Iowa Board of Pharmacy

INVESTIGATIVE REPORT ADDENDUM

Reporting Agent: Mark Mather, RPh & Compliance Officer & Danielle Watznauer, Pharmacy

Intern

Date: 5-24-17

Subject: Hornbill Asian Market License#-Non-licensed Entity

Owner: Mang Pau Phone: 319-464-1803

Address: 920 W. 5th Street

Waterloo, IA 50702

Subject: Shwe Nyiko Market & Asian Foods License#-Non-licensed Entity

Address: 911 Commercial Street

Waterloo, IA 50702

County: Black Hawk/7

Complaint No.: 2016-88

Original summary of complaint 6-5-16:

During a routine inspection by Brenda Corey, Environmental Health Officer, Black Hawk County Health Department of the Hornbill Asian Market, she noticed packages labeled "Pencillin" 500,000 I.U. tablets. She also noticed many other medicine-type bottles and tubes of cream claiming to cure all kinds of health maladies, from high cholesterol and blood pressure problems to nerve tonics and weight loss powders. Many of the packages containing these products were written in Burmese with very little to no English, which made identifying ingredients very difficult. Not exactly sure what to do about the possibility of prescription medicines being sold to the general public, she notified the Pharmacy Board office.

On June 14, 2016 Executive Director Andrew Funk and Compliance Officer Mark Mather visited the Hornbill Asian Market, finding 10 different products containing prescription ingredients, along with a large quantity of potentially harmful products that were embargoed until safety and chemical makeup could be ascertained. Samples from the embargoed product were taken back to the Board office for chemical assay. All products known to contain prescription ingredients were taken back to the Board office as well.

Concluding summary for complaint 5-24-17:

On May 24, 2017 a return visit was made to the Hornbill Asian Market by Pharmacist Mather and Intern Watznauer. The purpose of our visit was twofold: to ask the market owners to surrender the OTC product that had been embargoed on our first visit and to determine whether the market had received any further OTC preparations with prescription ingredients from their wholesaler.

Our visit revealed no further prescription OTC products for sale on their store shelves; the store had abided by their promise not to buy more of the same product from their wholesaler. The quarantined product that had been bagged and stored in a sealed cardboard box had not been tampered with; all products were present and accounted for. After the inspection the owner's assistant was informed that we would be taking the embargoed product with us for future destruction. As always, he was agreeable and helpful during our visit.

Summary of findings during second visit:

- The original large OTC section had been completely removed; the only OTC product was now behind the register. The small assortment of products did not contain any prescription ingredients; some of the writing was in Burmese so it was difficult to ascertain what some of the ingredients were.
- The original embargoed products were still kept in their Ziploc bags inside a large cardboard box. The box was labeled, sealed, and kept hidden on a shelf high above the sales floor. The associate brought the box down for us; we took a quick look inside, then resealed the box and removed it from the store premises.
- Ms. Watznauer and I then drove over to the second Asian market, Shwe Nyiko Market & Asian Foods to perform the same inspection again. The two of us could not find any product in their OTC area that contained prescription ingredients.

Narrative statement in Detail:

Our return trip to both Asian markets revealed that no new prescription-containing OTC product had been bought from their wholesaler and put out for sale to the public. The Hornbill Asian Market had totally removed their formerly large OTC section and replaced it with snacks and energy drinks. The OTC section had been moved to a small shelf behind the register that only contained a small fraction of the amount originally sold. We checked the ingredients on all the products sold and found no prescription ingredients listed. This was difficult at times because a fair amount of the labeling was written completely in Burmese. Unfortunately, our iPhone's translation App did not contain Burmese as one of its languages.

We did travel over to the second Asian market located close by to make sure they were being compliant as well. We did not find any prescription ingredients in any of Shwe Nyiko's OTC products as well. Both establishments seem to have heeded our instructions to not buy OTC products containing prescription ingredients.

