (VCRP).

INTERSTATE COMMERCE

Mr. Ronaldo M. Esteves, Office Manager and Ms. Meghan McHugh, Business Development/Marketing Manager, Van Tibolli Beauty Corp. stated their firm has offices in Australia, Italy, Brazil, UK and Pakistan.

Ms. McHugh, Business Development/Marketing Manager, continued by stating their firm promotes through trade shows, trade publications for salon professionals (Modern Salons and Beauty Launchpad), social media and through her company’s website, www.GKHair.com. In addition, Ms. McHugh, Business Development/Marketing Manager, stated her firm’s top three customers are Bassett Salon Solutions (Orange, CA), DePasquale Salon Systems (Fair Lawn, NJ), and Manoco Blue (Kentwood, MI) (EXHIBIT #30).

Interstate documentation was provided by Mr. Esteves, Office Manager, and relates to the following FDA regulated products:

- GK Hair Taming System with Juvexin Restistant 33.8 oz, 10.1 oz and 3.4 oz
- GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz
- GK Hair Taming System with Juvexin Fast Blow-Dry 8.5 oz
- GK Hair Taming System with Juvexin Color Sealing 22 oz and 5 oz

Raw material interstate documentation:

- Invoice #1022-005, dated 10/25/2012, shows the last purchase of Juvexin (keratin ingredient in most of firm’s products) from Keraplast Technologies, LLC located in San Antonio, TX and transported to the firm’s warehouse located in San Antonio, TX. This warehouse is now closed, identified under EXHIBIT #35.

- Bill of Lading #1011 shows all items, to include Juvexin that were moved from the San Antonio, TX warehouse to the firm’s warehouse in Fort Lauderdale, FL on 4/17/2012, identified under EXHIBIT #36.

Finished product interstate documentation:

- Purchase Order #PODXB000881, dated 2/09/2016, shows a recent manufacture of product
which contains Juvexin by Chemco Corporation located in Miami, FL, identified under EXHIBIT #37.

- Purchase Order #PODXB000550, dated 9/07/2015, shows the latest manufacture of GK Hair Taming System with Juvexin Resistant 3.4 oz by Chemco Corporation located in Miami, FL, identified under EXHIBIT #38.

- Bill of Lading # 68460885, dated 2/18/2016, shows the recent sale of the products GK Hair Taming System with Juvexin Restistant 33.8 oz and GK Hair Taming System with Juvenexin Restistant 10.1 oz to Princess Professional Salon and Spa Services located in San Antonio, TX, identified under EXHIBIT #39.

- Bill of Lading# 68262661, dated 2/12/2016, shows the recent sale of the products GK Hair Taming System with Juvexin Curly 33.8 oz, GK Hair Taming System with Juvexin Restistant 33.8 oz and 10.1 oz to Century Beauty Supply located in Louisville, KY, identified under EXHIBIT #40.

JURISDICTION
The firm is an Own Label Distributor of cosmetics. During the inspection we observed the storage, handling, and shipment of cosmetics to include the hair straightener GK Hair Taming System with Juvexin Resistant.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
During the inspection, Mr. Ronaldo Esteves, Office Manager and Ms. Meghan McHugh, Business Development/Marketing Manager, provided the information and documentation included in this report.

Mr. Ronaldo Esteves, Office Manager: He has been in position for 1 year. He is in part responsible for the organizing and coordination of office operations and procedures, controlling correspondences, reviewing and approving supply requisitions, monitoring of clerical functions, managing office expenditures and budget. His authority was observed during the inspection by his accepting the Form FDA 482, Notice of Inspection and of the Form FDA 483, Inspectional Observations, his directing employees to provide documentation, labels or information in general to us. His position description is identified under EXHIBIT #53.

Ms. Meghan McHugh, Business Development/Marketing Manager: She is in part responsible for the graphic an web design liaison with design management, developing new business stratagies, facilitating communication between her firm and her firm’s distributors/clients. Her authority was observed by her providing information and documentation (emails, FedEx Bills of Lading for the
shipment of new correction label to her firm’s distributors/clients). Her position description is identified under EXHIBIT #42.

The firm does have a list of other officers, identified under EXHIBIT #45.

**FIRM'S TRAINING PROGRAM**

The firm does not have a written training procedure. Mr. Ronaldo Esteves, Office Manager, stated that his firm does perform On-The-Job training for it’s warehouse personnel, e.g. First in First out process of finished goods and ingredients. The firm has an approved list of educators whom have been trained to the firm’s products. The list of educators is identified under EXHIBIT #52. For the relabeling of finished products the firm has a video on it’s web site, snapshots of this video are identified under EXHIBIT #54. During the inspection, we observed the relabeling of GK Hair Taming System with Juvexin Resistant 33.8 oz bottle. Photographs with description of this relabeling is identified under EXHIBIT #2, page 2.

**MANUFACTURING/DESIGN OPERATIONS**

**Overall Operations**

Mr. Esteves, Office Manager, provided a copy of the firm premises layout is identified under EXHIBIT #48. In addition, he stated his firm’s facility which we were at, is 20,000 sq. ft. and has been at this location since 2013.

Van Tibolli Beauty Corp. is its own label distributor and warehouse of their products. Mr. Esteves, Office Manager, stated his firm’s warehousing and distribution is based on a first in, first out basis. According to Mr. Esteves, Office Manager, there are no changes to the firm’s general overall operations since the previous inspection of 12/2014. Mr. Esteves continued to include that his firm’s contract manufacturer is Chemco Corp. located in Miami, FL.

