

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/23/2015 - 12/10/2015*
	FIR NUMBER 3011936057

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Ryan Goodkin, Co-Owner/Pharmacist

FIRM NAME Jack P. Herick, Inc. dba Glades Drugs	STREET ADDRESS 109 S Lake Ave
CITY, STATE, ZIP CODE, COUNTRY Pahokee, FL 33476-1803	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

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 I OBSERVED:

OBSERVATION 1

Each container or grouping of containers of components is not examined visually upon receipt and before acceptance for appropriate labeling as to contents.

Specifically, for Lots (b) (4) , and (b) (4) of cholecalciferol (b) (4) (vitamin D3) received from your supplier, (b) (4) ; the container labeling for these lots did not state the concentration of vitamin D3 (for example how many IU of vitamin D3 per gram). Documentation states you then used these lots to prepare and distribute the product known as Vitamin Supplement D3 1500 IU/ 50mg / 50mg / 0.5mg / 25mg / 12.5mg / 25mg / 25mg capsules under the assumption that the concentration of this vitamin D3 component was 100,000 IU/gram vitamin D3. However, after you were notified of adverse events your investigation documentation concluded that this vitamin D3 component had about (b) (4) .

OBSERVATION 2

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

Specifically, your firm does not test finished drug products prior to distribution. For example, documentation states since 8/15/2015 to the time of this inspection your firm prepared and distributed the following types of non-sterile drug products without testing to determine conformance with potency (for topical and capsule products) and microbial limit specifications (for topical products).

A. Creams, ointments, and gels containing different combinations of active pharmaceutical ingredients such as baclofen, flurbiprofen, gabapentin, itraconazole, lidocaine, tacrolimus, meloxicam, mupirocin, mometasone, piroxicam, and prilocaine.

B. Capsules containing ingredients such as vitamin D3 (cholecalciferol).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Joanne E. King, Investigator	<i>Joanne E. King</i>	DATE ISSUED 12/10/2015

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OBSERVATION 3

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, there are no established specifications for microbial limits for the non-sterile topical drug products produced by your firm.

OBSERVATION 4

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm does not test non-sterile drug products for the presence of objectionable microorganisms prior to distribution.

*** DATES OF INSPECTION:**
11/23/2015(Mon), 11/24/2015(Tue), 12/10/2015(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joanne E. King, Investigator <i>Joanne E. King</i>	12/10/2015