

Establishment Inspection Report

Acidchem International Sdn. Bhd.
Prai, Malaysia

FEI: 3004256236
EI Start: 09/05/2012
EI End: 09/07/2012

SUMMARY

The comprehensive inspection of this foreign manufacturer was conducted on a surveillance basis per a high priority assignment (FACTS 1423293) issued by FDA's Center for Veterinary Medicine (CVM). This inspection (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential were made under ORA's Division of Foreign Field Investigations' Trip #2012-220F. The current inspection was reported under Turbo #306909. The inspection was accomplished per instructions for conducting inspections of food facilities in C. P. 7303.803, Domestic Food Safety Program. Inspectional time was reported under PAC 03803 per FY 12 instructions for reporting foreign food inspections and PAC 71R801 Consumer Complaints- Post Approval Monitoring CVM. The firm manufactures glycerin (USP 99.5% minimum) and fatty acids made from palm-based oils. The glycerin is distributed (b)(4) - Commercial Confidential and used by a variety of manufacturers throughout the world in human foods, pet foods, pharmaceutical products, cosmetics and personal care products such as soap and shampoo. This was the initial inspection of the firm by FDA.

The inspection (b)(4) - Commercial Confidential was prompted by (b)(4) - Commercial Confidential that was documented by FDA during an inspection of a jerky pet treat manufacturer in (b)(4) - Commercial Confidential in March 2012. Since 2007, FDA has received approximately 2,000 reports of pet illnesses which may be associated with the consumption of jerky pet treats from (b)(4) - Commercial Confidential. FDA has tested over 700 imported jerky pet treat samples for a wide array of potential contaminants, but has not (b)(4) - Commercial Confidential. In March and April 2012, FDA conducted inspections of (b)(4) - Commercial Confidential jerky pet treat manufacturers in (b)(4) - Commercial Confidential whose products were the subject of most of the illness reports/complaints. One of the main constituents of the jerky treats is glycerin. One jerky pet treat manufacturer in (b)(4) - Commercial Confidential was found to (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential on-hand during the inspection, which was labeled as USP grade for food and pharmaceutical use. (b)(4) - Commercial Confidential was the same brand (b)(4) - Commercial Confidential. However, the inspection revealed that the manufacturer routinely had been using glycerin from (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential that was labeled for industrial use only because they claimed it was (b)(4) - Commercial Confidential labeled as industrial use rather than as food or pharmaceutical grade. They claimed the glycerin from Acidchem International was really (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential

The assignment from CVM (see Attachment 1) requested the inspections of (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential cover several aspects including (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

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The firm was in full production manufacturing fatty acids and glycerin during the inspection. I observed the complete processing operations for glycerin. I observed the physical condition of the plant's buildings and grounds, the condition of equipment, and storage conditions.

The general findings were as follows:

The firm only uses (b)(4) - Commercial palm kernel oil and (b)(4) - Commercial Co palm stearine as raw materials. It receives Certificates of Analysis (CoA) from suppliers for each load. Firm tests each load for (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential

No other raw materials are used. No biodiesel byproducts are used. The primary products manufactured by the firm are fatty acids (b)(4) - Commercial Confidential. Glycerin only accounts for about (b)(4) - Commercial Confidential of production. The equipment and processes are designed for (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. They said it would be impractical and expensive for them to use other raw materials. In addition, there is an ample supply of palms in Malaysia and (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential

The firm does not receive any (b)(4) - Commercial glycerin from other suppliers. It occasionally purchases (b)(4) - Commercial Confidential glycerin (b)(4) - Commercial Confidential from (b)(4) - Commercial other manufacturers in (b)(4) - Commercial Confidential who use palm-based oils as a raw material. Glycerin from other suppliers is held (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. They do not commingle their glycerin with glycerin from other suppliers.

The basic procedure for manufacturing glycerin is the palm-based oils undergo a process called (b)(4) - Commercial Confidential

All tanker trucks and storage tanks are dedicated for specific uses. No other materials are stored in them. For example, (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential

Glycerin is packed into (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

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(b)(4) - Commercial Confidential

The firm does (b)(4) - Commercial Confidential testing on each lot of (b)(4) - Commercial Confidential glycerin for the full USP monograph standards for glycerin including (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

All glycerin manufactured and exported by the firm meets Food Chemical Codex (FCC) and USP standards of 99.5% minimum glycerin. In regards to the firm labeling glycerin exported to (b)(4) - Commercial Confidential as (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential in (b)(4) - Commercial Confidential specified that the shipping marks (“labeling”) on the (b)(4) - Commercial Confidential drums state “for industrial use only” even though the label also states the glycerin is 99.5% minimum. They explained (b)(4) - Commercial Confidential want glycerin marked as industrial use only so (b)(4) - Commercial Confidential They repeatedly stated that all glycerin manufactured by Acidchem International meets 99.5% USP minimum standards. They do not manufacture a lower “industrial” grade glycerin.

I reviewed (b)(4) - Commercial Confidential Certificates of Analysis at Acidchem International for glycerin that had been identified as being from Acidchem International in the establishment inspection report of the jerky pet treat manufacturer in (b)(4) - Commercial Confidential who was found (b)(4) - Commercial Confidential These CoAs dated from November 2009 to February 2012. All were found to meet minimum USP standards for glycerin.

I informed the firm that intentionally labeling glycerin as industrial use only, when it is actually food grade and pharmaceutical grade could be construed as misbranding. I said typically misbranding happens when a company labels an inferior product as a superior product, whereas in this case the firm was labeling a superior grade of product as inferior. They replied that they were only following their customers’ request for shipping marks on the containers. They were aware that the intent of labeling the product as industrial use was (b)(4) - Commercial Confidential I mentioned that mislabeling the glycerin has thus far resulted in FDA and the (b)(4) - Commercial Confidential government addressing the issue with the jerky pet treat manufacturer in (b)(4) - Commercial Confidential They indicated that they understood and would discuss this matter with their distributors in (b)(4) - Commercial Confidential They stated that all glycerin exported by the firm to (b)(4) - Commercial Confidential meets USP monograph standards and is labeled as such for food grade and pharmaceutical uses.

No objectionable conditions were noted. No FDA-483 was issued. No refusals were encountered.

Five samples were collected during the inspection. They are INV 769886 crude glycerin, INV 769887 refined glycerin, INV 769888 refined glycerin, INV 769889 crude palm kernel oil, and INV 769890 refined palm stearine.

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The samples were shipped from Malaysia to FDA's Forensic Chemistry Center in Cincinnati, OH. The glycerin samples were to be analyzed for impurities and contaminants including DEG and EG. The palm kernel oil and palm stearine were to be analyzed for identity and composition.

The facility is registered with FDA under The Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

ADMINISTRATIVE DATA

Inspected firm: Acidchem International Sdn. Bhd.
Location: 2411 Lorong Perusahaan Satu
Prai Industrial Complex
13600 Prai, Penang, Malaysia
Phone: 60 4 390 7818
FAX: 60 4 390 7252
Mailing address: 2411 Lorong Perusahaan Satu
Prai Industrial Complex
13600 Prai, Penang, Malaysia
Website: www.ioioleo.com
Dates of inspection: 9/5/2012, 9/6/2012, 9/7/2012
Days in the facility: 3
Participants: David J. LeRay, Investigator

The firm is inspected by the Food Safety & Quality Division of the Penang State Health Department, under the Malaysian Ministry of Health (MOH). The firm is HACCP certified and undergoes audits per (b)(4) - Commercial Confidential. I was accompanied by Ms. (b)(4) - Commercial Confidential, Ms. (b)(4) - Commercial Confidential and Mr. (b)(4) - Commercial Confidential who are food technologists with the Penang State Health Department.

