DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Food and Drug Administration
College Park, MD

March 27, 2013

Dr. Hin Kai Chan
Chan Li Chai Medical Factory (H.K.) Ltd.
FLAT A2, 3/F., BLOCK A,
FORTUNE FACTORY BLDG, 40 LEE CHUNG ST.
HONG KONG, SAR

Reference: Inspection Date (s): 8/20/2012 - 8/21/2012

Location: same as above

Dear Dr. Hin Kai Chan:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at (240) 402- 2271 or write to:

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Food Adulteration Assessment Branch (HFS-607)
5100 Paint Branch Parkway
College Park, MD 20740-3835

For more information on the U.S. FDA, please visit our website at www.fda.gov. Information on FDA's international activities in the food and cosmetic program and the foreign food inspection program can be accessed at: http://www.fda.gov/Food/InternationalActivities/default.htm.

Sincerely,

Maria Lau -S

Digitally signed by Maria Lau -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Maria Lau -S, 0.9.2342.19200300.100.1.1=2000360446
Date: 2013.03.27 10:07:32 -04'00'

Compliance Officer
Food Adulteration Assessment Branch
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition

Enclosure: Establishment Inspection Report (EIR)

Establishment Inspection Report FEI: **3003105247**
Chan Li Chai Medical Factory (H.K.) Ltd. EI Start: 08/20/2012
Hong Kong, Hong Kong SAR EI End: 08/21/2012

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SUMMARY

This foreign dietary supplement inspection was conducted under DFFI trip #2012-173F, FACTS assignment # 1431176 / OP ID # 6281054, and in accordance with C.P 7321.008 Dietary Supplements - Import and Domestic, C.P. 7303.819 Imported Foods, and C.P. 7321.005 – General Food Labeling.

This is the initial inspection. There were no historical records on file regarding this firm including consumer complaints.

This inspection revealed that the firm is manufacturer of dietary supplements. The firm is currently exporting these products to the United States. The firm manufactures and sells its own line of dietary supplements to a single customer in U.S. The product manufactured for this customer is an herbal lozenge made up of approximately 50% mixture of pure honey and 50% powdered herbs and roots used in Chinese herbal medicines.

The firm was not manufacturing products for their U.S. Customer at the time of inspection; they were manufacturing a similar product for a customer in Indonesia.

I evaluated documentation required by DS GMP (21 CFR 111), manufacturing, raw material and finished product storage, storage of labeling and packaging materials, and employee practices.

A 5 item FDA 483 was issued at the close of this inspection. Observations included: 1) Faucets in two locations in raw material processing areas that were not equipped with backflow prevention devices. 2) Flaking and bubbled paint on ceiling in raw material processing room where a dietary supplement component was being sliced for use in production and flaking paint and dust on piping located above the copper kettles used to cook honey mixture. 3) Uncovered light bulbs located directly above dietary supplement production in several areas of the plant. 4) Firm did not establish written procedures for calibrating steam oven used to kill pathogens in dietary supplement components. 5) Firm did not establish written procedures for cleaning the physical plant

No refusals were encountered. No product samples collected. No signs of insect, rodent, or avian activity observed. Label samples for all the products shipped to U.S. were collected.

ADMINISTRATIVE DATA

On 08/20/2012 credentials were presented and business cards exchanged with Dr. Hin Kai Chan, who introduced himself as the firm's Chairman. With him were his two brothers, Mr. 'Micky' Chan Hin Kuen, who introduced himself as Assistant to Chief Executive, and Mr. Paul Chan, who introduced himself as the firm's Director, and Mr. Albert Ma, who introduced himself as the firm's Sales Manager. Dr. Chan stated that he is the most responsible person at the firm. During the course of the inspection I informed Dr. Chan and all present about FDA's Reportable Food Registry (RFR)

program, and I showed them where this document was available on FDA's Web site. Mr. Paul Chan saved the RFR page on his computer.

A 5 item FDA 483 was issued at the close of this inspection.

