DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/18/2014 - 09/30/2014* FEI NUMBER 3007749948

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eduardo (NMI) Gomez Gomes, Owner

FIRM NAME	STREET ADDRESS
Gopers Int LLC	6940 Camino Maquiladora Ste D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92154-7514	OTC contract manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Quality System

OBSERVATION 1

There is no quality control unit.

Specifically, since 09/10/12, approximately (b)(4) batches were manufactured and released without quality control oversight. Your firm failed to establish a quality control unit that has the responsibility and authority to:

a) Approve or rejecting all procedures, specifactions, components, drug products, and labeling .
b) Establish specifications impacting the identity, strength, quality, and purity of the drug product.
c) Establish production records.
d) Approve batches prior to distribution.
e) Investigate, evaluate, and approve discrepancies, failures, deviations, and complaints.
f) Assess material, production, packaging/labeling, and laboratory systems.

Additionally, your firm lacked written procedures describing quality control responsibilities and authority.

OBSERVATION 2

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, your firm failed to conduct a quality control review and disposition decision for all batches of finished drug products prior to distribution. Your firm does not maintain documentation of conducting such review.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Natalie J. Ayoub, Investigator Linda Thai, Investigator	09/30/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/18/2014 - 09/30/2014* FEI NUMBER 3007749948

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eduardo (NMI) Gomez Gomes, Owner

FIRM NAME	STREET ADDRESS
Gopers Int LLC	6940 Camino Maquiladora Ste D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92154-7514	OTC contract manufacturer

OBSERVATION 3

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, you do not have a stability program and procedures to support the two year expiration date on all analgesic ointments, analgesic oils, and acne medications. You have not conducted stability testing on all analgesic ointments, analgesic oils, and acne medications.

OBSERVATION 4

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, you have no process validation for all 35 drug products manufactured at your firm including analgesic ointments, topical acne medications, and analgesic oils.

OBSERVATION 5

Individuals responsible for supervising the manufacture, processing, packing, and holding of a drug product lack the education, training, and experience to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

Specifically, the owner acts as the owner, supervisor, and quality control manager that approves and releases all drug products. The owner has no prior experience and training for conducting a supervisor and quality control personnel role.

OBSERVATION 6

Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices, and written procedures required by current good manufacturing practice regulations.

Specifically, your firm does not conduct continuing current good manufacturing practices training for all employees. You do not have documentation of conducting training for employee functions of all (b) (4) production employees.

OBSERVATION 7

Records are not maintained stating the consultant's qualifications and type of service provided.

Specifically, you do not have documentation of the qualifications and services provided for the consultant used from approximately June 2011 to approximately March 2012. Additionally, you do not have records documenting the consultant's qualifications, training, and experience.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Natalie J. Ayoub, Investigator Linda Thai, Investigator	09/30/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/18/2014 - 09/30/2014* FEI NUMBER 3007749948

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eduardo (NMI) Gomez Gomes, Owner

FIRM NAME	STREET ADDRESS
Gopers Int LLC	6940 Camino Maquiladora Ste D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92154-7514	OTC contract manufacturer

Production System

OBSERVATION 8

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, you have not performed finished product testing for all your drug products since October 2011. You do not determine if the following active ingredient and strength for each drug product meets labeled specifications:

a) Analgesic ointments and oils containing the labeled specification of Menthol 1.3 %.
b) Analgesic ointments and oils containing the labeled specification of Methyl Salicylate 10%.
c) Analgesic ointment containing the labeled specification of Camphor 3%.
d) Acne medication containing the labeled specification of Sulfur 3%.

OBSERVATION 9

The master production and control records for each batch size of drug product are not prepared, dated, and signed by one person with a full handwritten signature and independently checked, dated, and signed by a second person.

Specifically, you have not created a master batch record for the following drug products:

[redacted]

Additionally, none of your [redacted] master batch records are signed and dated by the inital person that created the master batch

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Natalie J. Ayoub, Investigator Linda Thai, Investigator	09/30/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/18/2014 - 09/30/2014* FEI NUMBER 3007749948

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eduardo (NMI) Gomez Gomes, Owner

FIRM NAME	STREET ADDRESS
Gopers Int LLC	6940 Camino Maquiladora Ste D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92154-7514	OTC contract manufacturer

record and checked, dated, and signed by a second person.

OBSERVATION 10

Batch production and control records are not prepared for each batch of drug product produced.

Specifically, you do not create and maintain batch records for all drug products manufactured since 09/10/12. Since 09/10/12, you have manufactured and released (b)(4) batches of analgesic ointments, acne medication, and analgesic oils.

OBSERVATION 11

Written procedures are not established and followed that describe the in-process controls, tests, and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically, you have not conducted in-process testing for all batches manufactured after 09/10/12. Additionally, you have not established specifications for in-process weighing exam.

OBSERVATION 12

Records are not kept for the maintenance, cleaning, sanitizing, and inspection of equipment.

Specifically, since 07/25/12, you have not maintained records documenting the maintenance, cleaning, sanitizing, and use of each piece of equipment.

Facilities and Equipment System

OBSERVATION 13

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically, you have no cleaning validations for your cleaning and sanitizing procedures of your processing line and utensils used to manufacture analgesic ointments, acne medicine, and analgesic oils.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Natalie J. Ayoub, Investigator Linda Thai, Investigator	09/30/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	09/18/2014 - 09/30/2014* FEI NUMBER 3007749948

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eduardo (NMI) Gomez Gomes, Owner

FIRM NAME	STREET ADDRESS
Gopers Int LLC	6940 Camino Maquiladora Ste D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92154-7514	OTC contract manufacturer

OBSERVATION 14

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your standard operating procedure (SOP) for "Cleaning Procedure" does not include procedures for cleaning and maintenance of each piece of manufacturing equipment including the wax melter machine, pumping hoses connected to the wax melter machine, production tables, conveyer belts, plastic mixing drums, paddles, and scoops. For example, you clean your wax melter machine hoses by (b) (4) Your "Cleaning Procedure" SOP does not describe this procedure.

Materials System

OBSERVATION 15

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically, you do not conduct component testing, including identity testing, for all components used in your drug products. Components used in your drug products include but not limited to: (b) (4) (b) (4).

OBSERVATION 16

Each lot of components, drug product containers, and closures is not withheld from use until the lot has been sampled, tested, examined, and released by the quality control unit.

Specifically, you do not quarantine, sample, test, and conduct a quality control review for all components, drug product containers, and closures prior to use. Additionally, you do not maintain a receiving log.

*** DATES OF INSPECTION:**
09/18/2014(Thu), 09/19/2014(Fri), 09/22/2014(Mon), 09/23/2014(Tue), 09/30/2014(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Natalie J. Ayoub, Investigator Linda Thai, Investigator	09/30/2014