HISTORY

Acidchem International Sdn. Bhd. is a privately-owned Malaysian company that is a subsidiary of IOI Corporation Bhd. (a/k/a "IOI Group"). IOI Corporation is a large publicly traded Malaysian corporation. It was founded in 1980 as a palm kernel oil business. It has expanded through internal growth and acquisitions into a multi-faceted business with three main divisions- plantations, manufacturing, and property. It touts itself as the world's largest oleochemical producer.

The manufacturing division of IOI Corporation is called IOI Oleochemicals Industries Sdn. Bhd. It is a group of (b)(4) - Commercial Confidential plants in Malaysia that manufacture fatty acids, fatty esters, glycerin, and soap noodles (used to make soap). Acidchem International Sdn. Bhd. and (b)(4) - Commercial Confidential

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(b)(4) - Commercial Confidential are the business units of IOI Oleochemical Industries that manufacture fatty acids and glycerin.

Acidchem International began operations in 1980. It calls each of its five on-site processing units a "series". The oldest one is Series 1, which opened in 1980. The others are Series 2 in 1988, Series 3 in 1993, Series 4 in 1996, and Series 5 in 2002. All series plants produce glycerin USP 99.5% minimum. Mr. Lai Choon Wah is the General Manager and most responsible individual of Acidchem International.

All FDA correspondence should be addressed to:

**Mr. Lai Choon Wah, General Manager
Acidchem International, Sdn. Bhd.
2411 Lorong Perusahaan Satu
Prai Industrial Complex
13600 Prai, Penang, Malaysia**

The firm continuously operates 24 hours per day for seven days a week throughout the year. There are (b)(4) - Commercial Confidential shifts per day from (b)(4) - Commercial Confidential. The filling ("drumming") section works (b)(4) - Commercial Confidential. The firm shuts down every (b)(4) - Commercial Confidential for complete maintenance. (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential

The firm has about (b)(4) - Comm employees, of which about (b)(4) - Comm work in the production-related areas and the rest are administrative personnel in the office.

INTERSTATE COMMERCE

Dr. Lee Kim Eng, Assistant General Manager, Ms. (b)(4) - Commercial Confidential Marketing Manager (b)(4) - Commercial Confidential and Mr. (b)(4) - Commercial Confidential Marketing Manager for (b)(4) - Commercial Confidential provided production, sales, and export information.

The overall production and sales totals for Acidchem International during their fiscal year of July 1, 2011 to June 30, 2012 were about (b)(4) - Commercial Confidential of fatty acids, fatty esters and glycerin valued at about (b)(4) - Commercial Confidential. Fatty acids accounted for about (b)(4) - Commercial Confidential of production, fatty esters were about (b)(4) - Commercial Confidential and glycerin was about (b)(4) - Commercial Confidential. The firm exports products to over (b)(4) - Comm countries including (b)(4) - Commercial Confidential

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Acidchem International exported approximately (b)(4) - Commercial Confidential of glycerin valued at (b)(4) - Commercial Confidential and (b)(4) - Commercial Confidential of fatty acids valued at (b)(4) - Commercial Confidential to (b)(4) - Commercial Confidential from 7/1/11 to 6/30/12. The shipments of glycerin to (b)(4) - Commercial Confidential were as follows:

(b)(4) - Commercial Confidential

Acidchem has a sales office in the USA. It is called Acidchem (USA), Inc. in Rochelle Park, NJ (FEI 3001317724). Mr. Joe Emuang is the Vice-President of Acidchem USA. Most glycerin

(b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

Acidchem International in Malaysia also directly sells and exports (b)(4) - Commercial Confidential glycerin to two primary customers in (b)(4) - Commercial Confidential. They are (b)(4) - Commercial Confidential in (b)(4) - Commercial Confidential and (b)(4) - Commercial Confidential in (b)(4) - Commercial Confidential.

The firm regularly exports glycerin to (b)(4) - Commercial Confidential distributors in (b)(4) - Commercial Confidential mostly in (b)(4) - Commercial Confidential. Mr. (b)(4) - Commercial Confidential said Acidchem International does not sell glycerin directly to end-users (such as jerky net treat manufacturers). The firm's primary customer in (b)(4) - Commercial Confidential is (b)(4) - Commercial Confidential with locations in (b)(4) - Commercial Confidential (firm not listed in FACTS). According to Mr. (b)(4) - Commercial Confidential and other distributors in (b)(4) - Commercial Confidential routinely request Acidchem to apply a shipping mark (label) indicating the 99.5% minimum USP glycerin as (b)(4) - Commercial Confidential.

JURISDICTION

Acidchem International manufactures and exports primarily fatty acids such as lauric acid, stearic acid, palmitic acid and several others. Fatty acids account for over (b)(4) - Commercial Confidential of production. The firm also manufactures and exports fatty esters and glycerin. All of these products are made from palm kernel oil and palm stearine.

The glycerin is (b)(4) - Commercial Confidential and typically exceeds (b)(4) - Commercial Confidential. It meets FCC food grade and USP pharmaceutical grade standards for identity and purity. Glycerin is a bulk chemical used in manufacturing a wide variety of items including human foods as a GRAS food additive, pet foods, pharmaceuticals, cosmetics, and personal care products such as soap and shampoo. It serves as a

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humectant and solvent in products. It also has many industrial applications in products ranging from plastics to paint and lubricants.

Exhibit 1 is IOI Group's brochure listing its various fatty acid products and glycerin. It includes the specifications for each product. The firm labels and markets its products, including glycerin, under its brand name of "PALMAC".

Glycerin is packed into (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

caps are crimped onto both ports at the top of the (b)(4) - Commercial Confidential. The caps have Acidchem International's name and IOI Oleochemicals' name on them. Exhibit 2 is a copy of the (b)(4) - Commercial Confidential seal caps applied to (b)(4) - Commercial Confidential of glycerin. The firm (b)(4) - Commercial Confidential using

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential The container has a port on top and a spout at the bottom. (b)(4) - Commercial Confidential on the cage's metal plate indicating the product and its purity (e.g. glycerin 99.5%) and lot number, brand name and logo, the firm's name and location, and weight. Exhibit 3 is a labeled sticker for PALMAC brand glycerin. The firm prints only the number of stickers needed for the number of IBCs filled.

Exhibit 4 is an adhesive sticker labeled (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential Mr. (b)(4) - Commercial Confidential said this sticker is affixed to (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Lee Shin Cheng is the Chairman of the Board for IOI Corporation Bhd. He is the overall most responsible individual for the entire IOI Corporation's group of companies. He maintains an office at the firm's headquarters in Kuala Lumpur, Malaysia. He was not present during the inspection. He has the overall duty, power and responsibility to detect, prevent, and correct violative conditions at all of IOI Corporation's facilities.

Mr. Lee Yeow Chor is the Executive Director of IOI Corporation Bhd. He is the most responsible individual for the oversight of the entire IOI Corporation's group of companies. He reports to Mr. Lee Shin Cheng, Chairman of the Board. He maintains an office at the firm's headquarters in Kuala

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Lumpur, Malaysia. He was not present during the inspection. He has the duty, power and responsibility to detect, prevent, and correct violative conditions at all of IOI Corporation's facilities.