No refusals were encountered. No samples collected. No signs of insect, rodent, or avian activity observed. Label samples for all the products shipped to U.S. were collected.

No representatives from Hong Kong's Competent Authority (CA) were present for this inspection.

HISTORY

This is the initial inspection. There were no historical records on file regarding this firm including consumer complaints.

This inspection revealed that the firm is manufacturer of dietary supplements. The firm is currently exporting these products to the United States. There were no shipments from this facility to the U.S. in 2012.

Chan Li Chai Medical Factory was founded in 1600 by the Chan and Li families. Dr. Chan and his family are the 13th generation owners of this firm. Today, Chan Li Chai Medical Factory a privately held Hong Kong company. The ownership is shared by Dr. Chan and his two brothers.

The plant, laboratory, storage, and administrative offices occupy two buildings, each approximately 20,000 sq. ft. on second and third floors of a commercial building. The firm has been at this location for 15 years. The firm has 30 full time employees; they do not hire seasonal employees. Normal operating hours for administrative office are 08:30 to 5:00 pm, M – F; production starts at 8 am.

The firm sells 12 dietary supplement products to a single customer in U.S:

Madison One Acme Inc, (dba Solstice Medicine Company) (FEI: 3003275421)

215 West Ann Street

Los Angeles, CA 90012-1812

888-221-3496

www.solsticemed.com

Solstice uses Edward Jordan dba Commit CHB as their Customs Brokers to import products into U.S.

Edward Jordan dba Commit CHB,
20539 Madrona Ave,
Torrance, CA 90503-3617
Tel. 310-294-3834
Fax 310-295-2434

The firm is registered in conformance with the Bioterrorism Act.

Correspondence should be addressed to:
Dr. Hin Kai Chan
Chan Li Chai Medical Factory (H.K.) Ltd.
FLAT A2, 3/F., BLOCK A,
FORTUNE FACTORY BLDG, 40 LEE CHUNG ST.
HONG KONG, SAR

JURISDICTION

This inspection revealed that the firm is manufacturer of dietary supplements. The firm is currently exporting these products to the United States. I evaluated documentation required by DS GMP (21 CFR 111), processing, raw material and finished product storage, storage of labeling and packaging materials, and employee practices. According to Dr. Chan, the following 12 products are currently being exported to the U.S.:

1. **SO HUP YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

2. **PO LUNG YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

3. **WOOD LOCK YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

4. **LI CHUNG YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

5. **WOO GARM YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

6. **BAK FUNG YUEN*****Herbal Supplement*** 10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

7. **NING SAN YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

8. **BO SAN YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

9. **AU WONG YUEN*****Herbal Supplement***10 Pills***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

10. **RAW LOOK MAY DAY WONG YUEN*****Herbal Dietary Supplement***12 Packets – 2.66 oz (75.6 g) Each Packet-0.22 oz (6.3 g)***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED. COM ***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

11. **KWAI LOOK YUEN*****Dietary Supplement***12 Packets – 2.67 oz. (75.6 g) Each Packet-0.22 oz (6.3g)*** Distributed by: SOLSTICE MEDICINE COMPANY 215 West

Ann Street, Los Angeles, CA 90012***toll Free 1-888-2213496***WWW.SOLSTICEMED .COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

12. **STEAMED LOOK MAY DAY WONG YUEN***Herbal Dietary Supplement***12 Packets – 2.66 oz (75.6 g) Each Packet-0.22 oz (6.3 g)***Distributed by: SOLSTICE MEDICINE COMPANY 215 West Ann Street, Los Angeles, CA 90012***toll Free 1-888-221-3496***WWW.SOLSTICEMED.COM***manufactured by: Chan Li Chai Medical Factory (H.K.) Ltd. Hong Kong***

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Dr. Hin Kai Chan – Chairman and Managing Director. Dr. Chan is responsible for overall function of Chan Li Chai Medical Factory, which includes his role as head of Quality Control Department. Dr. Chan has a PhD in Analytical Chemistry and has developed the quality control procedures for raw materials, in-process and finished product analysis. Dr. Chan has detailed knowledge of the production process and he appears to be well versed and competent in the area of food safety. He shares ownership of the company with two younger brothers Mickey and Paul. Dr. Chan was present during all aspects of the inspection during both days, as well as the closing meeting. He provided most of the information about the firm contained in this report.