The new product and label development process as described by Ms. McHugh, Business Development/Marketing Manager, is as follows (EXHIBIT #2, page 23):

- Van Tibolli Corp. tells Chemco Corp. what type of products they want. Chemco Corp. requests ingredients and provides the usage, warnings and symbols for the products of Van Tibolli Beauty Corp. Then, Van Tibolli Beauty Corp. revises the usage and warnings and sends the labeling out for translations. Their lead designer (was located in Ireland, now in Pakistan) compiles the information, and marketing chooses the name of product before the start of production. Ms. McHugh, Business Development/Marketing Manager, provided us a copy of her firm’s brand guidelines, identified under EXHIBIT 41.
The packaging supplier located in China provides the printing space, colors available, dimensions, outer case size, specifications and sends the final sample to Van Tibolli Corp. before the start of production.

According to Ms. McHugh, Business Development/Marketing Manager, the final review and sign-off of the artwork is performed collaboratively amongst herself, Emerson Proenca, General Manager, Van Tibolli, Chief Executive Officer (CEO) and Nauman Akhtar, Web Designer.

In addition, Ms. McHugh, Business Development/Marketing Manager, provided a copy of her firm’s production flow chart, identified under EXHIBIT #55.

Raw Materials and Product Components

Methylene Glycol

During the inspection, Ms. McHugh, Business Development/Marketing Manager, stated that the following products contain Methylene Glycol:

- GK Hair Taming System with Juvexin Restistant 33.8 oz, 10.1 oz and 3.4 oz
- GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz
- GK Hair Taming System with Juvexin Fast Blow-Dry 8.5 oz
- GK Hair Taming System with Juvexin Color Sealing 22 oz and 5 oz

During our inspection of the firm, we collected the firm’s product specifications for the following:

- GK Hair Taming System with Juvexin Restistant 33.8 oz, 10.1 oz and 3.4 oz, identified under EXHIBIT #24.
- GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz, identified under EXHIBIT #25.
- GK Hair Taming System with Juvexin Fast Blow-Dry 8.5 oz, identified under EXHIBIT #26.
- GK Hair Taming System with Juvexin Color Sealing 22 oz and 5 oz, identified under EXHIBIT #27.

A summary table is below:

<table>
<thead>
<tr>
<th>Product</th>
<th>% Methylene Glycol - Firm Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restistant 33.8 oz</td>
<td>4%</td>
</tr>
<tr>
<td>Restistant 10.1 oz</td>
<td>4%</td>
</tr>
</tbody>
</table>

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In addition, we collected the firm’s product labels for the following:

- GK Hair Taming System with Juvexin Restistant 33.8 oz, 10.1 oz and 3.4 oz, identified under EXHIBITS #9-13.
- GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz, identified under EXHIBITS #10, 12, 14, 15.
- GK Hair Taming System with Juvexin Fast Blow-Dry 8.5 oz, identified under EXHIBIT #16.
- GK Hair Taming System with Juvexin Color Sealing 5 oz, identified under EXHIBIT #17.

The labeling of these products indicated they are to be applied to the hair and ultimately the hair is to be blown dry and flat ironed. During a heat process, the Methylene Glycol changes to formaldehyde. This is further discussed under the Objectionable Conditions and Management’s Response section of this report under Observation #1.

**Juvexin**

According to Mr. Esteves, Office Manager, the ingredient “Juvexin” is a protein which his firm uses in most of his firm’s finished products. Juvexin is supplied by Keraplex Technologies, LLC located in San Antonio, TX. Van Tibolli Beauty Corp. receives and stores it at their warehouse. Then, Chemco Corp. picks up the ingredient to manufacture Van Tibolli’s products. Once the product is manufactured and packaged, Chemco delivers the finished cosmetic products back to Van Tibolli.

On 2/29/2016, we observed the storage of an unlabeled ingredient in the warehouse in which Mr. Esteves stated was Juvexin. Printout of photographs of this is identified under EXHIBIT #2, page 20. We informed Mr. Esteves about the appropriate labeling of unmarked cosmetic ingredients during the walk through of the warehouse. On 3/1/2016, Mr. Esteves informed us he labeled the Juvexin ingredient. We observed the raw material ingredient labeled as, “GKHAIR JUVEXIN” Printout of photographs of this is identified under EXHIBIT #2, page 21.

The firm’s finished products were not labeled with expiration dates. Per Mr. Esteves, a shelf life of 3
years from the manufacturing date is provided by Chemco for the GK Hair Taming System Resistant, Curly, Fast Blow-Dry and Color Sealing products. A copy of the shelf life study is identified under EXHIBIT #49.

**Quaternium-95 and Propanediol**

We observed products with the labeling of UV/UVA Protection. According to Ms. McHugh, Quaternium-95 and Propanediol (trademarked as CHROMAVEIL), identified under EXHIBIT #29, are the ingredients associated with the labeling of UV/UVA Protection in the following products. Labels for these products are:

- GK Hair Taming System with Juvexin UV/UVA Shield Color Sealing 22 oz and 5 oz, identified under EXHIBIT #17.
- GK Hair Taming System with Juvexin UV/UVA Shield Color Protection Conditioner 22 oz, 8.11 oz and 5 oz, identified under EXHIBIT #32.
- GK Hair Taming System with Juvexin UV/UVA Shield Color Protection Shampoo 22 oz, 8.11 oz and 5 oz, identified under EXHIBIT #33.
- GKHair Lock Me Color Masque, identified under EXHIBIT #34.