Mr. Tan Kean Hua is the Executive Director of IOI Oleochemicals Industries Sdn. Bhd. He is the most responsible individual for the oversight of the five oleochemical plants in this division, including Acidchem International. He reports to Mr. Lee Yeow Chor. He maintains an office at the firm's headquarters. He was not present during the inspection. He has the duty, power and responsibility to detect, prevent, and correct violative conditions at all of IOI Oleochemicals Industries facilities.

Mr. Lai Choon Wah is the General Manager for Acidchem International. He reports to Tan Kean Hua, Executive Director of IOI Oleochemicals Industries. Mr. Lai Choon Wah provides general oversight and direction to Acidchem International. He oversees all aspects of operations. He was not present during the inspection. He has the duty, power and responsibility to detect, prevent, and correct violative conditions at Acidchem International.

Dr. Lee Kim Eng is the Assistant General Manager for Acidchem International. She reports to Mr. Lai Choon Wah, General Manager. Dr. Lee is responsible for the sales and distribution activities of Acidchem International. She also oversees general production operations and quality assurance. She maintains an office at the facility and is present on a daily basis. She was present and participated in the opening meeting on 9/5/12, the record review portion of the inspection on 9/6-7/12, and the closing meeting on 9/7/12. She demonstrated a thorough knowledge of the company and its operations and provided relevant information about such. She instructed sales and marketing staff, quality assurance staff, laboratory staff, and production staff to provide me with copies of requested records.

Dr. Lee Kim Eng, Assistant General Manager, has the duty, power and responsibility to detect, prevent, and correct violative conditions at Acidchem International.

Mr. Norzamy Ibrahim is the Senior Production Manager for the Series 5 plant. Mr. Khor Kok Hiang is the Senior Production Manager for the Series 1, 2, 3, & 4 plants. Messrs. Ibrahim and Khor are responsible for the production operations at their respective plants. They accompanied me throughout the inspection of their respective plants. They demonstrated a thorough knowledge of their plants and operations and provided relevant information about such. Mr. Ibrahim was present at the opening and closing meetings. Mr. Khor was present at the closing meeting.

Mr. **(b)(4) - Commercial Confidential** He is responsible for overseeing the quality control and research & development departments. He was present during the opening and closing meetings.

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Mr. (b)(4) - Commercial Confidential Ms. (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential Ms. (b)(4) - Commercial Confidential These individuals directly oversee the administration of the firm's quality assurance and control operations. Mr. (b)(4) - Commercial Confidential is responsible for overseeing the laboratory operations. They wrote the firm's food safety and QA manuals and procedures. They were present at the opening and closing meetings. They accompanied me throughout the inspection. They demonstrated a thorough knowledge of the firm and its operations and provided relevant information about such. They provided me with copies of documents when requested.

I provided Ms. (b)(4) - Commercial Confidential Marketing Manager for (b)(4) - Commercial Confidential markets, with ALERT information, FDA's Reportable Food Registry Guidance document, and the Food Safety Modernization Act information sheet about user fees and discussed these documents with her and other company officials.

MANUFACTURING OPERATIONS

Acidchem International is located in the Prai Industrial Complex near the shipping port. The plant and its related buildings are located on about (b)(4) - Commercial Confidential. The firm refers to the original site with Series 1, 2, 3, & 4 as "Acidchem 1". It is about (b)(4) - Commercial Confidential. Exhibit 5.1 is a site diagram provided by the firm of "Acidchem 1". The firm refers to the new site with Series 5 as "Acidchem 2". It is about (b)(4) - Commercial Confidential. Exhibit 5.2 is a site diagram provided by the firm of "Acidchem 2". I made handwritten notes and marks on the diagrams indicating significant areas of these sites.

Series 1 is the original fatty acid and glycerin plant built in 1980. (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential Series 2 & 3 use mostly crude palm kernel oil to make fatty acids and glycerin. Occasionally, Series 2 uses refined palm stearine as a raw material. Series 4 uses palm stearine to make fatty acids only. (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential Series 5 at Acidchem 2 uses crude palm kernel oil to make fatty acids and glycerin. It also bleaches palm kernel oil before splitting if a customer requests it.

The terms "series" and "plants" are used interchangeably by the firm. However, the firm further designates individual sections as plants. For example, (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

The firm was manufacturing fatty acids and glycerin during the inspection. I only covered the production of glycerin since that was the focus of the assignment. I observed the complete

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processing operations for glycerin at the Acidchem 2 site (Series 5), which is the newest plant. I also observed some operations at Series 2 & 3 of the Acidchem 1 site. The following is a description for processing glycerin primarily at Acidchem 2 using Series 5. Information in this section was obtained by observing production operations and interviews with management of the firm.

IOI Corporation's plantation division owns approximately (b)(4) - Commercial Confidential of palm tree plantations. Approximately (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

According to the firm, all tanker trucks are dedicated strictly for hauling palm-oil based products. Most tanker trucks are owned and operated by commercial transportation companies. Some are owned by the crushing facilities and refineries. Tanker ships must be able to demonstrate they

(b)(4) - Commercial Confidential

As noted previously, the firm only uses crude palm kernel oil and RBD palm stearine as raw materials to make fatty acids and glycerin. CPKO is the predominant raw material. The firm's flow diagram indicates RBD palm oil and RBD palm kernel oil may be used, but they said these two variations of refined palm oil products have not been used as raw materials at Acidchem International in several years.

The tanker trucks park at (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential crude palm kernel oil and palm stearine. The firm must (b)(4) - Commercial Confidential for each

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load of CPKO and palm stearine before it is accented. (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

Series 5 has the capability to bleach CPKO before further processing if a customer requests it. The CPKO is treated (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential Bleached CPKO can be used at Series 5 and also pumped through pipes (b)(4) - Commercial Confidential to Series 2 & 3. However, the firm uses mostly unbleached crude palm kernel oil to make fatty acids and glycerin. There are (b)(4) - Comm storage tanks for unbleached CPKO at Acidchem 2 totaling approximately (b)(4) - Commercial Confidential capacity.

At Acidchem 1 there are (b)(4) - Commercial raw material storage tanks totaling (b)(4) - Commercial Confidential capacity.

The first main step in the process is called (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

It should be noted that the entire aforementioned process (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

The process of filling glycerin into (b)(4) - Commercial Confidential is called “drumming” and occurs in a “drumming room”. There are separate drumming rooms for glycerin and fatty acids. The glycerin drumming room at Acidchem 1 is inside a small building located (b)(4) - Commercial Confidential. The glycerin drumming room at Acidchem 2 is inside a small building located (b)(4) - Commercial Confidential. The drumming rooms have restricted access. (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

The firm stores new, empty drums outside in (b)(4) - Commercial Confidential buildings. The drums have a (b)(4) - Commercial Confidential around them when received from the supplier. The drums are initially inspected upon receipt for (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential beneath the exterior metal caps. (b)(4) - Commercial Confidential The caps are (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

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During filling, the drums are (b)(4) - Commercial Confidential drumming room. Filling employees (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

Glycerin is filled into the drums through a (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. The operator (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. Mostly it is (b)(4) - Commercial Confidential but occasionally a customer wants (b)(4) - Commercial Confidential if glycerin in a drum. The filling machine has a (b)(4) - Commercial Confidential once the drum is positioned (b)(4) - Commercial Confidential. The operator pushes the start button allowing the glycerin to flow into the drum. When the drum is full, (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

The metal caps have Acidchem International's name and IOI Oleochemicals' name on them. Exhibit 2 is a copy of the metal caps applied to drums of glycerin. The employees use a (b)(4) - Commercial Confidential to tighten the caps and then a (b)(4) - Commercial Confidential to seal them tight.

The firm paints the lot code and net weight onto each drum using (b)(4) - Commercial Confidential. Customers' shipping marks are in the form of (b)(4) - Commercial Confidential onto the drums and adhesive stickers placed onto the drums.

The drums of glycerin are stored (b)(4) - Commercial Confidential until distribution. The drums are loaded into

(b)(4) - Commercial Confidential

Individual bulk containers (IBCs) can not fit into the drumming rooms. Therefore, the firm uses a

(b)(4) - Commercial Confidential

At Acidchem 2, the IBCs are positioned (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

IBCs are labeled with (b)(4) - Commercial Confidential adhesive stickers on a metal plate of the cage surrounding each plastic IBC. The stickers indicate the product and its purity (e.g. glycerin 99.5% check photo) and lot number, brand name and logo, the firm's name and location, and weight. The firm prints only the number of stickers needed for the number of IBCs filled.

There are separate filling stations at Acidchem 1 and Acidchem 2 to fill bulk ISO tanks, bulk flexitanks, and tanker trucks. The bulk tanks and tanker trucks are positioned (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

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Exhibit 6.1- 6.2 is a process flow diagram for glycerin provided by the firm. I verified its accuracy during the inspection.

The firm occasionally has to purchase refined glycerin from ^{(b)(4) - Commercial Confidential} other manufacturers in Malaysia. They are (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. I inspected ^{(b)(4) - Commercial Confidential} on 8/27-29/12. IOI Oleochemicals is a joint venture partner in a company called Fatty Chemicals Malaysia Sdn. Bhd. (FEI 3004688627) that manufactures fatty alcohols. Fatty Chemicals Malaysia is located behind Acidchem International (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential from Fatty Chemicals Malaysia. They said this glycerin is not exported ^{(b)(4) - Commercial Confidential}.

According to officials at Acidchem, all of these other manufacturers use palm-based oils to make glycerin. Acidchem has a dedicated storage tank for holding bulk glycerin from other suppliers. They do not commingle their glycerin with glycerin from the other suppliers. They have a traceability program to track the filling and distribution of glycerin.

Coding

The firm paints the lot code onto each drum using stenciled lettering. An example of a lot code is "BGSXGA 1264", whereas (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

In regards to (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential

The firm considers the shelf life for glycerin to be ^{(b)(4) - Commercial Confidential}. The expiration date on the label is two years.

Quality Control/Laboratory Testing

The firm has two laboratories. The main laboratory is at Acidchem 1 where ^{(b)(4) - Commercial Confidential} (b)(4) - Commercial Confidential tests are performed. The other smaller laboratory is at Acidchem 2 where ^{(b)(4) - Commercial Confidential} tests are performed. The firm also (b)(4) - Commercial Confidential for certain analyses. Mr. ^{(b)(4) - Commercial Confidential} Quality Control Manager, oversees the firm's laboratory operations and provided most of the information in this subsection.

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The firm samples and analyzes each load of crude palm kernel oil for (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. Each load of palm stearine is analyzed for (b)(4) - Commercial Confidential. The parameters must be met before the load is discharged from the trucks into the storage tanks.

The firm submits samples of raw material CPKO or palm stearine (b)(4) - Commercial Confidential to a lab in (b)(4) - Commercial Confidential to analyze for (b)(4) - Commercial Confidential. No adverse results have been found.

The firm's QC department routinely collects in-process samples that are analyzed at both of the firm's labs. The glycerin (b)(4) - Commercial Confidential. The glycerin (b)(4) - Commercial Confidential. Other in-process tests conducted at (b)(4) - Commercial Confidential intervals include (b)(4) - Commercial Confidential. Refined bleached glycerin is also checked for (b)(4) - Commercial Confidential.

The firm collects samples of RBD glycerin from the bulk storage tanks (b)(4) - Commercial Confidential and per customers' orders and analyzes it for (b)(4) - Commercial Confidential.

The firm collects samples of finished product RBD glycerin from drums, IBCs, and ISO tanks at its facility. Independent surveyors collect samples of RBD glycerin from bulk tanker ships at the port. The samples are submitted to and analyzed at the firm's main lab at Acidchem 1. The lab performs (b)(4) - Commercial Confidential testing for glycerin. It also performs (b)(4) - Commercial Confidential testing on glycerin for customers who require such.

If a product does not meet specifications, the lot is (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential.

They said the firm only manufactures and sells one grade of glycerin- USP 99.5% minimum. They explained that their minimum standard is 99.5%, but their process is consistent and nearly always results in a (b)(4) - Commercial Confidential glycerin concentration. All glycerin manufactured and exported by the firm meets Food Chemical Codex (FCC) and USP standards. They said they do not manufacture a lower "industrial" grade glycerin below 99.5%

The firm is currently using the testing protocol for glycerin found in current (b)(4) - Commercial Confidential Exhibit 8.1 is Acidchem International's general (b)(4) - Commercial Confidential minimum. It includes identification test (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. Exhibit 8.2 is Acidchem International's USP (b)(4) - Commercial Confidential sheet for glycerin 99.7% minimum sold through Acidchem USA to (b)(4) - Commercial Confidential.

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(b)(4) - Commercial Confidential

It varies somewhat from the firm's general specification sheet. For example, the general specification sheet specifically lists (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

The firm provides Certificates of Analysis (CoA) to its customers for each lot. They retain reserve samples of each lot of glycerin for (b)(4) - Commercial Confidential

The firm submits samples of finished product RBD glycerin (b)(4) - Commercial Confidential to a lab in (b)(4) - Commercial Confidential to analyze for (b)(4) - Commercial Confidential. Also, random samples are collected (b)(4) - Commercial Confidential for (b)(4) - Commercial Confidential testing. No adverse results have been found.

The firm does (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

Material Approval

The only raw material used to make glycerin is crude palm kernel oil and refined palm stearine. (b)(4) - Commercial Confidential Other materials used in the production of glycerin include (b)(4) - Commercial Confidential and (b)(4) - Commercial Confidential at Acidchem 1.

(b)(4) - Commercial Confidential

The firm has a written procedure for selection, approval, and review of all materials including raw materials, processing aids, chemicals, and packaging. (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

The firm has a vendor audit procedure. Audits are generally conducted (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

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(b)(4) - Commercial Confidential It covers (b)(4) - Commercial Confidential categories. (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential The firm also structures its internal procedures and self-audit using these categories.

Water

Acidchem International uses (b)(4) - Commercial Confidential water. It is held in dedicated storage tanks before undergoing (b)(4) - Commercial Confidential. The firm (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential water is pumped to (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

The firm collects samples of the (b)(4) - Commercial Confidential water before (b)(4) - Commercial Confidential water from both Acidchem sites on a (b)(4) - Commercial Confidential basis and submits them to an external laboratory for (b)(4) - Commercial Confidential analysis. Testing is done for (b)(4) - Commercial Confidential

HACCP

The firm has a HACCP plan for glycerin (Exhibit 7) which was approved by the Malaysian Ministry of Health. The CCP is the (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

The monitoring procedure is to (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential For purposes of the HACCP plan, a lot is considered (b)(4) - Commercial Confidential glycerin storage tank. (b)(4) - Commercial Confidential The firm completes monitoring records.

