DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	5/7/2024-5/22/2024* FEI NUMBER 1218077

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Ricardo A. Camuzzi, Director, End to End Manufacturing and Customer Service and Logistics

FIRM NAME	STREET ADDRESS
Tom's of Maine, Inc.	27 Community Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sanford, ME 04073	Human OTC drug 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:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, microbial recoveries and customer complaints were not investigated.

I. Your firm has recovered *Pseudomonas aeruginosa* in multiple (b) (4) water samples at points of use in your (b) (4) water (b) (4) system without investigating or assessing product impact. The (b) (4) water is generated in-house and is used as a component in making all your OTC drug products and as a final rinse after cleaning and sanitization.

Your firm's microbiology lab identified the gram-negative bacterium *Pseudomonas aeruginosa* in (b) (4) water system samples on the following dates at the following points of use:

SAMPLING DATE	SAMPLE LOCATION	WATER USAGE	LOTS IN WHICH WATER IS PRODUCT COMPONENT
06/01/2021	(b) (4)	Final rinse	
06/02/2021		Final rinse	

AMENDMENT 1

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	Lori M Newman, Investigator X Lori M Newman Investigator Signed By: 2003217756 Date Signed: 05-22-2024 17:40:54	5/22/2024

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06/03/2021	(b) (4)	Final rinse	
06/04/2021		Final rinse	
06/24/2021		Product component	Tom's Simply White Clean Mint Paste 4.7 oz lot 1175UST11D (mfg 6/24/21, exp 6/23)
08/26/2021		Final rinse	
09/09/2021		Final rinse	
09/10/2021		Final rinse	
10/04/2021		Final rinse	
10/20/2021		Final rinse	
11/06/2021		Final rinse	
11/12/2021		Final rinse	
02/01/2022		Final rinse	
10/24/2022		Final rinse	

#(b) (4) mixer is a point of use for water used in making product. No investigation was conducted into these findings of *Pseudomonas aeruginosa* in water samples. Your finished product specifications require the absence of gram-negative bacteria from all your OTC finished products according to the global procedure QMIC 0068-10.

Your firm continues to recover gram negative organisms from your water system at production use points, including the #(b) (4) Mixer usage point (b) (4) and (b) (4) used to

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(b) (4) for OTC products. Examples of recoveries appear below.

SAMPLING DATE	SAMPLE LOCATION	COUNT (Spec. (b) (4)	ORGANISM(S) IDENTIFIED	INVESTIGATION/REFERENCE
3/19/2024	(b) (4) Mixer	Initially TNTC, estimated to be 1200 (b) (4)	*Ralstonia insidiosa*	LIR 24-007
3/26/2024	(b) (4) Dosing Hose	Initially TNTC, estimated to be 3600 (b) (4)	*Ralstonia insidiosa*	LIR 24-008
5/13/2024	(b) (4) Dosing Hose	Initially TNTC, estimated to be 360 (b) (4)	*Ralstonia insidiosa*	Lab notebook QAL-1022F4-(b) (4) Hose Water Test, page 16 of 50

Per QMIC-0030-10, the specifications for water POU are as follows: alert level (b) (4) action level (b) (4) In the event a water sample is TNTC, a count is estimated and a resample is taken to count using dilution of the sample.

Your firm's contract laboratory (b) (4) recovered gram negative cocco-bacilli *Paracoccus yeei* in finished

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product testing of an OTC finished product, Wicked Cool! Anticavity TP, batch #3025UST11B, on 2/16/23. This is an OOS result for your products, where the specification is absence of gram negative bacilli. A definitive root cause of the OOS was not identified, and a retest of the original retain sample and testing of a duplicate sample taken from retains were within specification.

II. Since 2/2021, your firm has received approximately 402 customer complaints for off odor/off color/off taste in your OTC drug products such as Tom's Children Silly Strawberry Anticavity Toothpaste and Tom's Whole Care Toothpaste. None of these complaints have been investigated. ~~Your firm also did not document the rationale for not investigating individual complaints until approximately September 2023.~~ Following are some examples of complaints that were received and not investigated:

Date	**Complaint ID**	**Product/Lot #**	**Narrative/description**
3/12/2024	350469132 A	Tom's TP Nat Children Fluor Silly Strawberry/Lot 3322UST	"This tastes disgusting. Was the formula changed?"
3/4/2024	350453818 A	Tom's TP Nat Whole Care Fluor Gel Unspecified/Lot unspecified	"It tasted like vinegar can I get a replacement tube"
11/20/2023	320628804 A	Tom's TP Nat Children Fluor Silly Strawberry/Lot 3179UST11B	"It's the kid's silly strawberry, it tastes so disgusting."
8/30/2023	306285495	Tom's TP Nat	"I am writing to you as a

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	A	Whole Care Fluor Paste Spearmint/Lot 5101UST11D3	concerned customer who recently purchased a tube of your Whole Care Wintermint Toothpaste from an online retailer. Unfortunately, upon opening the product, I noticed an unusual smell and taste that differ from the usual characteri”

OBSERVATION 2

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

I. Specifically, your firm’s (b) (4)) water system for generating (b) (4) water has not undergone performance qualification. The in-house (b) (4) water made via (b) (4) is a component in all your OTC drug product formulations and as a final rinse after cleaning and sanitization of product-contact equipment and utensils. Examples of these OTC products include Tom’s Wicked Cool! Anticavity Mild Mint, Tom’s Charcoal Anticavity Toothpaste, Tom's Children Silly Strawberry Anticavity, Tom’s Simply White Clean Mint Paste, and Tom’s Children’s Anticavity Orange Mango. Approximately (b) (4) batches of OTC drug toothpaste products have been released from February 2021 to April 2024.

II. Your firm’s validation of the washing and sanitization process for the hoses used in your (b) (4) water system does not assess whether the washing and sanitization process adequately removes gram negative organisms (including objectionable microorganisms) from the hoses. Document CVP-035-00 “Washout

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and Sanitization Validation Protocol: (b) (4) Hoses" dated 7/23/2019 states, "The normal flora that is found in the Tom's of Maine, Sanford facility water system is R. insidiosa, which is a Gram-negative rod, thus the Gram-negative alert and action level limits will not be used to assess success of this (b) (4) validation protocol". Your finished product specifications require the absence of gram-negative organisms from all your OTC finished products. The (b) (4) dosing hose included in this validation protocol (point of use (b) (4) is used to dose water to OTC product lots such as Tom's Silly Strawberry Anticavity toothpaste, lot (b) (4), MFG 5/16/2024. You continue to recover gram negative organisms from the point of use at (b) (4), as shown in Observation 1.

III. Your firm's "Summary Report: Toothpaste Holding Time Test Summary (dated 6/27/2013) to support holding (b) (4) OTC product in bulk tanks for up to (b) (4) prior to filling in commercial packaging is inadequate. The room temperature and humidity were not monitored during the hold time study, so no temperature/humidity range has been validated for the (b) (4) hold period. The formulations used as representative formulations in the original study have not changed since 2013; however, there have been changes since 2013 to other formulations in your portfolio that are intended to be represented by those in the study. For example, Tom's Silly Strawberry Anticavity formulation was changed in 2019 and returned to its original formulation in 2021. Tom's Charcoal Anticavity Peppermint underwent flavor, sweetness, and surfactant changes in 2019.

OBSERVATION 3

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically, on 5/8/2024, I observed a black substance with the appearance of fungi at the base of the hose reel and behind the water storage tank in the (b) (4) ((b) (4)) room. I noted that the black substance was within 1 foot of stainless steel pails and other product-contact equipment used for OTC production on a storage rack. The base of the wall behind the water tank in the (b) (4) room

appeared to have an uneven surface that also contained a similar-appearing black substance.

The stainless steel sink surface in the (b) (4) room also appeared to be covered over most of its surface in apparent rouging, pitting, and cloudy white discoloration. The (b) (4) room is used to clean product-contact equipment used for production of OTC drug products such as Tom's Silly Strawberry Anticavity.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically, the quality unit does not maintain adequate control and oversight over the firm's manufacturing systems.

I. Storage/sanitiation controls:

- On 5/7/24, your facility lacked hot water at handwashing sinks at the entrance to the production area and in employee restrooms.
- On 5/8/24, your production area contained equipment of unknown status. For example, I noted racks of filler cups for holding toothpaste tubes for filling for the products (b) (4) in plastic-wrapped racks in the production area with blank status placards. I also noted heads for the filler machinery wrapped in plastic in the production area that were not in service but were not labeled with a status.
- On 5/8/24, I observed stainless steel pails with visible whitish residue on their outer surfaces on a storage rack in the cleaning room with a sign that said "Clean and sanitize before use". These pails are used to dispense flavor components into OTC drug products. Your firm also has not established a hold time for dirty equipment.
- On 5/16/24, at the start of compounding of Tom's Silly Strawberry Anticavity lot (b) (4), prior to the operators starting the addition of powder materials into (b) (4) tank (b) (4), I observed loose white

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powder debris on a stainless steel tray adjacent to the manway of (b) (4) tank (b) (4) The tray is used to support bags of powder material as the powders are being added to the (b) (4) tank.

II. Document control:
- Your firm has a (b) (4) for pre-weighing raw materials. The logbook "(b) (4) Operational Parameters Verification Log" containing entries from 4/4/23-4/21/23 was signed off as reviewed by Quality during the inspection on 5/7/24, approximately 13 months after the data was entered. SOP GEN-1000-13 "Document Content, Numbering, and Lifecycle Management at Tom's of Maine" is inadequately specific because it states that logbooks used to document activities are reviewed "on a frequency that will provide the opportunity to identify missing or incorrect information so that there is little or no impact to product or processes".

- SOP GEN-1000-13 "Document Content, