

# FDA Establishment Inspection Report

Alclin Pty Ltd

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**Establishment Inspection Report**

Alclin Pty Ltd

Riversdale, South Africa

FEI: **3008953748**

EI Start: 06/18/2013

EI End: 06/18/2013

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# Summary

Alcin Pty Ltd

Comprehensive inspection of this dietary supplement manufacturer was conducted in accordance to South Africa Trip 2013-164F, FACTS Assignment # 8674912. Inspectional coverage was given according to CP #7321.008 - Dietary Supplements -Import and Domestic. PACs reported in this inspection were #21008 and 21008A.

This is the first FDA inspection conducted at this site, Inspection disclosed one labelling deficiency which was not listed on an FDA - Inspectional Observations form. No official samples were collected and no refusals were encountered during this inspection. The firm is registered with the FDA.

# Administrative Data

Alcin Pty Ltd

Inspected firm: **Alclin Pty Ltd**

Location: **No 5 First Ave, Industrial Area, Riversdale, South Africa 6670**

Phone: **28 0 713 4282**

FAX: **27 0 86 502 7352**

Mailing Address: **Suite # 4 Private Bag X 422, Riversdale, South Africa 6670**

Dates of inspection: **6/18/2013**

Days in the facility: **1**

Participants: **Lourdes Andujar, Investigator**

Upon arrival to the firm on 06/18/2013, I presented my credentials and gave a business card to Mr. Christo Coetzee, CEO and most responsible person, Mrs, Renske Coetzee, Production Manager and Safety Officer and Mr, Peter Parks, Pharmacist, I explained the purpose of my visit to Mr. Coetzee who accompanied me throughout the whole inspection along with Mrs. Coetzee and Mr. Parker and they provided all the necessary information to complete this report, I explained and prived a copy of the information sheet - Assessment of Reinspection and Recall User Fees for FY 2012 by the FDA to Mr. Coetzee.

# History

Alcin Pty Ltd

Alcin Pty Ltd (Alclin) started in 2010 when they started negotiations with a company known as Nimue Skin Technology and then decided to set up the bioscience division for a new product called Nimue Nad anti-ageing. Prior to this firm, Mr. Coetzee had created Covant Pharmaceutical Products in 1971 where the firm was dedicated to the production of pharmaceutical products, such as sterile eye drops, capsules, tablets, antibiotics and painkillers. In 1995 Covant Pharmaceutical Products was sold to Aspen Pharmaceuticals.

Alclin LLC is a sister firm located in 11 South, 2nd Avenue, Suite 6, St. Charles, IL, 60174 USA. Mr. Coetzee explained that the Alclin LLC firm located in Illinois is mainly for tax purposes and they produce the USA products with the Alclin LLC address on the label.

Today Alclin Pty Ltd produces dietary supplements, such as fatigue assist capsules, Hoodia capsules and DP tablets. Mr. Coetzee told me that Alclin is interested in producing pharmaceuticals in the future. This is a small plant site located in a small industrial area. See Exhibit # 1 for a copy of the site plan.

The firm currently has the capability of manufacturing tablets, capsules, blister packs, tamper evident packs. Most of the mentioned capabilities are manufactured and packaged as part of the business and as part of third-party manufacturing requests. Hours of operation are 8:00 am - 5:00 pm (Monday - Thursday) and 8:00 am - 3:00 pm on Fridays.

Any official correspondence between FDA and the firm should be addressed to: Suite # 4 Private Bag X 422, Riversdale South Africa 6670. The firm has 7 full-time employees and 4 part-time. See Exhibit # 2 for a copy of the organisational chart which had been recently prepared, but not authorised yet.

# Interstate Commerce

Alcin Pty Ltd

The USA products are manufactured for Alclin LLC, located in Illinois. At one time according to Mr. Coetzee product was shipped to Nutritional Products International, located in Delray Beach, FL, but he never received any payment from this distributor and has not shipped anything else to any distributor in the USA. The DPN tablets used to be sold previously to a doctor in the USA. The doctor's information was not available.

The firm will be shipping to the USA in the future when they find a USA broker and/or distributor that can help them with the USA distribution.

# Jurisdiction

Alcin Pty Ltd

The products fall within the regulations and statutes enforced by FDA.  
See Exhibit # 3 for label specimens of some of their products.

## Individual Responsibility and persons interviewed

Mr. Christo Coetzee identified himself as the most responsible person at the firm during the time of the inspection. Mrs. Renske Coetzee is the Production Manager and Safety Officer while Mr. OPeter Parks is the Pharmacist.