Sanitation Procedures

The firm has several sanitation SOPs that describe cleaning and sanitation procedures and frequencies. They mainly involve housekeeping and grounds since actual cleaning of equipment is

minimal and is seldom necessary due to the nature of the operations. The processing of glycerin from palm-based oils occurs (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential The only time the glycerin exits the closed system is when it is filled into drums and bulk containers from filling lines

(b)(4) - Commercial Confidential

The outer surface of the filling machine in the drumming rooms is (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential They wash the outer surface of the filling machine's tube with (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential They

(b)(4) - Commercial Confidential
Instead, they will (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential They will return this glycerin (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

The firm restricts access into the drumming rooms. (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

COMPLAINTS

The firm has a written customer complaint procedure. The firm did not acknowledge receiving any complaints regarding illness or injury. There were no records of complaints about the firm in FACTS.

RECALL PROCEDURES

The firm has not conducted any recalls of products. It has a written recall procedure. Exhibit 11 is the product recall checklist that is part of the written recall procedure.

The firm has a traceability program. It assigns tracking numbers to track (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential It also assigns tracking numbers to (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential Each container of finished product glycerin has a lot number. The firm is able to trace backward from a lot of finished product glycerin to determine all the substances used in its manufacture. They are able to trace forward a lot of glycerin to its customer. The traceability records are (b)(4) - Commercial Confidential

The firm conducts a mock recall, which also serves as a traceability exercise, (b)(4) - Commercial Confidential For example, their most recent mock recall was performed on (b)(4) - Commercial Confidential The scenario was an (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

GLYCERIN EXPORTED TO CHINA

The firm routinely exports glycerin to (b)(4) - Commercial Confidential Mr. (b)(4) - Commercial Confidential Marketing Manager for (b)(4) - Commercial Confidential provided most of the sales and export information for glycerin to (b)(4) - Commercial Confidential Dr. Lee Kim Eng, Assistant General Manager, and Ms. (b)(4) - Commercial Confidential Marketing Manager for (b)(4) - Commercial Confidential also provided sales and export information. Mr. (b)(4) - Commercial Confidential Ms. (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential and Ms. (b)(4) - Commercial Confidential provided laboratory records and Certificates of Analysis.

As previously noted, FDA has received approximately 2,000 reports of pet illnesses since 2007 which may be associated with the consumption of jerky pet treats from (b)(4) - Commercial Confidential. FDA has tested over 700 imported jerky pet treat samples for a wide array of potential contaminants, (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. In March and April 2012, FDA conducted inspections of (b)(4) - Commercial Confidential jerky pet treat manufacturers in (b)(4) - Commercial Confidential whose products were the subject of most of the illness reports/complaints. One of the main constituents of the jerky treats is glycerin.

The inspection of Acidchem International was prompted by (b)(4) - Commercial Confidential documented by FDA during an inspection of (b)(4) - Commercial Confidential on (b)(4) - Commercial Confidential manufactures and exports a variety of jerky pet treats to (b)(4) - Commercial Confidential under several private labels. The information in the following six paragraphs (not counting the parenthetical "NOTE" paragraph) is summarized from the EIR of (b)(4) - Commercial Confidential

FDA investigators observed drums of glycerin in stock at (b)(4) - Commercial Confidential. The drums were labeled as being (b)(4) - Commercial Confidential brand USP 99.7% glycerin from (b)(4) - Commercial Confidential. The (b)(4) - Commercial Confidential brand USP 99.7% glycerin from (b)(4) - Commercial Confidential is food and pharmaceutical grade per Food Chemical Codex and USP standards.

(NOTE: (b)(4) - Commercial Confidential manufactures fatty alcohols, methyl esters, and glycerin. It is a joint venture between (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential and (b)(4) - Commercial Confidential is a business unit of (b)(4) - Commercial Confidential. Glycerin manufactured by (b)(4) - Commercial Confidential is labeled under the (b)(4) - Commercial Confidential name and marketed by (b)(4) - Commercial Confidential office in (b)(4) - Commercial Confidential. I inspected (b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential had (b)(4) - Commercial Confidential drums of (b)(4) - Commercial Confidential glycerin in stock on 3/28/12. The lot number was (b)(4) - Commercial Confidential with a manufacturing date of FEB 2, 2012. According to (b)(4) - Commercial Confidential, it had used (b)(4) - Commercial Confidential glycerin for the (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential initially provided FDA investigators with documents showing

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receipt of shipments of glycerin from on different dates between
Further review by FDA of receiving records and Certificates of Analysis

(CoAs) revealed (b)(4) - Commercial Confidential

When confronted with these discrepancies and asked to explain them, officials at eventually acknowledged that these CoAs supposedly pertaining to brand glycerin. They said that until a week before the FDA inspection, they routinely had been using glycerin manufactured by Acidchem International in Malaysia. They stated the glycerin from Acidchem International was labeled

(b)(4) - Commercial Confidential

jerky pet treats. They provided FDA with letters from Acidchem International attesting that the glycerin is fit for food processing. They said they purchased the glycerin before the pre-announced FDA inspection because

(b)(4) - Commercial Confidential

Later during the inspection, provided FDA with copies of certificates of analysis for different lots of glycerin with dates ranging from reportedly received from Acidchem International. After the inspection, provided FDA with separate CoAs reportedly covering all glycerin shipments it received from Acidchem International from also provided lab reports for additional lots of glycerin reportedly from Acidchem International that were not on either of the lists provided to FDA during and after the inspection.

Apparently, the (b)(4) - Commercial Confidential, who accompanied FDA on the inspection of (b)(4) - Commercial Confidential was not aware that (b)(4) - Commercial Confidential had been using glycerin labeled for (b)(4) - Commercial Confidential by Acidchem International. As a result, (b)(4) - Commercial Confidential

According to the EIR for (b)(4) - Commercial Confidential, its (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

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I fully discussed this matter with officials from Acidchem International during the subject inspection. Mr. (b)(4) - Commercial Confidential Marketing Manager for (b)(4) - Commercial Confidential provided most of the information in the following paragraphs. The following three points are noted here before continuing further:

1) Mr. (b)(4) - Commercial Confidential and other officials of Acidchem International voluntarily stated that they marked glycerin exported to (b)(4) - Commercial Confidential before I even broached the subject. I had simply begun a conversation by asking what grades of glycerin they manufacture and export. They replied all glycerin exceeds 99.5% minimum USP meaning it was food and pharmaceutical grade. I asked if they manufactured an industrial grade glycerin. They replied no. They said all glycerin was the same, and then added about marking USP 99.5% minimum glycerin exported to (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

2) The Malaysian Ministry of Health (MOH) was made aware recently of Acidchem International marking USP 99.5% minimum glycerin as being (b)(4) - Commercial Confidential. The inspectors from MOH said they recently visited the firm and discussed the matter with them. Normally, certain countries including (b)(4) - Commercial Confidential require the MOH to issue a health certificate for each shipment of food/pharmaceutical grade glycerin exported to its country. However, no health certificate is required if the glycerin is labeled for industrial use. The MOH investigators did not seem concerned about this matter because they said the (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

3) I did not mention or provide the name of (b)(4) - Commercial Confidential or any other jerky pet treat manufacturers to anybody during the inspection.

Mr. (b)(4) - Commercial Confidential said Acidchem International routinely exports glycerin to (b)(4) - Commercial Confidential mostly in (b)(4) - Commercial Confidential drums, and has done so (b)(4) - Commercial Confidential. It regularly sells glycerin to (b)(4) - Commercial Confidential distributors. Mr. (b)(4) - Commercial Confidential said Acidchem International does not sell glycerin directly to end-users (such as jerky pet treat manufacturers like (b)(4) - Commercial Confidential). The firm's primary customer in (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

He explained that following episodes of illnesses and deaths from cough syrups containing glycerin contaminated with diethylene glycol (DEG) around 2007, (b)(4) - Commercial Confidential implemented new regulations requiring stricter oversight and testing of glycerin, including imported glycerin, intended for use in foods, pharmaceuticals, and cosmetics. This resulted in higher costs and longer clearance times for imported glycerin labeled for food and pharmaceutical use. Therefore, (b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential
(b)(4) - Commercial Confidential Mr. (b)(4) - Commercial Confidential and other officials of Acidchem International emphasized that it was not Acidchem International that instituted the procedure of labeling food/pharmaceutical grade glycerin as being (b)(4) - Commercial Confidential. Rather, it was and continues to be their customers in (b)(4) - Commercial Confidential who specifically request the (b)(4) - Commercial Confidential statement as a shipping mark on each drum in the sales orders.