In addition, these products are listed on the copy of the firm’s US Distributor Sales Order Form, identified under EXHIBIT #28.

**Color Developer**

During the walk through of the firm, we observed the storage of color developer ingredients at the firm’s warehouse. Mr. Esteves, Office Manager, stated the developer ingredients are used as an activator for hair coloring. According to Mr. Esteves, Office Manager, the developer ingredients were supplied from Vital Farco located in Italy. In addition, he stated that his firm receives the developer at his warehouse and then the developer is sent to Chemco Corp. for packaging. Photographs of the developer in storage at the firm’s warehouse are identified under EXHIBIT #2, pages 22-23.

**Label Update Process**

We observed the process of the placement of the temporary label updates onto the GKHair Taming System Juvexin Restistant 33.8 oz bottle. The temporary labels, which included the updates to the warnings as discussed in the Warning Letter dated 9/2/2015, were affixed directly over the previous product labeling. Photographs of the process of the placement of temporary label onto GKHair Taming System with Juvexin Restistant 33.8 oz bottle are identified under EXHIBIT #2, page 2. In addition, Mr. Esteves, Office Manager, provided a copy of a printout of a video snapshot of the label application process, identified under EXHIBIT #6 and copies of documentation related to the new label purchases, identified under EXHIBIT #8.
We observed the updated warnings on the GK Hair Taming System with Juvexin Restistant 33.8 oz, 10.1 oz and GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz, which read in part as:

“…product releases formaldehyde when treated hair is heated with a blow dryer and hot flat iron. This may cause short term and long term health effects, such as eye, skin, and throat irritation, headache, dizziness, burning sensations, breathing problems, and certain cancers, particularly for those who are sensitive to formaldehyde. This product must be applied by hair professionals only and in conditions that provide adequate ventilation. Concurrent use in the same facility may increase the concentration of formaldehyde in the air, which could increase the risk of adverse effects. Avoid unnecessary repeated use. If you are nursing or pregnant do not use the product without first consulting your physician. Avoid direct eye and skin contact. If skin contact occurs, wash immediately. If ingestion or eye contact occurs, call a physician immediately. Salon professional and client must wear protective clothing. Keep out of reach of children…”

Mr. Esteves stated his firm’s distributors have been supplied with these new labels, notified via email and by telephone of how to apply these new labels and his firm has documentation that the labels were applied appropriately. There were two prints of temporary sticker labels with the updated warnings and a third permanent print which has the updated warnings imprinted on the bottles.

We observed deficiencies when we examined the product labeling requirements for the warning statements of:

- GK Hair Taming System with Juvexin Restistant 3.4 oz
- GK Hair Taming System with Juvexin Color Sealing 22 oz and 5 oz
- GK Hair Taming System with Juvexin Fast Blow-Dry 8.5 oz

According to Mr. Esteves, there were no label updates for the warnings of these products in contrast to the label updates performed for GK Hair Taming System with Juvexin Restistant 33.8 oz and 10.1 oz and GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz. The following table summarizes the actions and progress taken and made by the firm:

<table>
<thead>
<tr>
<th>Product</th>
<th>% Methylene Glycol - Per Product Technical Specifications</th>
<th>Qty sold in Sept 2015-Feb 2016</th>
<th>Finished product Actual Inventory</th>
<th>1st Print of Temporary Labels Barcode</th>
<th>1st Print of Temporary Labels Quantity</th>
<th>2nd Print of Temporary Labels Barcode</th>
<th>2nd Print of Temporary Labels Quantity</th>
<th>3rd Print (Permanent Imprinted Bottles) Barcode</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistant 33.8 oz</td>
<td>4%</td>
<td>1460</td>
<td>2329</td>
<td>815401019496</td>
<td>800</td>
<td>815401019625</td>
<td>5200 shared</td>
<td>815401019496</td>
</tr>
<tr>
<td>Resistant 10.1 oz</td>
<td>4%</td>
<td>1965</td>
<td>9900</td>
<td>815401019502</td>
<td>none left</td>
<td>815401019632</td>
<td>~5000 shared</td>
<td>815401019502</td>
</tr>
<tr>
<td>Resistant 3.4 oz</td>
<td>4%</td>
<td>627</td>
<td>3321</td>
<td>No Label Correction</td>
<td></td>
<td>No Label Correction</td>
<td></td>
<td>No Label Correction</td>
</tr>
</tbody>
</table>
### Establishment Inspection Report

**Van Tibolli Beauty Corp**

**Fort Lauderdale, FL 33309-3781**

**FEI:** 3008327674  
**El Start:** 2/29/2016  
**El End:** 3/9/2016

<table>
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<th></th>
<th></th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Curly 33.8 oz</td>
<td>3%</td>
<td>115</td>
<td>954</td>
<td>815401019519</td>
<td>none left</td>
<td>815401019625</td>
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<tr>
<td>Curly 10.1 oz</td>
<td>3%</td>
<td>293</td>
<td>2363</td>
<td>815401019526</td>
<td>none left</td>
<td>815401019632</td>
<td>~5000 shared</td>
<td>Not Printed Yet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Curly 1.5 oz</td>
<td>3%</td>
<td>For Sample Use</td>
<td>756</td>
<td>For Sample Use</td>
<td>For Sample Use</td>
<td>For Sample Use</td>
<td>For Sample Use</td>
<td>Not Printed Yet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color Sealing 22 oz</td>
<td>1.5%</td>
<td>1084</td>
<td>144</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>Not Printed Yet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color Sealing 5 oz</td>
<td>1.5%</td>
<td>3108</td>
<td>19</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>Not Printed Yet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fast Blow Dry 8.5 oz</td>
<td>1.85%</td>
<td>245</td>
<td>8694</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>No Label Correction</td>
<td>Not Printed Yet</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### MANUFACTURING CODES

