January 30, 2018

Dear Valued Customer,

Since the implementation of new federal regulations, MeriCal LLC has received a large volume of questionnaires and surveys regarding our services and procedures. Many of the questionnaires ask questions and request information addressing very similar issues.

Unfortunately, we are not able to complete each customer's individual form as this can be very time consuming and redundant. Therefore, to expedite this information to our customers in an efficient manner, MeriCal assembled all of the pertinent information into a comprehensive format to issue to our valued customers.

We are confident that this company profile will successfully provide all of the information requested to our customers. Using this form of response to surveys and questionnaires, allows MeriCal to respond quickly and efficiently to all requests and insure the information provided is consistent in all cases.

To assure that all the information requested by our customers is addressed, we ask that you review the information provided and let us know if any additional information is required. MeriCal hopes that you will find this a helpful and beneficial way to share information and provide our customers with excellent service.

Thank you for understanding as we value your continued support and interest in our products and services.

Sincerely,

Shelly Meagher

Shelly Meagher
Sr. Quality Manager, Quality Assurance

MeriCal, LLC

Manufacturing Complex
233 E. Bristol Lane
Orange, CA 92865
(714) 283-9551

Packaging Center
2995 E. Miraloma Ave.
Anaheim, CA 92806
(714) 238-7225

Facility Overview

Manufacturing, Technology, and Packaging Complex
233 E. Bristol Lane, Orange, California 92865
CA Department of Toxic Substances Control EPA ID# CAL000200395
U.S. FDA Food Facility Registration# 10430778510

MeriCal's Research, Manufacturing and Specialty Packaging Facility in Orange
Approximately 110,000 square feet:

- Manufacturing – 40,000 sq. Feet
- Packaging – 17,000 sq. Feet
- Warehouse – 39,000 sq. Feet
- Office – 9,000 sq. Feet
- Analytical Lab – 2,000 sq. Feet
- Research & Development – 3,000 sq. Feet

Bottling, Blister, and OTC Packaging Center
2995 E. Miraloma Avenue, Anaheim, California 92806
CA Department of Toxic Substances Control EPA ID# CAD983653072
U.S. FDA Food Facility Registration# 15245989538

MeriCal's Flagship Bottling Plant in Anaheim
Approximately 92,000 square feet:

- Warehouse – 38,000 sq. Feet
- Packaging – 40,000 sq. Feet
- Office – 14,000 sq. Feet

Finished Goods Warehouse
447 W. Freedom Avenue, Orange, California 92865
U.S. FDA Food Facility Registration# 17568045604

MeriCal's Finished Good Distribution Warehouse in Orange
Approximately 32,000 square feet:

- Warehouse – 30,000 sq. Feet
- Office – 2,000 sq. Feet

Packaging Components Warehouse
1315 N. Blue Gum Street, Anaheim, California 92806
U.S. FDA Food Facility Registration# 11588256516

MeriCal's Incoming Packaging Component Warehouse in Anaheim
Approximately 43,000 square feet:

- Warehouse – 41,000 sq. Feet
- Office – 2,000 sq. Feet

Employees

Total employment: (All facilities) 370

- QA/QC/Regulatory 35
- Engineering 20
- R&D 10
- Manufacturing 89
- Packaging 170
- Administration 50

Certifications and Quality

1 Food & Drug Administration – U.S. Department of Health & Human Services
- Anaheim –
  - Registered Drug Establishment – Facility Establishment #2010498
- Orange –
  - Registered Drug Establishment – Facility Establishment #3001574462

2 State of California – Board of Pharmacy
- All Facilities –
  - Manufacturer of Dangerous Drugs
  - Registered Representative License, Drug Wholesaler

3 State of California – Department of Public Health Food & Drug Branch
- Anaheim –
  - Drug Manufacturing License #41441
  - Organic Processed Product Registration #16482
  - Processed Food Registration #16482
- Orange –
  - Drug Manufacturing License #23417
  - Organic Processed Product Registration #23417
  - Processed Food Registration #23417
  - Pet Food Production License #23417
- Blue Gum -
  - Processed Food Registration #78643
- Freedom -
  - Organic Processed Food Registration #78089
  - Processed Food Registration #78089

4 Health Canada – Natural Health Products Directorate
- Anaheim –
  - Foreign Site Reference Number 5000079
- Orange –
  - Foreign Site Reference Number 5000077

5 NSF International
- GMP Requirements in NSF/ANSI 173, Section 8
- Anaheim –
  - GMP for Sport™ #C0076554-16
- Orange –
  - GMP for Sport™ #C0076555-16
- Freedom Warehouse –
  - GMP Requirements #C0227882-10
- Blue Gum Warehouse –
  - GMP Requirements # C0312090-02

6 UL (formerly STR-Registrar) – Certificate of Conformance
- Anaheim –
  - Registration Number – 13-101243
- Orange –
  - Registration Number – 13-101243

7 Quality Assurance International (QAI)
- Orange –
  - Handler (Processor)
  - Certificate of Compliance (#106545-A)

8 OneCert International
- Orange –
  - Certificate of Compliance (#ONE-754-171019-H-NOP)

Recent Government Agency Inspections

U.S. Food and Drug Administration

- Audit performed in Orange Manufacturing facility 11/14-11/16 & 11/20/2017
  - Review of compliance with 21 CFR – Part 110 "cGMP's"
  - No warning letters or recalls in past 5 years