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According to the EIR for (b)(4) - Commercial Confidential officials at (b)(4) - Commercial Confidential said Acidchem International sent them letters explaining that even though the glycerin was marked (b)(4) - Commercial Confidential the glycerin (b)(4) - Commercial Confidential Officials at (b)(4) - Commercial Confidential say they requested Acidchem International provide them with CoAs for glycerin marked as being for (b)(4) - Commercial Confidential. These reportedly are the (b)(4) - Commercial Confidential CoAs that (b)(4) - Commercial Confidential provided to FDA during and after the inspection.

Attachment 1 is a letter provided by (b)(4) - Commercial Confidential to FDA during its inspection. It is written in (b)(4) - Commercial Confidential and signed by Mr. (b)(4) - Commercial Confidential of Acidchem International. It was subsequently translated and written in English at the bottom. It is generally addressed as "Dear Customer". It says the glycerin exported by "my firm" (Acidchem International) is fit for food processing and application. I showed this letter to Mr. (b)(4) - Commercial Confidential. He was aware of it and confirmed that he wrote it and sent it to their customers. He stated that the English translation was accurate.

Attachment 2 is a letter provided by (b)(4) - Commercial Confidential to FDA during its inspection. It is written in English with some (b)(4) - Commercial Confidential. It is also dated (b)(4) - Commercial Confidential and also signed by Mr. (b)(4) - Commercial Confidential Regional Manager (b)(4) - Commercial Confidential of Acidchem International. The (b)(4) - Commercial Confidential were subsequently translated and written in English. The letter explains the methods for painting the drums of glycerin. It says (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential. The letter concludes by indicating the quality is the same regardless of the labeling method. I showed this letter to Mr. (b)(4) - Commercial Confidential. He was aware of it and confirmed that he wrote it and sent it to their customers. He stated that the English translation of the (b)(4) - Commercial Confidential was accurate.

It should be noted that according to officials at (b)(4) - Commercial Confidential they requested Acidchem International send them a letter regarding the suitability of using the glycerin labeled as (b)(4) - Commercial Confidential. However, the facsimile mark at the bottom of the letter seems to indicate that it was sent to (b)(4) - Commercial Confidential which most likely is (b)(4) - Commercial Confidential in (b)(4) - Commercial Confidential. As previously noted, (b)(4) - Commercial Confidential is the major distributor of Acidchem International's glycerin in (b)(4) - Commercial Confidential. According to Mr. (b)(4) - Commercial Confidential he sent the letters (Attachments 1 & 2) only to the distributors, not to end-users (such as (b)(4) - Commercial Confidential). He said that he does not even know who the end-users are.

Attachment 3 is a letter provided by (b)(4) - Commercial Confidential to FDA during its inspection. It is written in English followed by (b)(4) - Commercial Confidential. Both statements reportedly say the same thing. It is dated September 20, 2011 and signed by (b)(4) - Commercial Confidential at Acidchem International. The reason for the letter is a label change for glycerin 99.5% USP. It says that starting on August 1, 2011, Acidchem International began adding a new label "Prohibited for human food and feed processing" because of (b)(4) - Commercial Confidential requirements for non-food application. It says the quality of the

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glycerol is not changed/affected in food application. I showed this letter to Mr. (b)(4) - Commercial Confidential. He was aware of it. He explained that beginning on 8/1/11, (b)(4) - Commercial Confidential began requiring that glycerin labeled for industrial use contain the statement about prohibited for human food and feed processing. He said Acidchem International sent the letter to its customers to assure them that the glycerin was still 99.5% USP and fit for food applications.

Attachment 4 is a letter provided by (b)(4) - Commercial Confidential to FDA during its inspection. It is written in (b)(4) - Commercial Confidential with some English characters in quotation marks. It is dated September 22, 2011. The English words are "Prohibited for human food and feed processing", a date of 2011 8 1 (August 1, 2011), and the letters "COA" and "USP". Reportedly, this letter also was sent from Acidchem International to explain why the drums of glycerin began having shipping marks stating "Prohibited for human food and feed processing". I showed this letter to Mr. (b)(4) - Commercial Confidential. He was aware of it and said it was issued for the same reason as noted in Attachment 3.

Mr. (b)(4) - Commercial Confidential and the other marketing managers and quality assurance/control managers at Acidchem International who are noted in the first paragraph of this section, repeatedly and strongly stated that all glycerin manufactured, sold, distributed, and exported by Acidchem International meets all USP specifications and is at least USP 99.5% minimum glycerin. They said there is no lower grade industrial glycerin manufactured by the firm. It is only labeled for (b)(4) - Commercial Confidential per the customers in (b)(4) - Commercial Confidential who request it.

Exhibit 12 is Acidchem International's specification sheet for glycerin under its specification code (b)(4) - Commercial Confidential. Mr. (b)(4) - Commercial Confidential said it is the specification code most commonly requested by customers in (b)(4) - Commercial Confidential. Glycerin marked (b)(4) - Commercial Confidential is sold under this specification code. Current Specification (b)(4) - Commercial Confidential references the older USP 31 methods for monograph testing. The assay shows the glycerin is 99.50 minimum, which is food and pharmaceutical grade. (NOTE: The product name gives the appearance that the drums are (b)(4) - Commercial Confidential. This is the gross weight of glycerin plus the drum. The net weight of glycerin is (b)(4) - Commercial Confidential as shown on sales orders).

On 9/6/12, I verbally provided Acidchem International the (b)(4) - Commercial Confidential lot numbers for glycerin CoAs referenced in (b)(4) - Commercial Confidential EIR. I asked them to provide me with their versions of the CoAs and the sales orders for each. They were able to provide me with all the CoAs within a few hours except for (b)(4) - Commercial Confidential as explained in the paragraph below. They also were able to provide most of the sales orders except for some older ones (b)(4) - Commercial Confidential when they were using a different software system.

The only CoAs they could not find were those for lot numbers (b)(4) - Commercial Confidential on 8/15/10 as written in the (b)(4) - Commercial Confidential EIR. The (b)(4) - Commercial Confidential character is the letter symbol for (b)(4) - Commercial Confidential. For this lot code it is (b)(4) - Commercial Confidential. The other (b)(4) - Commercial Confidential. The last four digits of the firm's lot code (b)(4) - Commercial Confidential. Each

(b)(4) - Commercial Confidential

(b)(4) - Commercial Confidential

I was able to review the CoAs for all (b)(4) - Com lot numbers of glycerin plus the accompanying sales orders. Some sales orders pertained to more than one lot number. All the CoAs showed full USP monograph testing. The results indicated the glycerin met all USP standards and was at least 99.50% minimum. The following paragraphs in this section explain some of the CoAs and sales orders.