Iowa Board of Pharmacy

INVESTIGATIVE REPORT

Reporting Agents: Mark Mather, RPh & Compliance Officer, Andrew Funk, RPh & Executive

Director

Date: 6-15-16

Subject: Hornbill Asian Market

License#-Non-licensed Entity

Owner: Mang Pau Phone: 319-464-1803

Address: 920 W. 5th Street

Waterloo, IA 50702

Subject: Shwe Nyiko Market & Asian Foods License#-Non-licensed Entity

Address: 911 Commercial Street

Waterloo, IA 50702

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County: Black Hawk/7 JUN 20

Complaint No.: 2016-88 | OWA BOARD OF PHARMACY

Summary of complaint:

During a routine inspection by Brenda Corey, Environmental Health Officer, Black Hawk County Health Department of the Hornbill Asian Market, she noticed packages labeled "Pencillin" 500,000 I.U. tablets. She also noticed many other medicine-type bottles and tubes of cream claiming to cure all kinds of health maladies, from high cholesterol and blood pressure problems to nerve tonics and weight loss powders. Many of the packages containing these products were written in Burmese with very little to no English, which made identifying ingredients very difficult. Not exactly sure what to do about the possibility of prescription medicines being sold to the general public, she notified the Pharmacy Board office.

On June 14, 2016 Executive Director Andrew Funk and Compliance Officer Mark Mather visited the Hornbill Asian Market, finding 10 different products containing prescription ingredients, along with a large quantity of potentially harmful products that were embargoed until safety and chemical makeup could be ascertained. Samples from the embargoed product were taken back to the Board office for chemical assay. All products known to contain prescription ingredients were taken back to the Board office as well.

During our investigation, Health Officer Corey informed us of a second Asian market in Waterloo that had the same type of questionable products behind their counter. We visited Shwe Nyiko Market & Asian Foods and found 12 items containing known prescription ingredients,

along with other questionable products and ingredients with Burmese labels.

History of license:

None.

Summary of findings:

- Hornbill Asian Market is owned by a man named Mang Pau, who lives in either
 Marshalltown or Michigan, comes to the store reportedly once a month and speaks
 limited English over the phone. His employee manning the store (name unknown) spoke
 hardly any English but fluent Burmese; this made communication difficult.
- The 10 different products found containing prescription ingredients included:
 - o Orlistat 120mg capsules, penicillin tablets, ketoconazole cream, amoxicillin 125/5ml suspension for reconstitution, cyproheptadine 2mg/5ml syrup, and fluocinonide 0.025% ointment.
- There were many different bottles claiming to treat all kinds of common ailments, like blood pressure, diabetes, cholesterol and others. Most of the bottles had limited English and mostly Burmese on the labels, making ingredient determination difficult. Any product that looked suspicious was embargoed; a sample of each product was kept for chemical assay.
- Mr. Pau informed us that his invoices were kept at a business called Morrison Consulting, which does accounting work for the Hornbill Market. We sat down with one of their employees and looked at past invoices and bank statements. The invoices for the suspect products were all written in Burmese and did not contain the name or address of the wholesaler. We could not match the invoice amounts to the bank statements from Wells Fargo. The invoices were sent to the FDA for further scrutiny.
- The Shwe Nyiko Market had 12 different products containing similar prescription ingredients as the Hornbill location. A few additional prescription items were found:
 - Mebendazole 500mg tablets, diclofenac 50mg, metronidazole 200mg, ketoconazole 200mg tablets, mebendazole 100mg/5ml liquid, and an antidiarrheal tablet containing atropine 0.130mg.
- Actions taken were the same as at the Hornbill; all prescription containing product was surrendered and brought back to the Board office.
- Invoices at Shwe Nyiko Market contained the name Thiri Aung Enterprises, which is out of Lincoln, Nebraska. I called the listed number, and a foreign man explained in broken English that they do not sell medicines, only food products.
- The Thiri Aung invoice contains an entry for Decolgen, which is a cold tablet that contains 25mg of phenylpropanolamine, a C-V controlled substance similar to pseudoephedrine but was taken off the U.S. market for OTC sale in 2005.
- Shwe Nyiko Market gave us a phone number (270-314-7039) and the name Thein as their contact for ordering product. A call placed to that number immediately went to voicemail in a foreign language.
- Both markets were instructed not to sell or reorder any of the surrendered or embargoed products. Pictures of the banned product were taken by the market employees to help them identify what not to reorder.

- The invoices and prescription product inventory lists were forwarded to the FDA office for their investigation into the matter.
- A court order will be sought to have the surrendered prescription drug products destroyed. The other sample products will be sent to a lab to determine their chemical composition. Their future path will be determined by what the lab results reveal.

Narrative statement in Detail:

I received a phone call from Brenda Corey, an Environmental Health Officer with the Black Hawk County Health Department explaining what she had found at the Hornbill Asian Market during one of her recent store inspections. The general sentiment upon first learning of the possibility of penicillin tablets being sold was that it was not part of our jurisdiction. Neither of the Asian markets or their purported wholesalers are licensed with the Board of Pharmacy, so if there really was prescription drugs involved, it was more of a criminal matter. Upon further review, it was decided that it was more important to protect the public interest by investigating what really was stocked at the Hornbill market and take whatever action was deemed necessary. A complaint was initiated so the investigation could commence [EXHIBIT A].