Mr. Mickey Chan Hin Kuen – Assistant to the Chief Executive. Mr. Mickey Chan is the head of the Sales and Marketing Department, and he reports to Dr. Chan. He is a co-owner in the firm. Mr. Mickey Chan was present during all aspects of the inspection during both days, as well as the closing meeting.

Mr. Paul Chan – Director of Production. Mr. Paul Chan has been with the company for over 20 years, and has gained his knowledge in production form Dr. Chan and his experience at the firm. He is responsible for overseeing all aspects of production, raw material purchasing from the firm's 21 suppliers. He reports to Dr. Chan. He has detailed knowledge of the production process and he appears to be well versed and competent in the area of food safety. He was present during all aspects of the inspection during both days, as well as the closing meeting.

Mr. Alber Ma - Sales Manager. Mr. Ma is responsible for domestic and export sales, which includes the products which are exported to U.S. He reports to Dr. Chan. He was present during all aspects of the inspection during both days, as well as the closing meeting.

FIRM'S TRAINING PROGRAM

See Subpart B – Personnel

MANUFACTURING/DESIGN OPERATIONS

The product sold to Solstice Medicine Company is an herbal lozenge made up of approximately 50% mixture of pure honey and 50% powdered herbs and roots used in Chinese herbal medicines. According to Dr. Chan, most of the formulations date back to the company's beginning in the 17th century. Chan Li Chai has 12 different formulations for Solstice, all of which consists of the lozenge formulation of honey and pulverized herbs.

The product is sold in 3.7g and 6.3g lozenges which are individually sealed in a plastic ball, which is coated in food grade wax. The lozenge has a stated shelf life of 4 years; however, Dr. Chan said they can last up to 20 years if not exposed to air.

I showed Attachment E to Dr. Chan, and he stated that the firm does not use any of the botanicals on this list in the products they manufacture for Solstice Medicine Company.

Firm's flow diagram is provided as Exhibit 1.

Production starts with initial inspection of raw material for quality and conformance with product specifications. Some of the herbs require cleaning before pulverizing before incorporating into lozenge production. Some herbs are soaked, then cut into smaller pieces, then steam sterilized, oven-dried, and then pulverized into a fine powder. A sample of pulverized herbs is sent to QC for microbial testing. Product is held until sample is released by QC.

Lozenge production begins with heating of honey in a copper bowl to 128°C (262°F) (Exhibit 3). A worker measures the temperature with and infrared thermometer during the heating process. Once the honey reaches this temperature, a few drops of honey are dropped into cold water to test hardness. When honey reaches appropriate temperature, the kettle is removed from heat and honey is transferred to an empty copper kettle using stainless steel scoops (Exhibit 4).

The honey is cooled slightly and added to a separate copper bowl which contains a pre-measured amount of pulverized herbal ingredients and mixed thoroughly by a worker with a plastic paddle (Exhibit 5). A worker then rolls honey/herb mixture into logs and lets them cool (Exhibit 6) before placing logs into a cutting machine which forms the lozenges (Exhibit 7). The lozenges are collected into stainless steel trays and cooled under an electric fan until they harden (Exhibit 8).

Hardened lozenges are transferred to encapsulation room where they are manually placed into plastic shells (Exhibit 9) and dipped twice into hot wax to keep air out (Exhibit 10). Once the wax hardens, the lozenges are moved to packaging (Exhibit 11).

The general production flow for lozenges is as follows:

Receiving/storage → raw material inspection → initial processing of herbs → QC sample → cooking of honey → addition of pulverized herbs → transfer to cooling/molding table → cutting machine → cool with fans → encapsulating/hot wax dip → packaging → shipping/storage.