Exhibit 13.1- 13.2 is the CoA dated December 17, 2009 for glycerin lot (b)(4) - Commercial Confidential. It shows the glycerin content as 99.79%. Exhibit 14.1-14.2 is the CoA dated February 27, 2010 for glycerin lot (b)(4) - Commercial Confidential. It shows the glycerin content as 99.80%. Each lot contains (b)(4) - Commercial Confidential. Both CoAs indicate the test methods were (b)(4) - Commercial Confidential, which was the version used by the firm at the time for former specification code (b)(4) - Commercial Confidential. Both indicate the sales order number ("SO No") as (b)(4) - Commercial Confidential. Exhibit 15 is Sales Order (b)(4) - Commercial Confidential for (b)(4) - Commercial Confidential deliveries to (b)(4) - Commercial Confidential, which includes these (b)(4) - Commercial Confidential lot numbers (as handwritten on the sales order by the firm during the inspection) plus other unidentified lot numbers that apparently were not distributed to (b)(4) - Commercial Confidential. At the bottom of the sales order is a header called "Shipping Marks". According to Mr. (b)(4) - Commercial Confidential, shipping marks are labeling placed on the drums (b)(4) - Commercial Confidential. The shipping mark for this order is (b)(4) - Commercial Confidential. It also requires that (b)(4) - Commercial Confidential be stencil marked in (b)(4) - Commercial Confidential. Mr. (b)(4) - Commercial Confidential said several years ago, customers wanted the firm's name stencil marked in (b)(4) - Commercial Confidential on the drums, but this practice was discontinued (b)(4) - Commercial Confidential.

Exhibit 16.1- 16.2 is the CoA dated February 10, 2012 for glycerin lot (b)(4) - Commercial Confidential. It shows the glycerin content as 99.84%. Exhibit 17.1-17.2 is the CoA dated February 10, 2012 for glycerin lot (b)(4) - Commercial Confidential. It shows the glycerin content as 99.84%. Each lot contains (b)(4) - Commercial Confidential. Both CoAs indicate the test methods were (b)(4) - Commercial Confidential, which is the version currently used by the firm for glycerin exported to (b)(4) - Commercial Confidential under specification code (b)(4) - Commercial Confidential. (See Exhibit 12). Both indicate the sales order number as (b)(4) - Commercial Confidential. Exhibit 18 is Sales Order (b)(4) - Commercial Confidential for (b)(4) - Commercial Confidential of glycerin in (b)(4) - Commercial Confidential to (b)(4) - Commercial Confidential, which includes these (b)(4) - Commercial Confidential lot numbers (as handwritten on the sales order by the firm during the inspection) plus other unidentified lot numbers. The shipping mark for this order is (b)(4) - Commercial Confidential. According to Mr. (b)(4) - Commercial Confidential, this shipping mark is the labeled adhesive sticker identified in this report as Exhibit 4.

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Most sales orders indicate a (b)(4) - Commercial Confidential is required. Mr. (b)(4) - Commercial Confidential said a (b)(4) - Commercial Confidential is a Certificate of Origin issued by the Malaysian Ministry of International Trade and Industry under the (b)(4) - Commercial Confidential agreement. Exhibit 19 is the Certificate of Origin for the glycerin noted in the previous paragraph that was exported to (b)(4) - Commercial Confidential

Exhibit 20.1- 20.2 is the CoA for glycerin lot (b)(4) - Commercial Confidential. The sample date is December 7, 2011. The CoA is dated September 6, 2012, which was the date they provided the CoA to me. (NOTE: Malaysia uses the format of dd/mm/yyyy, thus 06/09/2012 is September 6, 2012). This was one of the first CoAs they provided to me. When I showed them the date of September 6th, 2012 on this CoA and several other ones, they said it was an error in retrieving the CoAs from their computer system whereby (b)(4) - Commercial Confidential. They later provided the correct copies of the CoAs for me to review. The correct CoA for lot (b)(4) - Commercial Confidential was correctly dated December 16, 2011. They provided me with a copy of the correctly dated CoA, but later during the inspection when sorting through the multiple records, I mistakenly returned the correct CoA to them and kept the incorrectly dated CoA. (NOTE: I had not provided the firm with the dates of the CoAs from the (b)(4) - Commercial Confidential EIR. I orally gave them only the lot numbers. The date of 12/16/11 matched the CoA for (b)(4) - Commercial Confidential in that EIR.)

The CoA for (b)(4) - Commercial Confidential shows the glycerin content as 99.76%. The lot contains (b)(4) - Commercial Confidential. The sales order number is (b)(4) - Commercial Confidential. Exhibit 21 is Sales Order (b)(4) - Commercial Confidential of glycerin in (b)(4) - Commercial Confidential to (b)(4) - Commercial Confidential under specification code (b)(4) - Commercial Confidential. The shipping marks for this order are (b)(4) - Commercial Confidential, (b)(4) - Commercial Confidential, and another one in (b)(4) - Commercial Confidential. According to Mr. (b)(4) - Commercial Confidential the shipping mark correlating to (b)(4) - Commercial Confidential is the one saying the glycerin is prohibited for human food. Exhibit 22 is a copy of the (b)(4) - Commercial Confidential as identified by Mr. (b)(4) - Commercial Confidential. He said it has the (b)(4) - Commercial Confidential as they appear on the drums of glycerin with the English translation below them as (b)(4) - Commercial Confidential. Mr. (b)(4) - Commercial Confidential said sometimes customers request shipping mark (b)(4) - Commercial Confidential having this statement and sometimes they do not.

As previously noted, (b)(4) - Commercial Confidential with offices in (b)(4) - Commercial Confidential is the major customer/distributor of Acidchem International's glycerin in (b)(4) - Commercial Confidential. At least (b)(4) - Commercial Confidential of the sales orders I reviewed showed (b)(4) - Commercial Confidential as the consignee. Thus, it appears that (b)(4) - Commercial Confidential is the major supplier of Acidchem International's glycerin to (b)(4) - Commercial Confidential.

Exhibit 23.1- 23.2 is the CoA dated April 22, 2011 for glycerin lot (b)(4) - Commercial Confidential. It shows the glycerin content as 99.80%. The lot contains (b)(4) - Commercial Confidential. The sales order number is (b)(4) - Commercial Confidential. Exhibit 24 is Sales Order (b)(4) - Commercial Confidential of glycerin in (b)(4) - Commercial Confidential to (b)(4) - Commercial Confidential. This lot number plus glycerin lots (b)(4) - Commercial Confidential (as handwritten on the sales order by the firm during the inspection) plus other unidentified lot numbers were included in the shipment. Glycerin lots (b)(4) - Commercial Confidential and

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(b)(4) - Commercial Confidential were identified in the EIR for (b)(4) - Commercial Confidential. I reviewed the CoAs at Acidchem International for all (b)(4) - Commercial Confidential lots and they appeared to meet USP standards. The shipping mark for all the glycerin in this order is (b)(4) - Commercial Confidential. Exhibit 25 is the Certificate of Origin for this shipment of glycerin to (b)(4) - Commercial Confidential.

Exhibit 26.1- 26.2 is the CoA dated July 15, 2010 for glycerin lot (b)(4) - Commercial Confidential. It shows the glycerin content as 99.80%. The lot contains (b)(4) - Commercial Confidential. The sales order number is (b)(4) - Commercial Confidential. Exhibit 27 is Sales Order (b)(4) - Commercial Confidential for (b)(4) - Commercial Confidential separate deliveries of glycerin in (b)(4) - Commercial Confidential to (b)(4) - Commercial Confidential. (b)(4) - Commercial Confidential This lot number was included as part of the (b)(4) - Commercial Confidential delivery as handwritten on the sales order by the firm during the inspection. The shipping mark for all the glycerin in this order is (b)(4) - Commercial Confidential.