Mr. Esteves, Office Manager, stated that his firm does not add the manufacturing lot codes to his firm’s products. He continued to state that when Chemco Corp. manufactures his firm’s finished products, Chemco Corp. identifies the manufacturing code. Mr. Esteves, Office Manager, stated he does not know how the lot codes are generated.

In reference to lot trace back, Mr. Esteves, Office Manager, stated his firm does not know who receives what lot. In addition, he stated if needed, his firm would call all of his firm’s customers, and they (his customers) would then provide the lot they have on hand. Mr. Esteves, Office Manager, stated the warehouse began writing lot numbers on picking tickets/packing lists on international orders at the requests of customers. Per Mr. Esteves, Office Manager, the first five numbers of the MO# of the label on the shipping cartons is the same as the lot number. Photograph of the MO# on the shipping carton is identified under **EXHIBIT #2**, page 10.

The firm’s products are not labeled with an expiration date. However, the finished product labels do have a 30 month symbol which indicates shelf life. Per Mr. Esteves, Office Manager, a shelf life of 3 years from the manufacturing date is provided by Chemco for the GK Hair Taming System Resistant, Curly, Fast Blow-Dry and Color Sealing products, identified under **EXHIBIT #49**.
COMPLAINTS
There were no consumer complaints observed in FACTS since the previous inspection of 12/2014. Ms. McHugh, Business Development/Marketing Manager, and Mr. Esteves, Office Manager, stated they were unaware of any other complaints and their firm does not have a complaint file.

When asked if the firm had any documentation of feedback from customers, Ms. McHugh, Business Development/Marketing Manager, stated that customer service calls are outsourced to a call center in the Philippines and the customer service employees refer to a FAQ list, identified under EXHIBIT #47, to answer phone inquiries. When an item is not listed in the FAQ list, calls are directed to firm. When the complaint refers to use of the product, the firm directs the complainant to contracted educators who are also salon professionals, identified under EXHIBIT #52.

Ms. McHugh, Business Development/Marketing Manager, stated that these phone conversations between educators and customers are summarized in a spreadsheet log covering the dates from 6/26/2015 to 2/25/2016, identified under EXHIBIT #43. This spreadsheet log contains summaries of 34 educator inquiries. From these 34 inquiries:

- Thirteen (13) inquiries were in reference to the GK Hair Taming System with Juvexin Resistant, its results and use.
- One (1) inquiry was in reference to the GK Hair Taming System with Juvexin Curly and its result.
- One (1) inquiry was in reference to the GK Hair Taming System with Juvexin Fast Blow-Dry use.

According to Ms. McHugh, product exchanges are completed with a Return Authorization Request Form, identified under EXHIBIT #50. Ms. McHugh, Business Development/Marketing Manager, stated exchanges are typically trade outs, which occur when salons decide to switch brands. Ms. McHugh provided the firm’s Distributor Policies and Procedures for the U.S. and Canada (EXHIBIT #51), which reads in part as, “Distributors should notify their VTB account manager to report any defective products. Once verified, a Return Material Authorization (RMA) will be issued and credit will then be given to the distributor.”

RECALL PROCEDURES
The firm does not have recall procedures and the firm has not had any recalls or market withdraws. In reference to lot trace back, Mr. Esteves, Office Manager, stated his firm does not know where a particular lot of finished product is sent to among his distributors. In addition, he stated if needed, his firm would call all of his firm’s customers (distributors), and they (his customers) would then provide the lot they have on hand. Mr. Esteves, Office Manager, stated the warehouse began writing lot numbers on picking tickets/packing lists on international orders at the requests of customers.
Establishment Inspection Report
Van Tibolli Beauty Corp
Fort Lauderdale, FL 33309-3781

FEI: 3008327674
EI Start: 2/29/2016
EI End: 3/9/2016

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1
Your cosmetic bears or contains a poisonous or deleterious substance which may render it injurious to users under the conditions prescribed in the labeling or under the conditions of use that are customary or usual.

Specifically, during the inspection of your firm we observed the GK Hair Taming System with Juvenxin Resistant; GK Hair Taming System with Juvenxin Curly; GK Hair Taming System with Juvenxin Fast Blow-Dry; and GK Hair Taming System with Juvenxin Color Sealing products to contain Methylene Glycol. These products labeling indicate they are to be applied to the hair and ultimately the hair is to be blown dry and flat ironed. Your firm’s has been updating product labeling for some, but not all of these products. The updated labeling contain warnings for the use of those products. The list below summarizes the products (with sizes) of products which contain methylene glycol, versus new labels.