SUBPART B – PERSONNEL

- The firm has a written employee health policy which includes provisions for determining employee's health in order to work in production of dietary supplements, doctor visits, and reassignment to non-food contact duties.
- Firm has written procedures for training personnel in various job functions; they maintain written records of date and type of training received for the length of the person's employment.
- Dr. Chan is responsible for overseeing training and associated record keeping.

SUBPART C – PHYSICAL PLANT AND GROUNDS

- The firm does not have written procedures and records for plant sanitation and pest control (Observation 5).
- Because the firm is located on the 2nd and 3rd floors, they have never had rodent issues. The production room and storage areas are air conditioned, and windows are kept closed. Plant appears well screened against rodents and flying insects. No signs of insect, rodent, or avian activity observed.
- Water is municipally supplied. Water is not used as an ingredient in any of the firm's finished product, however, it is used to re-hydrate some of the herbs before steam sterilization. The firm does not test the water, but relies on the water testing results provided by local government authorities.
- Hand-washing facilities are provided in close proximity to production area; bathrooms appear sanitary and well maintained.
- The firm does not have an assigned sanitation supervisor; instead, workers in each production room are responsible for clean-up.

SUBPART D – EQUIPMENT AND UTENSILS

- Mechanical and electric equipment is checked pre-operation and appears to be well maintained and monitored by qualified employees.
- Temperature of heated honey is monitored by an employee using an infra-red thermometer. The thermometer is not calibrated; however, the correct temperature of boiling honey is verified by drizzling several drops of honey into cold water to test the hardness.
- Equipment and utensils are made of stainless steel and non-reactive plastics; they appear to be well designed, constructed and maintained. Designated wood dowels are used to stir the honey while it's cooking.
- The firm has written procedures and records for calibrating laboratory equipment, but not for thermometers and oven used in production.

- The firm has written procedures for cleaning and maintenance of the equipment, and they appear to be performing these functions. Each production area maintains log books to monitor cleaning and maintenance (Exhibit 12)
- Freezers and refrigerators are not used in production or storage.

Production and Process Control System

SUBPART E – **REQUIREMENTS TO ESTABLISH A PRODUCTION AND PROCESS CONTROL SYSTEM**

- The firm has written specifications for their products which include steps and procedures covering all stages of manufacturing, packaging, labeling, and holding to ensure quality of dietary supplements.
- QC personnel test raw material, in process samples, and finished product to ensure dietary supplements conform to specifications.
- Not all ingredients received from supplier are accompanied by Certificates of Analysis for purity, product identity and safety. According to Dr. Chan, the certificates of analysis are not a common practice in Hong Kong. The firm performs its own analysis on incoming ingredients prior to using these ingredients in production.
- Firm has written procedures for conformance of all raw materials, and finished products to specifications, and rejects procedures if specifications are no met.

Production and Process Control

SUBPART F – QUALITY CONTROL

- QC personnel have written procedures for determining supplier qualification criteria.
- Dr. Chan has developed QC procedures to help ensure that identity, purity, strength, and composition of dietary supplements are met.
- The firm does not exempt any products from verification of conformance with their standards.

Laboratory Operations

- QC personnel review and approve all laboratory quality control processes associated with production of dietary supplements. The laboratory appears clean, well lit, and sufficiently equipped to conduct the various analyses the firm performs.
- QC personnel test raw material, in process samples, and finished product to ensure dietary supplements conform to standards, and are manufactured to ensure quality of the dietary supplement

Material Review and Disposition.

- Dr. Chan stated that due to the relatively simple manufacturing process and few ingredients, they have not had a corrective action to their manufacturing process.

Equipment, Instruments and Controls.

- The firm has written procedures and records for calibrating laboratory equipment, but not for thermometers and oven use in production.

Components, Packaging and Labeling.

- Components, packaging and labels are reviewed by QC prior to use in production. This process involves proofreading the labels by 2 employees to make sure the labels meet specifications; components and packaging is inspected for suitability.

