

**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	DATE(S) OF INSPECTION 5/21/2018-5/30/2018* FEI NUMBER 1035794
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Daniel W. Knorr, President
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FIRM NAME Tropical Seas, Inc.	STREET ADDRESS 346 Flomich St
CITY, STATE, ZIP CODE, COUNTRY Holly Hill, FL 32117-1770	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:
QUALITY SYSTEM**

OBSERVATION 1

The written record did not include the reason an investigation was found not to be necessary when an investigation into unexplained discrepancies was not conducted.

Specifically, your firm received a consumer complaint on 05/03/16 regarding a (b) (6), (b) (7)(C) year old child that had an allergic reaction while using your (b) (4) product. Per the documentation on the record, "child allergic to (b) (4) which is not in our product." Although the complainant provided the batch number (b) (4) used to formulate this product, you concluded that it was not necessary to inspect and retest the retain sample for this product and advised the complainant to avoid (b) (4) and (b) (4). Additionally, you instructed the complainant to test the product on a small patch on the child and to communicate the results, despite your awareness of the potential risk of the product.

OBSERVATION 2

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

Specifically, you stated on 05/24/18 that your staff (b) (6), (b) (7)(C) is responsible for maintaining the document control system and has the authority to issue product labels. You stated your staff (b) (6), (b) (7)(C) has the

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<p>authority to release incoming materials and product labels. You stated both staff are trained to perform final reviews on quality documents such as laboratory results, however, you could not provide documentation to indicate that these persons were trained in the roles they perform. Additionally, you, the top official for the quality unit, cannot provide documentation to support training in the roles you perform, including document review and finished product release.</p>			
FACILITIES AND EQUIPMENT SYSTEM			
<p>OBSERVATION 3</p> <p>Equipment and utensils are not maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.</p> <p>Specifically,</p> <ol style="list-style-type: none"> 1. On 05/21/18, I observed foreign material that appeared to be rust on a clip that secures the (b) (4) scraper for a (b) (4) kettle (Kettle (b) (4)). This foreign material appeared to have discolored the scraper. The clip and scraper are internal components of the kettle that come into direct contact with (b) (4) products while batching. Additionally, because there is discoloration of the scaper, there is concern that this component is displaying reactive/absorptive properties. 2. On 05/21/18, I observed a toxic chemical spray can intended to loosen metal parts, stored on the same counter next to product contact utensils designated as "clean". Due to its close proximity, clean utensils could be exposed to toxic chemicals not intended for the finished product. 3. On 05/21/18, I observed a hose designated as "clean" hanging from a tank with the hose ends resting on the floor. Hoses are used to transfer (b) (4) products from the mixers/kettles to holding containers for filling. 			
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4. On 05/29/18, I observed the use of a (b) (4) meter which is connected inline with the (b) (4) (b) (4) system used to calculate (b) (4) consumption quantities for (b) (4) "Original" Lotion (b) (4) batch Lot (b) (4) I also observed the use of a (b) (4) thermometer to take in-process temperatures of the same batch of product. You could not provide documentation to show that these equipment are calibrated and maintained to provide accurate readings.

5. You cannot provide documentation to indicate that equipment used to manufacture, process, package or hold drug product are appropriately designed, qualified and controlled. Examples of these equipment include kettles, scales, pumps, labeling machines as well as analytical equipment such as the (b) (4) spectrophotometer, the incubator and the (b) (4)

LABORATORY CONTROLS SYSTEM

OBSERVATION 4

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

Specifically,

1. Finished drug product testing for aerobic microbes is deficient in that the preservatives used in each product are not neutralized or deactivated so that the test results are accurate. Preservatives used include (b) (4) and (b) (4) for (b) (4) Spray products and (b) (4) for all other over the counter drug products.

2. Microbial testing for aerobic microbes is deficient in that growth promotion testing is not performed on each lot of media prepared to ensure the media is capable of growth. You stated for the lots of media

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that are tested for growth, you perform an analysis of your saliva, which is an uncontrolled bacterial source. Additionally, you could not provide documentation of this analysis.

OBSERVATION 5

Laboratory records do not include a complete record of all data secured in the course of each test, including all graphs, charts and spectra from laboratory instrumentation, properly identified to show the specific component and drug product tested.

Specifically, your firm uses an internally developed software (b) (4) that creates master batch records and stores test results. You stated this software currently does not maintain previous revisions of master batch records for document management, nor is there a system in place to ensure that master batch records and analytical results are complete, unaltered and inclusive of all activities performed. Additionally, this software has not been validated to demonstrate its ability to ensure data accuracy and security.

PRODUCTION SYSTEM

OBSERVATION 6

Each component is not added to the batch by one person and verified by a second person..

Specifically, I observed your production staff perform batching operations for the formulation of (b) (4) "Original" Lotion (b) (4) Lot (b) (4). On 05/29/18, a production operator combined Phase (b) (4) an (b) (4) phase component mixture with phase (b) (4) phase component mixture and thereafter added a (b) (4) mixture and (b) (4) with (b) (4). These steps were documented as performed and verified per the batch record, however, there was no additional operator present performing the verification of these additions.

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OBSERVATION 7

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, your process validations for the production of (b) (4) products are inadequate in that they do not include an evaluation of the elements identified below:

1. A requirement for training prior to execution of the validation protocol.
2. Identification of failure modes and critical process steps
3. A method of assessment based on scientific principles
4. Pre-determined acceptance criteria that are specific, measurable and clearly defined

(This is a repeat observation from the cGMP inspection performed 11/09/2015 – 11/19/2015)

OBSERVATION 8

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

Specifically, on 05/21/18, I observed your production staff perform in-process weight and torque checking during the filling of (b) (4) Lotion, Lot (b) (4). The batch record requires in-process testing to be performed (b) (4). With the prior in-process test documented as occurring at 10:30am, the production staff proceeded to perform the next in-process interval at (b) (4) (b) (4). I observed the staff perform this check and document the time as (b) (4). The staff changed the documentation to the correct time only after instruction from management following my inquiry. Additionally, your employees failed to initiate an investigation for

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the late performance of the in-process testing, which exceeded the established limit as defined on the batch record, as required by your written procedure entitled "Failure Investigation" revision 0 dated 03/22/18.

***DATES OF INSPECTION**

5/21/2018(Mon), 5/22/2018(Tue), 5/23/2018(Wed), 5/24/2018(Thu), 5/25/2018(Fri), 5/29/2018(Tue), 5/30/2018(Wed)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."