On 6/14/16, Executive Director Andrew Funk and Compliance Officer Mather inspected the Hornbill Asian Market and their version of an OTC section. First, all the prescription ingredient products were found and recorded on a surrender form [EXHIBIT B]. Second, all of the product deemed suspect or possibly dangerous to the public were removed from the shelves and placed in Ziploc bags. One sample product from each bag was kept in a separate Ziploc bag for later lab testing; each product was cataloged on the Embargo Sample List [EXHIBIT C]. The numerous Ziploc bags full of suspect product were placed in a sealed cardboard box and an embargo tag was attached. The box was left at the store with specific instructions to not open the box or sell the merchandise until further notice.

Mr. Funk and I next went to Morrison Consulting, a small tax preparation and consulting business that kept Mr. Pau's invoices for the Hornbill Asian Market. We were attempting to find out which wholesaler was sourcing the prescription ingredient-containing products, along with their contact information. Unfortunately, the invoices thought to include suspect products were all written in Burmese, and none of the invoices contained any wholesaler contact information [EXHIBIT D]. We also tried a little reverse investigative thinking, by attempting to match an invoice total with the bank statements provided by Wells Fargo. If we could find the bank that the invoice payments were going to, maybe we could determine the wholesale company through their bank deposits. Again, no success; none of the invoice totals matched any of the deposit amounts listed on the Wells Fargo bank statements.

It was suggested by an employee at Morrison that the lack of company contact information on the invoices may be a tactic by the wholesaler to cover their tracks. It's also possible that the invoices were paid with cash, instead of going through Wells Fargo-which would be another way to stay anonymous. We had copies made of each invoice to pass along to the FDA for further investigation.

Mr. Funk and I made one last stop at a second Asian market called Shwe Nyiko Market & Asian Foods. We were tipped off to this location by a phone call from Health Officer Corey, who remembered seeing the same types of suspicious medicinal products behind their front sales counter. And she was correct; we found many of the same types of prescription ingredients, plus a few new ones totaling 12 different products [**EXHIBIT E**]. All of the 12 different products were bagged, tagged, and surrendered to us by the helpful store staff.

This market is not owned by Mang Pau; we did not get the name of the owner, but the man who was in charge was very forthcoming. He was able to supply us with copies of their invoices that did contain the name of a wholesaler and a phone number. I called the number and was able to reach a foreign-speaking man who spoke broken English. He informed me that the Thiri Aung Enterprises company is located out of Lincoln, Nebraska which I verified through the internet. We attempted to discuss the problem with shipping prescription medications to their various Asian markets; his response was they only ship food, no medicine.

The Shwe Nyiko market was also able to provide us with similar handwritten invoices that we knew contained the prescription drug containing products [**EXHIBIT F**]. We knew this because one of the entries on an invoice said "TIFFY," which matched the name on one of the surrendered product boxes [**EXHIBIT G**]. But, as before, the invoices did not contain any type of wholesaler name or contact information. The Shwe market employee helping us was able to supply us with a name, Thein, and a phone number (270-314-7039) that they use to order various products. I called the number and reached an immediate voicemail with loud music playing and some type of foreign language message.

The surrendered product from both markets were placed in the back of Mr. Funk's vehicle and driven back to the Board office. The sample products taken for lab analysis were also bagged and taken back to the Board office. All embargoed product was bagged, placed in a sealed cardboard box, tagged and left at the Hornbill Asian Market until further notice. The lists of surrendered prescription-containing products and the invoices from each market were sent to the FDA for their pending investigation. The Board office will endeavor to obtain a court order for destruction of the surrendered prescription drug products.

This completes my report.

Complaint Received How Received Incident Date Complaint ID# Complaint # 7193 2016 88 06/03/2016 Letter/Written 05/31/2016 Lic./Reg. #'s CSA Pharmacist Pharmacy Technician Wholesaler **PSP** Intern Name Hornbill Asian Market **Complainant Name** Department of Inspections and Address **Complainant Address** 920 W 5th Street Mark Speltz Food and Consumer Safety Bureau Waterloo 50702-Des Moines, 50309-IA IA **Complainant Phone** Phone (515) 669-3266 (641) 750-5249 Complaint filed on behalf of: Unknown Date/To Whom Complaint Routed for Investigation: 06/14/2016 M Mather

Status: Open

Penicillin tablets and repackaged vitamins found by DIA inspector at Chinese Grocery store.