Master Manufacturing Record, Batch Record and Manufacturing Operations

- QC personnel review and approve all MMRs, all modifications, in-process, batch release records, as well as making a determination that finished product meets specifications.
- Production records from date of inspection were signed off by employees who performed various production steps, and the records are forwarded to QC for monitoring. Although the records are in Chinese, I was able to review the necessary information with translation provided by Dr. Chan.
- QC personnel determine compliance with in-process specifications.
- QC personnel make final determination as to conformance of finished dietary supplement with product specifications.

Packaging and Labeling

- Firm does not repack dietary supplements.
- QC personnel have a written procedure for packaging and labeling, and approve packaging and labeling prior to use in production.
- Finished dietary supplements are lot coded only after QC releases the batch. Firm uses color coded tags to identified released and 'QC hold' products.

Returned Dietary Supplements

- QC manager has written procedure for returned dietary supplements; the firm has never had a returned product from their U.S. customers.
- QC personnel have written procedures for determining if returned product can be reworked, or if it has to be disposed. If product could be re-processed, it would be considered a new product, and undergoe the same QC procedures as a new product.

Product Complaints

- QC personnel would be involved in the decision to investigate product complaint. The firm has never had a complaint from their U.S. customers.

SUBPART G – COMPONENTS, PACKAGING AND LABELING

- Firm has a designated reception area where incoming raw material is received and held until QC releases the products.
- The firm maintains batch production records, which include a copy of the label for at least 6 years; which is two years past firm's products with longest shelf life of 4 years. Records are signed by analyst and QC Supervisor.

SUBPART H – MASTER MANUFACTURING RECORD

- The firm maintains a Master Manufacturing Record (MMR) for each unique formulation which includes the necessary monitoring steps and specifications to ensure a quality dietary supplement product.

SUBPART I – BATCH PRODUCTION RECORDS

- I examined batch production record from 08/20/2012 (1st day of inspection). The record appears to be complete under requirements of 21 CFR parts 255, and 260. Although the records are in Chinese, I was able to review the necessary information with translation provided by Dr. Chan.

SUBPART J – LABORATORY OPERATIONS

- The firm has written procedures for laboratory operations, including testing of raw materials, in-process batches and finished product for conformance to specifications.
- Laboratory uses well established methods to perform quality analysis on their products, such as the Chinese pharmacopeia, and analytical methods developed by Dr. Chan in-house.
- Laboratory maintains records for at least 6 years; which is two years past firm's products with longest shelf life of 4 years. Appropriate records are signed by analyst and QC Supervisor.

SUBPART K – MANUFACTURING OPERATION

- The firm established and follows written manufacturing procedures.
- The firm appears to take appropriate precautions to prevent contamination of components and dietary supplements. The firm does not use any allergenic ingredients.
- Incoming raw material is received and held until QC releases the products. Firm uses color coded tags to identified released and 'QC hold' products. A different color tag is applied when QC clears the product for production.

SUBPART L – PACKAGING AND LABELING OPERATION

- Firm has written procedures for packaging and labeling which includes the name of the product, volume, product number, lot number, and lot code; examination of labels prior to shipping; labeling and packaging in a clean and sanitary environment; and with use of finished product lot codes to determine complete manufacturing history of dietary supplement.

SUBPART M – HOLDING AND DISTRIBUTING

- Firm has written procedures for holding raw materials and finished product. The warehouse area is temperature controlled, and products are held under suitable conditions. At time of inspection, temperature was approximately 23°C (73°F) and 68% humidity as indicated by a temperature/humidity gauge in the storage room (Exhibit 13).
- Firm has written procedures and maintains written and electronic distribution records for products exported to U.S.
- Retain samples are held for at least 6 years; which is two years past firm's products with longest shelf life of 4 years. Appropriate records are signed by analyst and QC Supervisor.
- Retain samples are held in original packaging under ambient temperature.