Mr. Coetzee has the duty, power and responsibility to prevent, detect, and correct the violations found during this inspection. Mr. Coetzee, Mrs. Coetzee and Mr. Parks accompanied me throughout the entire inspection and provided all the necessary documents to complete this report.

# Firm's Training Program

Alcin Pty Ltd

Key personnel are trained in GMP, Hygiene and Safety.  
GMP training is also given as a refresher course and when  
new employees start with the firm.

# Manufacturing/Design Operations

Alcin Pty Ltd

Water used in the production is purchased from Era Juice, which is a local firm that produces reverse osmosis water. I reviewed the water testing and did not have any objectionable conditions.

No production was taking place during the inspection. Some weighing of raw ingredients was being done, but not a full flow of the production was being done to follow.

I was able to view the supplier of raw materials list. Suppliers are, Warrenchem, Chempure and Kirsh Pharma. All of these suppliers are located in South Africa in the areas of Cape Town, Pretoria and Johannesburg.

I was able to take a tour of the firm and follow the process flow as explained by Mr. Coetzee.

Mr. Coetzee mentioned that during the dates of June 5-6 he had contacted a consultant firm named Registra Corp, located in 144 Research Drive, Hampton, Virginia,

23666 to come and do a complete inspection of the firm and to find out what they needed to correct in order to be in full compliance with the FDA regulations. He mentioned he wanted to be in full compliance for this audit and had implemented all the corrections recommended by the consultant firm. I asked to see the report from the consultant firm which was an 18-page document. Upon my review, I was able to notice that the firm had implemented all the corrections that the consultant firm had recommended. Therefore, most of the written procedures are new but were implemented prior to this inspection.

Final product testing is done by North-West University, located in South Africa. An identification of components testing was also submitted to North West University on June 14, 2013, for their products. Third party manufacturing and testing is done by Pharma-Q, located in South Africa and Cenqam, located in South Africa is also used for additional testing and double check. In house testing is also done for appearance, disintegration, friability, hardness and average mass. I reviewed the Master Manufacturing Record for DPN

Tablets. I noticed that the label needs corrections to the nutritional facts table, dietary supplement not listed. The label is making medical claims by stating that it helps improve mental clarity, alertness and concentration and may assist to improve chronic fatigue. In addition to the label deficiencies, no other observations were noted. See Exhibit # 3, pages 1 and 2 for a label specimens of DPN tablets and fatigue assist.

I reviewed calibration records. I reviewed the cleaning SOP and the cleaning records. I did not see any objectionable conditions in these areas.

I also did a review of the freezers/coolers, warehouse, washing stations and bathrooms as part of the walk through. No observations were noted in these areas. Premises and firm was clean and all bathrooms and hand washing facilities were well stocked with hot water, soap, and paper towels/hand drying equipment.

No pests were observed, Suid-Kaap-Plaagbeheer, located in Riversdale pest control services every 3 months, The last service date was 5/25/13.

# Manufacturing Code

Alcin Pty Ltd

Manufacturing codes are based on batch number which is sequential and the expiration date.

# Complaints

I reviewed the complaint SOP. The firm has no complaints. No objectionable conditions were found with the complaints system.

# Recall Procedures

Alcin Pty Ltd

The firm has a recall system in place. I reviewed the recalls SOP. A mock recall is done every year. No objectionable conditions were found with the recall system.

## OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

I told Mr. Coetzee that the DPN label had deficiencies, such as the Nutritional Facts table was not updated, the label also lacks the statement "Dietary Supplement". I told that the label is making medical claims by stating that it helps improve mental clarity, alertness and concentration and may assist to improve chronic fatigue. I explained to Mr. Coetzee that he needed to do a full evaluation of the label and all of his product labels. I also reviewed the fatigue assist label. The fatigue assist label was in compliance.

Mr. Coetzee mentioned that he will get in contact immediately with the consulting firm Registrar Corp. and have the label updated and will have the firm check all of his product labels for accuracy. He mentioned this should take about 4 weeks to have the final printed label.

# Refusal

Alcin Pty Ltd

No refusals were encountered.

# Refusal

A coseout meeting was held with Mr. Christo Coetzee, CEO, Mrs. Renske Coetzee, Production Manager and Safety Officer and Mr. Peter Parks, Pharmacist I explained the label deficiencies with the DPN tablets label. Management agreed and said they will have the label ready with 4 weeks.

# Samples Collected

No official samples were collected.



Lourdes Andujar, Investigator

# Exhibits Collected

Alcin Pty Ltd

1. Copy of the site plan
2. Copy of the organizational chart
3. Copies of label specimens

# FDA 482 - Notice of Inspection

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