U.S. Food and Drug Administration

- Audit performed in Anaheim Packaging facility 6/9 & 6/12 - 6/13/2017
  - Review of compliance with 21 CFR – Part 210 & 211 "OTC's"
  - No warning letters or recalls in past 5 years

State of California Department of Public Health

- Audit performed in Blue Gum Component warehouse 7/6/2016
  - Initial review of Food Handling processes and procedures
  - No violations or observations cited
  - Processed Food Registration issued

State of California Department of Public Health

- Audit performed in Freedom Avenue Finished Good Warehouse 3/24/2016
  - Review of Food Handling processes and procedures
  - No violations or observations cited
  - Processed Food Registration

U.S. Food and Drug Administration

- Audit performed in Anaheim Packaging facility 1/22 - 1/23/2015
  - Review of compliance with 21 CFR – Part 111 "cGMP's"
  - No warning letters or recalls in past 5 years

State of California Department of Public Health

- Audit performed in Orange Manufacturing facility 10/3 - 10/7/2013
  - Initial review of OTC processes and procedures
  - No violations or observations cited
  - Drug Manufacturing License issued

U.S. Food and Drug Administration

- Audit performed in Orange Manufacturing facility 2/25 - 2/27/2013
  - Review of compliance with 21 CFR – Part 111 "cGMP's"
  - No warning letters or recalls in past 5 years

Quality Assurance

Orange Manufacturing and Packaging

- Products are manufactured by MeriCal and are held, packaged, and/or distributed here; other materials are shipped from customer for contract packaging services.

Anaheim Packaging Facility

- Many products packaged are manufactured in MeriCal's Orange manufacturing facility; other materials are shipped from customer for contract packaging services.

General Requirements

Do you have:	Yes	No	N/A
Separate areas for different operations	X		
Cross contamination control	X		
Safety Program	X		
GMP training program	X		
MSDS available to your employees	X		
Proper uniforms/gowning in production areas	X		
Job descriptions	X		
General Sanitation	X		
Humidity control	X		
Temperature control	X		
Water purification system	X		

Pest Control

Do you have:	Yes	No	N/A
SOP documenting pest control procedures	X		
Internal or external licensed applicator	X		
Applicators license on file	X		
Proper storage of pesticides	X		
Map of facility indicating trap, bait stations, etc.	X		
List of approved pesticides and MSDS	X		
Formal contract with outside Service	X		
Documented Scheduled Inspection	X		
Corrective Action Response	X		

Receiving & Warehouse

Do you have:	Yes	No	N/A
A written cleaning program	X		
A quarantine area	X		
Materials segregated	X		
Materials properly identified	X		
Rejected materials identified and controlled via written procedures	X		
Records on receipt of your raw materials	X		
SOP for Receiving and Warehousing	X		
SOP for sampling	X		

Manufacturing

Do you have:	Yes	No	N/A
SOPs for different operations	X		
SOPs available to operators	X		
A product rework procedure	X		
Equipment cleaning and use logs	X		
Equipment maintenance logs	X		
A documented equipment calibration program	X		
Water hoses properly stored to prevent contamination	X		
Batch production and control records	X		
Raw materials inventory tracking	X		
Master production and control records	X		
Materials & equipment identified throughout process	X		
Equipment cleanliness identifiable	X		

Packaging

Do you have:	Yes	No	N/A
SOP for line set-up and approval	X		
SOPs available to operators	X		
SOP for product sampling	X		
Equipment cleaning and use logs	X		
Written procedures outlining in-process controls	X		
Packaging component specifications	X		
Spatial or physical separation between lines	X		
Components inspection program	X		

Product reconciliation	X		
Label control and reconciliation	X		
Equipment identified	X		
Packaging lines identified	X		

Analytical Microbiological Lab

Do you have:	**Yes**	**No**	**N/A**
Raw materials testing program	X		
Raw material test results compared to vendor's COA	X		
In-process testing	X		
Finished product testing	X		
Raw material and product specifications	X		
QC samples identified and retained	X		
Raw material and product test records	X		
Assay methods validated	X		
Instrument calibration and maintenance program	X		
Lab standards program	X		
Reagent control program to assure potency	X		
Written cleaning and sanitizing procedures	X		
Periodic instrument calibration	X		
Autoclave validation	X		
Stock Culture Maintenance program	X		
Exposure plate controls	X		
Positive and negative controls	X		
Media growth promotion	X		

Stability Program

Do you have:	Yes	No	N/A
Stability Failure Documentation	X		
Methods are Stability Indicating	X		
Stability protocols consistent with industry standard	X		
Stability rooms validated for temp and RH control	X		
Temperature/ humidity monitored daily or by chart recorder	X		
Annual Stability Program	X		
SOP defining program	X		

Note: Some stability studies currently ongoing

Failure Investigations

Do you have:	Yes	No	N/A
SOP for failure investigations (Non conformances)	X		
SOP for Out Of Specification test results	X		

Quality Assurance

Do you have:	Yes	No	N/A
Separate QC and QA departments (Quality Unit)	X		
Quality Unit a separate group from Operations	X		
SOPs for monitoring critical unit operations	X		
Perform Quality Standard Evaluation (trend studies)	X		
Finished product retain program	X		
Internal Audit program	X		
Vendor Certification program	X		
Batch record review and retention	X		
SOP for complaint handling	X		