Product Complaint and returns.

SUBPART N – RETURNED DIETARY SUPPLEMETS

- Firm has written procedures for handling returned products. QC manager has written procedure for returned dietary supplements, the firm has never had a returned product from its U.S customer.
- If product is re-processed, it is considered a new product, and undergoes the same QC procedures as a new product.

SUBPART O – PRODUCT COMPLAINTS

- The firm has a written complaint file and procedures in English; they have never had a complaint from their U.S, customers for their products. QC personnel would be researching the nature of the complaint, and determining if product was out of specifications, contaminated, or otherwise unfit for use. The firm has never had consumer complaints for safety.

SUBPART P – RECORDS AND RECORD KEEPING

- All records associated with production are kept for at least 6 years; which is 2 years past firm's products with longest shelf life of 4 years.

MANUFACTURING CODES

Production lot code on labels for the products shipped to U.S. The example code consists of the following sequence:

CLC 006 030712

Expiry date xx xx xx where:

CLC – indicates name of manufacturer i.e. Chan Li Chai

006 - indicates 3 digit product code

030712 - indicates 6 digit day of production i.e. 3 July, 2012

Expiration date is always 4 years from date of production: 2 digit day, 2 digit month, 2 digit year.

RECALL PROCEDURES

The firm maintains a written recall plan in English. The plan includes directions for traceability, and notification of customers (Exhibit 17). The firm has never had to conduct a recall of their products.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

A 5 item FDA 483 was issued at the close of this inspection.

Observations listed on form FDA 483

OBSERVATION 1

The plumbing in your physical plant allows backflow from piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.

Specifically, I observed faucets in two locations in raw material processing areas that were not equipped with backflow prevention devices.

Reference: 21 CFR 111.15(f)(5)

Supporting Evidence and Relevance:

(Photo Exhibit 14). Photo shows rubber hose connected to a faucet and laying in a floor sink. Use of backflow prevention devices is important in a food processing facility to protect potable water supply from contamination from waste water.

Discussion with Management:

Dr. Chan stated that he will consult with plumbers to determine the proper type of backflow protection device to install in the plant. He estimates to have the plumbing issue corrected within one month.

OBSERVATION 2

You did not maintain your physical plant in repair sufficient to prevent components, dietary supplements, or contact surfaces from becoming contaminated.

Specifically, I observed

1) Flaking and bubbled paint on ceiling in raw material processing room where a dietary supplement component was being sliced for use in production.

2) Flaking paint and dust on piping located above the copper kettles used to cook honey mixture.

Reference: 21 CFR 111.15(b)(2)

Supporting Evidence and Relevance:

(Photo Exhibit 15,16). Flaking and peeling paint directly above dietary supplements and its components constitutes a risk of contamination from falling paint fragments and other debris.

Discussion with Management:

Dr. Chan stated that he will consult with contractors to determine the proper course of repairs to be undertaken to refinish the ceiling. He estimates to have the work completed within one month.

The flaking paint and dust in observation 2 was cleaned up before start of inspection on the second day.

OBSERVATION 3

You did not use safety-type light bulbs over exposed components or dietary supplements.

Specifically, I observed uncovered light bulbs located directly above dietary supplement production in several areas of the plant.

Reference: 21 CFR 111.20(f)

Supporting Evidence and Relevance:

Use of safety-type light bulbs when light bulbs are suspended over exposed components or dietary supplements must be used to protect against contamination in case of breakage of glass.

Discussion with Management:

Dr. Chan stated that he will research to determine the proper type of safety light bulbs, or light covers to purchase. He estimates to have the work completed within one month.

OBSERVATION 4

You did not make and keep written procedures for calibrating instruments or controls that you use in manufacturing a component or dietary supplement.

Specifically, You have not established written procedures for calibrating steam oven used to kill pathogens in dietary supplement components.

Reference: 21 CFR 111.35(b)(1)(i)

Supporting Evidence and Relevance:

Written procedures for calibrating instruments and controls that you use in manufacturing a component or dietary supplement must be made and kept.