The penicillin tablets appeared to be packaged by a manufacturer I n Bangkok, Thailand.

Inv. Rpt. Received

Description of Complaint

From:

Funk, Andrew [IBPE]

To:

Jorgenson, Debbie [IBPE]; Mather, Mark [IBPE]

Subject:

FW: Black Hawk Co, IA Reply - Penicillin and Vitamin Embargo Email 1 of 2

Date: Attachments: Friday, June 10, 2016 4:35:32 PM

Importance:

DSCF0897.JPG

High

Debbie,

Will you please initiate a complaint against Hornbill Asian Market?

Mark, I know we originally decided that we had no jurisdiction over the matter since they were not a licensee. However, the bottom line is, they are in possession of a prescription drug and they have no authority to possess it. Let's plan to have them surrender the drug to us (it's currently embargoed) and try to determine how they received it in the first place.

I'll plan to go with you when we collect the drug. Does Tuesday next week work with your schedule?

Sound OK?

Andrew Funk, Pharm.D.
Executive Director
Iowa Board of Pharmacy
RiverPoint Business Park
400 SW 8th Street, Suite E
Des Moines, Iowa 50309-4688
515.281.5944 Main Line
andrew.funk@iowa.gov

From: Close, Kathleen [mailto:Kathleen.Close@fda.hhs.gov]

Sent: Friday, June 10, 2016 4:21 PM

To: Funk, Andrew [IBPE]

Subject: Black Hawk Co, IA Reply - Penicillin and Vitamin Embargo Email 1 of 2

From: Eileen R. Daley [mailto:edaley@co.black-hawk.ia.us]

Sent: Tuesday, June 07, 2016 12:44 PM

To: Close, Kathleen; StateRFR-Mandernach, Steven

Cc: Brenda Corey; StateRFR-Platt, Scott; Speltz, Mark [DIA]

Subject: RE: Black Hawk Co, IA Reply - Penicillin and Vitamin Embargo Email 1 of 2

Hello,

After speaking with the Health Officer involved with this case, the following information is provided in response to your inquiry.

The Penicillin tablets and repackaged vitamins were found May 30, 2016 at:

Hornbill Asian Market

920 W 5th Street Waterloo, IA 50702

Phone on file: 641-750-5249 or Owner personal cell (Mang Pau): 319-464-1803 (note – owner

speaks limited English)

1. Eight (8) boxes of Penicillin that contained 12 tablets in each box. The Penicillin was embargoed 5/31/2016 (tag #660) with no expiration date.

The Penicillin tablets appear to be packaged by a manufacturer. It is described on the box as 12 Tablets in foil (2x6 tablets in foil). The labeling appears to be:

Distributed by A.N.B. Laboratories
The Medicpharma Co. LTD
450 Sol Rama II
Soi 50 Sameo Dam
Bangkok, Thailand

2. Vitamin embargo:

Vitamin B1 (30) packages with 20 tablets in each package Vitamin B2 (29) packages with 25 tablets in each package Vitamin B6 (49) packages with 20 tablets in each package

The label on each package stated the type of vitamin and the dollar amount, no other labeling. Mang Pau, one of the owner's of Hornbill Asian Market, states, "The vitamins were repackaged by them in the store." The vitamins were embargoed (tag #s 661 & 662) 5/31/2016 with no expiration date.

All embargoed items (Penicillin and Vitamins) were being sold over the counter and there is no retail pharmacy in this establishment. Please also refer to this and next email with photo attachments (a single file was too large to send in one email).

If additional information is requested, please do not hesitate to contact me or Brenda Corey, Environmental Health Officer.

Eileen R Daley, MPH
Division Manager - Enforcement, Surveillance & Preparedness
Black Hawk County Health Department
1407 Independence Ave., 5th Floor
Waterloo, Iowa 50703
Office (319) 291-2413
Secure Fax (319) 291-2529
Direct Line (319) 292-2233

Brenda Corey, B. S. Environmental Health Officer Black Hawk County Health Department Northeast Iowa Inspections

Office (319)291-2413 Cell: (319)415-8923 Fax: (319)-291-2529

bcorey@co.black-hawk.ia.us

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From: Close, Kathleen [mailto:Kathleen.Close@fda.hhs.gov]

Sent: Monday, June 6, 2016 4:01 PM **To:** StateRFR-Mandernach, Steven

Cc: Brenda Corey; Eileen R. Daley; StateRFR-Platt, Scott; Speltz, Mark [DIA]

Subject: RE: repackaging vitimans

Two more questions: How are both products repackaged and how are they sold?