<table>
<thead>
<tr>
<th>Product</th>
<th>% Methylene Glycol - Per Product Technical Specifications</th>
<th>Qty sold in Sept 2015-Feb 2016</th>
<th>Finished product Actual Inventory</th>
<th>1st Print of Temporary Labels Barcode</th>
<th>1st Print of Temporary Labels Quantity</th>
<th>2nd Print of Temporary Labels Barcode</th>
<th>2nd Print of Temporary Labels Quantity</th>
<th>3rd Print (Permanent Imprinted Bottles) Barcode</th>
<th>3rd Print (Permanent Imprinted Bottles) Bottle Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33.8 oz</td>
<td>4%</td>
<td>1460</td>
<td>2329</td>
<td>815401019496</td>
<td>800</td>
<td>815401019625</td>
<td>5200 shared</td>
<td>815401019496</td>
<td></td>
</tr>
<tr>
<td>10.1 oz</td>
<td>4%</td>
<td>1965</td>
<td>9900</td>
<td>815401019502</td>
<td>none left</td>
<td>815401019632</td>
<td>~5000 shared</td>
<td>815401019502</td>
<td></td>
</tr>
<tr>
<td>3.4 oz</td>
<td>4%</td>
<td>627</td>
<td>3321</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Curly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33.8 oz</td>
<td>3%</td>
<td>115</td>
<td>954</td>
<td>815401019519</td>
<td>none left</td>
<td>815401019625</td>
<td>5200 shared</td>
<td>Not Printed Yet</td>
<td>Not Printed Yet</td>
</tr>
<tr>
<td>10.1 oz</td>
<td>3%</td>
<td>293</td>
<td>2363</td>
<td>815401019526</td>
<td>none left</td>
<td>815401019632</td>
<td>~5000 shared</td>
<td>Not Printed Yet</td>
<td>Not Printed Yet</td>
</tr>
<tr>
<td>1.5 oz</td>
<td>3%</td>
<td>For Sample Use</td>
<td>756</td>
<td>For Sample Use</td>
<td>For Sample Use</td>
<td>For Sample Use</td>
<td>For Sample Use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color Sealing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22 oz</td>
<td>1.50%</td>
<td>1084</td>
<td>144</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No Label Correction</td>
<td>No Label Correction</td>
</tr>
<tr>
<td>Color Sealing</td>
<td>1.50%</td>
<td>3108</td>
<td>19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No Label Correction</td>
<td>No Label Correction</td>
</tr>
</tbody>
</table>
5 oz Fast Blow Dry 8.5 oz
1.85% 245 8694 No Label Correction No Label Correction No Label Correction

Reference: FDCA 601(a)

Supporting Evidence and Relevance:
During the inspection, we were informed by Mr. Ronaldo Esteves, Office Manager and Ms. Meghan McHugh, Business Development/Marketing Manager that the firm informed us that as a correction to the Warning Letter ((FLA-15-31 dated 9/2/15) their firm had ordered, received, sent to distributors, and are using overlay labels for the additional warning statements needed for their firm’s products of:
- GK Hair Taming System with Juvexin Resistant 33.8 oz, and 10.1 oz;
- GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz;

The Warning Letter and overview email are identified as ATTACHMENTS.

We requested information on if any other of the firm’s product contain Methylene Glycol and we preformed a physical inventory of the firm’s GK Hair Taming System with Juvexin Resistant and GK Hair Taming System with Juvexin Curly finished products. We were informed that the following products contain Methylene Glycol (and these products are to undergo the same process of blow drying and flat ironing):
- GK Hair Taming System with Juvexin Resistant 33.8 oz, 10.1 oz, and 3.4 oz;
- GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz;
- GK Hair Taming System with Juvexin Fast Blow-Dry;
- GK Hair Taming System with Juvexin Color Sealing 22.6 oz and 5 oz.

Further discussion to include the table cross referencing the product, to presentation size, specification sheet listing of Methylene Glycol, actual inventory, and label correction status is located under the Manufacturing/Design Operations section of this report.

We observed that the products of
- GK Hair Taming System with Juvexin Resistant 3.4 oz;
- GK Hair Taming System with Juvexin Fast Blow-Dry;
- GK Hair Taming System with Juvexin Color Sealing 22.6 oz and 5 oz.
did not have any label correction for the warnings for use due to the Methylene Glycol and its change to Formaldehyde vapor when heated. Mr. Ronaldo Esteves, Office Manager and Ms. Meghan McHugh, Business Development/Marketing Manager stated that they misunderstood the scope of the warning letter, since the previous inspection of 12/2014 discussion, to include physical samples collected was for the
- GK Hair Taming System with Juvexin Resistant 33.8 oz, 10.1 oz;

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Establishment Inspection Report

Van Tibolli Beauty Corp
Fort Lauderdale, FL 33309-3781

FEI: 3008327674
EI Start: 2/29/2016
EI End: 3/9/2016

- GK Hair Taming System with Juvexin Curly 33.8 oz and 10.1 oz.
We stated that the Warning Letter does not identify size of product, just the name of the product. In
addition, we stated that all products which contain Methlyene Glycol and which undergo a heating
process of blow dry and heating iron met the same criteria as listed in the Warning Letter.

Discussion with Management:
Mr. Ronaldo Esteves, Office Manager and Ms. Meghan McHugh, Business Development/Marketing
Manager stated that they understood that all of the products which contain Methlyene Glycol and
which undergo a heating process of blow dry and heating iron must contain the update warning.
They committed to start the process to develop and to print temporary labels immediately for the
- GK Hair Taming System with Juvexin Resistant 3.4 oz;
- GK Hair Taming System with Juvexin Fast Blow-Dry;
- GK Hair Taming System with Juvexin Color Sealing 22.6 oz and 5 oz.