Discussion with Management:

Dr. Chan stated that he will research the regulation and write an appropriate procedure for calibrating steam oven and retain calibration records for a specified period. He estimates to have the work completed within one month.

OBSERVATION 5

You did not establish written procedures for cleaning the physical plant.

Specifically, You have not established written procedures to comply with this section of the regulations.

Reference: 21 CFR 111.16

Supporting Evidence and Relevance:
You must establish and follow written procedures for cleaning the physical plant and for pest control.

Discussion with Management:
Dr. Chan stated that he will write an appropriate procedure for cleaning the plant and for pest control. He estimates to have the work completed within one month.

REFUSALS

No refusals encountered.

GENERAL DISCUSSION WITH MANAGEMENT

For closing of the inspection I was joined by Dr. Hin Kai Chan, the firm's Chairman; Mr. Micky Chan Hin Kuen, Assistant to Chief Executive; Mr. Paul Chan, Director; and Mr. Albert Ma, Sales Manager. FDA 483, Inspectional Observations was issued to Dr. Hin Kai Chan.

ADDITIONAL INFORMATION

CFSAN to review labels for possible health benefit claims.

SAMPLES COLLECTED

No samples collected.

VOLUNTARY CORRECTIONS

The flaking paint and dust in observation 2 was cleaned up before start of inspection on the second day.

EXHIBITS COLLECTED

Photo/Doc Exhibits

Exhibit 1. Copy of invoice and Bill of Lading to Madison One Acme Inc. (2 pages)

Exhibit 2. Firm's flow diagram for lozenge production.

Exhibit 3. Lozenge production begins with heating of honey in a copper bowl to 128°C (262°F).

Exhibit 4. When honey reaches appropriate temperature, the kettle is removed from heat and honey is transferred to an empty copper kettle using stainless steel scoops.

Exhibit 5. Honey is transferred to copper bowl which contains a pre-measured amount of pulverized herbal ingredients and mixed thoroughly by a worker with a plastic paddle.

Exhibit 6. A worker then rolls honey/herb mixture into logs and lets them cool.

Exhibit 7. A cutting machine which forms the lozenges.

Exhibit 8. The lozenges are collected into stainless steel trays and cooled under an electric fan until they harden.

Exhibit 9. Hardened lozenges are manually placed into plastic shells.

Exhibit 10. plastic shells are dipped twice into hot wax to keep air out

Exhibit 11. Lozenges are individually packaged.

Exhibit 12. Each production area maintains log books to monitor cleaning and maintenance.

Exhibit 13. At time of inspection, temperature was approximately 23°C (73°F) and 68% humidity as indicated by a temperature/humidity gauge in the storage room.

Exhibit 14. Rubber hose connected to a faucet and laying in a floor sink.

Exhibit 15. Flaking and peeling paint directly above dietary supplements processing.

Exhibit 16. Flaking and peeling paint directly above dietary supplements processing.

Exhibit 17. Firm's a written recall plan in English (2 pages).

Label Exhibits (also on CD)

Exhibit 18. **SO HUP YUEN**
Exhibit 19. **PO LUNG YUEN**
Exhibit 20. **WOOD LOCK YUEN**
Exhibit 21. **LI CHUNG YUEN**
Exhibit 22. **WOO GARM YUEN**
Exhibit 23. **BAK FUNG YUEN**
Exhibit 24. **NING SAN YUEN**
Exhibit 25. **BO SAN YUEN**
Exhibit 26. **AU WONG YUEN**
Exhibit 27. **RAW LOOK MAY DAY WONG YUEN**

Exhibit 28. **KWAI LOOK YUEN**
Exhibit 29. **STEAMED LOOK MAY DAY WONG YUEN**
Exhibit 30. Firm's response to 483.
Exhibit 31. Sealed envelope containing disk with photographs.

ATTACHMENTS

FDA Form 483 Inspectional Observations.

Samuel Rudnitsky, Investigator