Exhibit 28.1- 28.2 is the CoA dated January 9, 2010 for glycerin lot (b)(4) - Commercial Confidential. It shows the glycerin content as 99.79%. The lot contains (b)(4) - Commercial Confidential. The sales order number is (b)(4) - Commercial Confidential. Exhibit 29 is Sales Order (b)(4) - Commercial Confidential for (b)(4) - Commercial Confidential deliveries of glycerin in (b)(4) - Commercial Confidential to (b)(4) - Commercial Confidential firm not listed in FACTS). This lot number plus glycerin lots (b)(4) - Commercial Confidential (as handwritten on the sales order by the firm during the inspection) plus other unidentified lot numbers were included in the shipment. Glycerin lots (b)(4) - Commercial Confidential were identified in the EIR for (b)(4) - Commercial Confidential. I reviewed the CoAs at Acidchem International for all (b)(4) - Commercial Confidential lots and they appeared to meet USP standards. The shipping mark for all the glycerin in this order is (b)(4) - Commercial Confidential.

Exhibit 30 is Sales Order (b)(4) - Commercial Confidential for glycerin in (b)(4) - Commercial Confidential to (b)(4) - Commercial Confidential (b)(4) - Commercial Confidential firm not listed in FACTS). Mr. (b)(4) - Commercial Confidential said this is an example of a sales order for a customer who wants the glycerin to be marked as food grade for food use and not marked for industrial use. It requests a shipping mark correlating to (b)(4) - Commercial Confidential with the production date and expiry date completed. Exhibit 31.1 is an example of the shipping mark in (b)(4) - Commercial Confidential correlating to (b)(4) - Commercial Confidential. Exhibit 31.2 is the translation of this shipping mark as made by Mr. (b)(4) - Commercial Confidential. It indicates the glycerin is a food additive manufactured by Acidchem International and is intended for use in the food industry as a sweetener.

SAMPLES COLLECTED

I collected five investigational samples during the inspection on 9/6/12. The CVM assignment requested that samples be collected of crude glycerin, all different grades of finished product glycerin, and raw material oils used to make glycerin. All samples were submitted to FDA's Forensic Chemistry Center in Cincinnati, OH via (b)(4) - Commercial Confidential from Malaysia. The glycerin samples were to be analyzed for impurities and contaminants, including diethylene glycol (DEG) and ethylene glycol (EG). The raw material oils were to be analyzed for identity and

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composition. The five samples are as follows with the collection reports being included as attachments to this report.

INV 769886 consisted of 6/ 500 ml. bottles (3 liters total) of crude glycerin collected from spigot of bulk glycerin storage tank (b)(4) - Comments

INV 769887 consisted of 6/ 500 ml. bottles (3 liters total) of refined, bleached, deodorized (RBD) glycerin collected from spigot of refined glycerin storage tank (b)(4) - Comments

INV 769888 consisted of 6/ 500 ml. bottles (3 liters total) of RBD glycerin collected by employees of firm inside the drumming room. They collected the sample due to restricted access into this room. I observed the sample collection through a window. They filled approximately 500 ml. of glycerin into each plastic bottle from an auxiliary filling line. The sample was collected from glycerin transferred from bulk tank (b)(4) - Commercial Confidential. The firm was not filling glycerin on the date of sample collection (9/6/12). They had filled glycerin from bulk storage tank (b)(4) - Comments into IBCs on 9/5/12.

INV 769889 consisted of 2/ 500 ml. bottles (1 liter total) of crude palm kernel oil collected from a tanker truck while it was unloading the palm kernel oil into a bulk storage tank.

INV 769890 consisted of 2/ 500 ml. bottles (1 liter total) of RBD palm stearine collected from a tanker truck while it was unloading the palm stearine into a bulk storage tank.

Exhibit 32 is a compact disk (CD) with digital photographs of sample collection sites copied onto it. It is sealed in an FDA-525.

REFUSALS

No refusals were encountered during the inspection.

EXHIBITS COLLECTED

- Exhibit 1: Company brochure of various fatty acids products and glycerin
- Exhibit 2: Copy of the metal seal caps applied to drums of glycerin
- Exhibit 3: Labeled sticker for PALMAC brand glycerin
- Exhibit 4: Sticker for glycerin labeled '(b)(4) - Commercial Confidential'
- Exhibit 5.1: Site diagram of "Acidchem 1"
- Exhibit 5.2: Site diagram of "Acidchem 2"

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Exhibit 6.1-6.2: Flow diagram for glycerin
Exhibit 7: HACCP plan for glycerin
Exhibit 8.1: General USP 35 specification sheet for glycerin 99.7% minimum
Exhibit 8.2: USP 35 spec. sheet for glycerin 99.7% min. for (b)(4) - Commercial Confidential
Exhibit 9: List of boiler water chemicals
Exhibit 10.1- 10.6: Vendor audit checklist
Exhibit 11: Product recall checklist
Exhibit 12: Specification sheet for glycerin specification code (b)(4) - Commercial Confidential
Exhibit 13.1-13.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 14.1-14.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 15: Sales Order (b)(4) - Commercial Confidential glycerin to (b)(4) - Commercial Confidential
Exhibit 16.1- 16.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 17.1-17.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 18: Sales Order (b)(4) - Commercial Confidential for glycerin to (b)(4) - Commercial Confidential
Exhibit 19: Certificate of Origin for above glycerin to (b)(4) - Commercial Confidential
Exhibit 20.1- 20.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 21: Sales Order (b)(4) - Commercial Confidential for glycerin to (b)(4) - Commercial Confidential
Exhibit 22: Shipping mark stating glycerin prohibited for human food and feed
Exhibit 23.1- 23.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 24: Sales Order (b)(4) - Commercial Confidential for glycerin to (b)(4) - Commercial Confidential
Exhibit 25: Certificate of Origin for above glycerin to (b)(4) - Commercial Confidential
Exhibit 26.1- 26.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 27: Sales Order (b)(4) - Commercial Confidential glycerin to (b)(4) - Commercial Confidential
Exhibit 28.1- 28.2: Certificate of Analysis for glycerin lot (b)(4) - Commercial Confidential
Exhibit 29: Sales Order (b)(4) - Commercial Confidential glycerin to (b)(4) - Commercial Confidential
Exhibit 30: Sales order (b)(4) - Commercial Confidential for glycerin to (b)(4) - Commercial Confidential
Exhibit 31.1: Shipping mark in (b)(4) - Commercial Confidential indicating glycerin as food additive
Exhibit 31.2: English translation of above shipping mark for glycerin
Exhibit 32: CD with digital photographs of sample collection sites

ATTACHMENTS

Collection Report for Sample INV 769886
Collection Report for Sample INV 769887
Collection Report for Sample INV 769888
Collection Report for Sample INV 769889

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Collection Report for Sample INV 769890

Attachment 1: Memorandum from FDA's Center for Veterinary Medicine dated 7/12/12 requesting inspections and sample collections at glycerin manufacturers in (b)(4) - Commercial Confidential

Attachment 2: Letter from Acidchem International to customers indicating glycerin marked as being for industrial use only is fit for food processing and application

Attachment 3: Letter from Acidchem International to customers explaining the methods for labeling drums of glycerin as being for industrial use

Attachments 4 & 5: Letters from Acidchem International to customers explaining why phrase "Prohibited for human food and feed processing" was added to drums of glycerin

(NOTE: Attachments 2-5 were originally provided to FDA during inspection of (b)(4) - Commercial Confidential in (b)(4) - Commercial Confidential)



David J. LeRay, Investigator