They committed to send these new labels to their distributors and verify that their distributors had
received and used for the update of the respective finished product warning labels. In addition, they
committed to send a written response to this observation within 15 working days of the close of this
inspection.

REFUSALS
No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

On 3/9/16, we held a closeout meeting with Mr. Ronaldo Esteves, Office Manager, and Ms. Meghan
McHugh, Business Development/Marketing Manager. We informed the management that the
conditions discussed may, after further review by the Agency, be considered to be violations of the
Food, Drug and Cosmetic Act or other statutes. Legal sanctions available to the FDA may include
seizure, injunction, civil money penalties and prosecution. Also that the your firm’s (written)
response may impact the FDA’s determination of the need for follow-up action, if FDA receives an
adequate response to the FDA 483 within 15 business (working) days of the end of the inspection.

ADDITIONAL INFORMATION
District follow-up items:
• Ensure the warning statements on the labels are consistent with the “mock” labels provided to FDA and that it appears on the labels prominently and conspicuously as compared to other words.

• The mock labels observed were for the GK Hair Taming System with Juvexin Resistant 33.8 oz and Curly 10.1 oz. We reviewed the labels for GK Hair Taming System with Juvexin Resistant 33.8 oz, Resistant 10.1 oz, Curly 33.8 oz and Curly 10.1 oz, identified under EXHIBIT #2, pages 3, 4 and 6. The warning statements on these labels are similar to the “mock” labels.

• There are no correction labels for the GK Hair Taming System with Juvexin Resistant 3.4 oz (EXHIBIT #2, page 7). The documentation we collected from the firm relating to sales, identified under EXHIBIT #31, indicated the Resistant 3.4oz as sold. Mr. Esteves, Office Manager, stated the Resistant 3.4oz is sold as part of promotional packages.

• We observed two additional products, GK Hair Taming System with Juvexin Color Sealing 22 oz and 5 oz and GK Hair Taming System with Juvexin Fast Blow-Dry 8.5 oz that did not have label corrections and the current labels are not similar to the other “mock” labels (EXHIBIT #2, pages 12-19).

• Ensure relabeled products are labeled in English and Spanish only. If not, ensure the label information is matching in other foreign languages.

• GK Hair Taming System with Juvexin Resistant and Curly labels are in English and Spanish only, identified under EXHIBIT #2, pages 3, 4 and 6.

• The GK Hair Taming System with Juvexin Color Sealing and Fast Blow-Dry labels have more languages e.g. French, Portuguese, Russian, Arabic, Turkish (EXHIBIT #2, pages 14, 16, 18-19). Ms. McHugh, Business Development/Marketing Manager stated that all the information in the various languages is the same.

• Ensure that the placements of the corrective labels do not interfere with mandatory cosmetic labeling information and that it meets all other applicable statutory and regulatory requirements (reference 21 CFR 701).

• The placement of correction temporary labels is directly over the same, but violative label. The process of the placement of the temporary labels is identified under EXHIBIT #2, page 7.

• Reconcile the volume of product to be relabeled prior to distribution. The firm indicated 5,500 bottles were held in their warehouse and approximately 1,000 bottles are estimated to be held by their distributors. The firm indicated labels will be provided to the distributors to be affixed to the bottles. The firm also indicated they intends to follow-
up with their distributors, via phone calls, to ensure the labels were appropriately used and that the advisory notice found on FDA’s website at [http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm228898.htm](http://www.fda.gov/Cosmetics/ProductsIngredients/Products/ucm228898.htm) was sent to the salons and their employees and made available to the salon’s customers.

- The firm sent emails to each of their distributors along with labels and they mailed labels to each of their distributors via FedEx. We collected a list of the firm’s distributors, a copy of each FedEx shipping label for the correction labels being sent to each respective distributor, and a copy of each email sent to each distributor (EXHIBITS #3-5). Ms. McHugh, Business Development/Marketing Manager, stated that her firm called each distributor. We collected confirmation emails identified under EXHIBIT #7, indicating that the firm received from distributors that the labels were applied appropriately.
- The following table summarizes the actions and progress taken and made by the firm to follow up with distributors:

<table>
<thead>
<tr>
<th>Distributor</th>
<th>Location</th>
<th>Email Sent</th>
<th>Fedex Label Date</th>
<th>Confirmation of Label Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manoco Blue</td>
<td>Kentwood, MI</td>
<td>12/16/15</td>
<td>1/18/16</td>
<td>Awaiting reply</td>
</tr>
<tr>
<td>Hair-Lines</td>
<td>Shrewsbury, MA</td>
<td>1/4/16</td>
<td>1/19/16</td>
<td>3/8/2016</td>
</tr>
<tr>
<td>Bassett Salon Solutions</td>
<td>Orange, CA</td>
<td>1/20/16</td>
<td>1/18/16 &amp; 1/26/16</td>
<td>Awaiting reply</td>
</tr>
<tr>
<td>FineLine Distributors</td>
<td>Chicago, IL</td>
<td>1/20/16</td>
<td>1/19/16</td>
<td>3/8/2016</td>
</tr>
<tr>
<td>Professional Only Beauty Supply</td>
<td>Montgomery, AL</td>
<td>1/20/16</td>
<td>Did not have in stock</td>
<td>Did not have in stock</td>
</tr>
<tr>
<td>Freeman Salon Systems</td>
<td>Denver, CO</td>
<td>1/20/16</td>
<td>1/18/16</td>
<td>Awaiting reply</td>
</tr>
<tr>
<td>Oken Enterprises Inc.</td>
<td>Coconut Creek, FL</td>
<td>Verified on 3/4/16</td>
<td>1/19/16</td>
<td>3/8/2016</td>
</tr>
<tr>
<td>Beauty Trade LLC</td>
<td>Orlando, FL</td>
<td>12/11/15</td>
<td>1/19/16</td>
<td>3/8/2016 - Distributor stated there was no need to label.</td>
</tr>
<tr>
<td>Cook Beauty Supply</td>
<td>Monroe, LA</td>
<td>12/11/15</td>
<td>1/19/16</td>
<td>Awaiting reply</td>
</tr>
<tr>
<td>Beau Beauty</td>
<td>Macon, GA</td>
<td>1/20/16</td>
<td>Did not have in stock</td>
<td>Did not have in stock</td>
</tr>
<tr>
<td>A&amp;A Beauty Supply</td>
<td>Lockport, NY</td>
<td>1/20/16</td>
<td>1/18/16</td>
<td>Awaiting reply</td>
</tr>
<tr>
<td>Princess Professional Salon &amp; Spa</td>
<td>San Antonio, TX</td>
<td>Verified on 3/4/16</td>
<td>1/18/16</td>
<td>Awaiting reply</td>
</tr>
<tr>
<td>Beauty Scope</td>
<td>Dulles, VA</td>
<td>1/20/16</td>
<td>1/19/16</td>
<td>3/8/2016</td>
</tr>
<tr>
<td>Classic Beauty</td>
<td>Bolivar, MO</td>
<td>12/11/15</td>
<td>1/19/16</td>
<td>3/8/2016 - Distributor requested more labels.</td>
</tr>
<tr>
<td>FourStar</td>
<td>Milwaukee, WI</td>
<td>Verified on 3/4/16</td>
<td>1/19/16</td>
<td>Awaiting reply</td>
</tr>
</tbody>
</table>
Ms. McHugh, Business Development/Marketing Manager, stated her firm hires salon professionals as contractors to educate salons on their products, identified under EXHIBIT #52. She continued by stating the following are the contract manufacturers and suppliers that their firm currently uses, identified under EXHIBITS #46, 35, 29, 44:

**US Contract Manufacturers**
- American Spray Tech (Branchburg, NJ) – manufactures firm’s hairsprays
- Chemco Corp. (Miami, FL) - manufactures most of firm’s products including:
  - GK Hair Taming System with Juvexin Restistant 33.8 oz, 10.1 oz and 3.4 oz
  - GK Hair Taming System with Juvexin Curly 33.8 oz, 10.1 oz and 3.4 oz
  - GK Hair Taming System with Juvexin Color Sealing 22 oz and 5 oz
  - GK Hair Taming System with Juvexin Fast Blow-Dry 8.5 oz
- Cosmo Fragrances (Fort Lauderdale, FL) – where firm purchases their fragrances

**International Contract Manufacturers**
- Edelstein (Italy) – manufactures firm’s wax products
- Silvio Maro (Italy) – manufactures firm’s oil hair color
- HAS (Italy) – manufactures firm’s Shield additive

**US Suppliers**
- Keraplast Technologies, LLC (San Antonio, TX) – supplies Juvexin, protein ingredient in most of the firm’s products (See Interstate Commerce section)
- Croda Inc (Edison, NJ) – supplies CHROMAVEIL (Quaternium-95 and Propanediol), used in the products labeled with UV/UVA Protection

**International Suppliers**
- Vital Farco (Italy) – supplies developer ingredients
- Guangzhou Jinyao Plastics (China) – bottle supplier for Color Sealing
- Foshan Nanhai Fengmei Plastic Packaging Co., Ltd. (China) – bottle supplier for GK Hair Taming System with Juvexin Fast Blow-Dry and GK Hair Taming System with Juvexin Resistant and Curly

Mr. Esteves, Office Manager, provided us with the following promotional material that his firm uses for its products:

- Four (4) pamphlets titled, “GK HAIR PROFESSIONAL DO’S & DON’TS,” identified under EXHIBIT #18.
- Four (4) pamphlets titled, “GK HAIR PROFESSIONAL Resistant & Curly APPLICATION PROCESS,” identified under EXHIBIT #19.
- Four (4) pamphlets titled, “GK HAIR PROFESSIONAL INTRODUCTION PACKAGES 2016,” identified under EXHIBIT #20.
- Four (4) pamphlets titled, “GK HAIR PROFESSIONAL FAST BLOW DRY APPLICATION PROCESS,” identified under EXHIBIT #22.
- One (1) pamphlet titled, “GK HAIR PROFESSIONAL INTRODUCING GKhair JUVEXIN CREAM COLOR & GKhair Shield Series,” identified under EXHIBIT #23.

SAMPLES COLLECTED
No samples were collected during the inspection.

VOLUNTARY CORRECTIONS
No completed corrections were observed during the inspection. FACTS CARS was not updated.