Thank you,

Katie Jo

Kathleen J. Close

State Liaison

U.S. Food & Drug Administration

Kansas City District/ Des Moines Resident Post 210 Walnut Street, Suite 369 Des Moines, IA 50309

Direct Line: (515) 244-0480 x 1003

Blackberry: (515) 333-1621

Fax: (515) 244-0618

Kathleen.Close@FDA.HHS.GOV

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From: Close, Kathleen

Sent: Monday, June 06, 2016 10:51 AM

To: 'Speltz, Mark [DIA]'

Cc: Brenda S. Corey (bcorey@co.black-hawk.ia.us); Eileen R. Daley (edaley@co.black-hawk.ia.us);

StateRFR-Mandernach, Steven; StateRFR-Platt, Scott

Subject: RE: repackaging vitimans

Importance: High

Title 21 CFR 111 applies to facilities that repackage dietary supplements. Vitamins are considered dietary supplements. 21 CFR 111 states that the requirement set forth under the provision relating to "holding" do not apply at a retail establishment for the sole purpose of direct retail sale to individual consumers. However, all other applicable sections would apply.

I would like to reach out to our Compliance Branch, however I'd like to obtain more information before I do. Would you be able to provide me the name and address of the retail firm that is repackaging penicillin and vitamins? How many kinds of vitamins are involved? What is the repackaged unit size? How long are the product(s) embargoed by Black Hawk Co?

Thank you,

Katie Jo

Kathleen J. Close State Liaison

U.S. Food & Drug Administration Kansas City District/ Des Moines Resident Post 210 Walnut Street, Suite 369 Des Moines, IA 50309

Direct Line: (515) 244-0480 x 1003

Blackberry: (515) 333-1621

Fax: (515) 244-0618

Kathleen.Close@FDA.HHS.GOV

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From: Speltz, Mark [DIA] [mailto:Mark.Speltz@dia.iowa.gov]

Sent: Friday, June 03, 2016 7:17 PM

To: Close, Kathleen

Cc: Brenda S. Corey (bcorey@co.black-hawk.ia.us); Elleen R. Daley (edaley@co.black-hawk.ia.us);

StateRFR-Mandernach, Steven; StateRFR-Platt, Scott

Subject: repackaging vitimans

Katy-Jo,

One of our local contracting agencies ran across a facility repackaging vitamins. I believe they were receiving these from overseas and were repackaging into unlabeled bags. They were also repacking penicillin. We have contacted the lowa's Board of Pharmacy about the drugs, but we were not sure

588-8014

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EXHIBIT D Page 1 of 6

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EXHIBIT D Page 3 of 6

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INVENTORY OF DRUGS	OR SURRENDE	RED
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City Westerlos, IA County VSLACK HA	9	•
NAME OF DRUG	STRENGTH	QUANTITY (tabs,gms,mls)
1. Dignicron MR 30mg TABLET	30mg	169 tobs
2. Skineal compound kotoconarde acom i	U	24 Boxe
3. Fluocinonide Cream (Frostite) 2.5gm		90 tubes
4. Fugacar (moberdazole) 500mg ted		1 tack
5. Novasin Analgorie TABLET - Didoferace		90 tolos
6. ALupep tublets-Antaciel -contains At	rophe 0.130y	100 tembs
7. Metronidazole Tablet 200mg		60 talos
<u>u</u>		40 telps
9. Decolgen Forte tales CI alloghammine)	Phonylpropanolamine	150 tubs
10. FOB-meben Lig mebondazok 100		18 bottles
11. Cyproheptacline 2mg/5ml Ligurel	(LOWL)	2 potales
12. Disento terbs, Dirodohydroxygoin 250	on Furazolilone	224 tabs
13.		
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The control by:	surrendere	d. (CIRCLE ONE)
(signature) Jama Ran	(date) (0-14-14
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That & Myanmar food package distribution

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city, state, zp SE O UM Elis 90 address 31666006 garage gives Shyra 300 person 300g Seg-Seg-ပ်ကြော <u></u> cash Charge Cod On acct C 3000 # ŏ ₽ 18 9 2:30 70 22 800 5 S

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