ATTACHMENTS
1(KDH)  Issued 483
2(KDH)  Form FDA 482, Notice of Inspection issued to Mr. Ronaldo Esteves, Office Manager dated 29Feb16, 3 pages
3(KDH)  FDA Form 463a, Affidavit - Not Signed due to corporate policy, 5 pages
4(KDH)  Warning letter, 4 pages
5(KDH)  email with email from compliance with background for CFU, 2 pages
6(KDH)  email of background to warning letter, 2 pages

EXHIBITS COLLECTED
1(KDH)  Tibolli all photographs taken during EI, 99 pages
2(KDH)  ex2 Selected tibolli photos with description, 23 pages
3(KDH)  ex3 List of Firm Distributors, 3 pages
4(KDH)  ex 4 Printout of email and text sent to distributor for the update of labels, 28 pages
5(KDH)  ex 5 Printout of Fedex Bill of Lading sending updated labels to each distributor, 17 pages
6(KDH)  ex6 Printout of video snap shot of label application, 1 page
7(KDH)  ex7 Confirmation of label application, 21 pages
8(KDH)  ex8 Copies of documentation related to new label purchase (PODXB000714 and PODXB000861), 8 pages
9(KDH)  ex9 Four labels GK Hair Juvexin Resistant 33.8 oz (815401019496 1st print), 4 pages
10(KDH) ex10 Four labels Resistant and Curly second print, 4 pages
11(KDH) ex11 Four label Resistant 33.8 3rd print, 4 pages
12(KDH) ex 12 four label GK Hair taming system juvenix Resistant & Curly 2nd print, 4 pages
13(KDH) ex13 four label GK Hair taming system juvenix resistant 10.1 3rd print, 4 pages
14(KDH) ex14 four label GK Hair Taming System juvenix Curly 33.8 1st print, 4 pages
15(KDH) ex15 two label GK Hair taming system juvenix Curly 10.1 2nd print, 2 pages
16(KDH) ex16 four label GK Hair Taming system juvenix fast blow dry, 4 pages
17(KDH) ex 17 Four label GK hari taming system juvexin color sealing 5 oz, 4 pages
18(KDH) ex18 four pamphlets "dos and donts", 8 pages
19(KDH) ex19 four pamphlets titled GK Hair Professional Resistant and Curly Application Process, 8 pages
20(KDH) ex20 four pamphlets titled GK Hair Professional Introduction Packages 2016, 16 pages
21(KDH) ex21 four pamphlets titled GK Hair Professional Promotions March-April 2016, 8 pages
22(KDH) ex22 four pamphlets titled GK Hair Professional Fast Blow Dry Application Process, 8 pages
23(KDH) ex23 one pamphlet GK Hair Professional GK Hair Juvexin cream color and shield series, 4 pages
24(KDH) ex24 Product specification sheet for GK Hair Taming System with Juvexin Resistant, 1 page
25(KDH) ex25 Product specification sheet for GK Hair Taming System with Juvexin Curly, 1 page
26(KDH) ex26 Product specification sheet for GK Hair Taming System with Juvexin Fast Blow-Dry, 9 pages
27(KDH) ex27 Product specification sheet for GK Hair Taming System with Juvexin Color Seal, 10 pages
28(KDH) ex28 Copy of US Distributor Order Form, 5 pages
29(KDH) ex 29 opy of Tech sheet for Quaternium-95 and Propanediol (UVUVA ingred in Color Shield, 24 pages
30(KDH) ex30 Copy of List of Sales by Customer Summary from Jan 2015 - Dec 2015, 14 pages
31(KDH) ex31 Copy of List of Items sold from Sept 2015 to Dec 2015 (February 2016), 1 page
32(KDH) ex32 artwork & summary of ingredients for GKHair Taming Systemm Juvexin Color Protect Cond 22, 8, 5oz, 5 pages
33(KDH) ex33 artwork & summary of ingred for GKHair Taming Sys Juvexin Color Prot Shampoo 22,8,5oz., 7 pages
34(KDH) ex34 Copy of artwork and summary of ingredients for the GK Lock Me Color Masque , 3 pages
35(KDH) ex35 Copy of Keraplast Technologies, LLC CofA, PO POGKUS0339, Invoice 1022-005, 3 pages
36(KDH) ex36 Copy of Bill of Lading 1011, 2 pages
37(KDH) ex37 Copy of PCODB000881 Purchase Orders, Packing Slips, Invoices, 7 pages
38(KDH) ex38 Copy of PODXB000550 Purchase Order, Invoice, Packing Slip , 3 pages
39(KDH) ex39 Copy of inv & BL for recent sale of prod to Princess Profess Salon & Spa BL68460885, 6 pages
40(KDI) ex40 Copy of inv& BL for recent sale of prod to Century Beauty Supply BL 6826261, 6 pages
41(KDH) ex41 Brand Guidelines, 9 pages
42(KDH) ex42 Business Development and Marketing Job Description, 1 page
43(KDH) ex43 Call Log, 2 pages
44(KDH) ex44 China Suppliers, 1 page
45(KDH) ex45 Company Positions, 2 pages
46(KDH) ex46 Contract Manufacturers, 2 pages
47(KDI) ex47 Customer Service FAQ, 2 pages
48(KDH) ex48 firm layout, 1 page
49(KDH) ex49 keratin shelf life, 1 page
50(KDH) ex50 RMA, 6 pages
51(KDH) ex51 Distributor Policy, 1 page
52(KDH) ex52 list of educators, 2 pages
53(KDH) ex53 office manager position description, 1 page
54(KDH) ex54 product training video snapshots, 1 page
55(KDH) ex55 production flow chart, 1 page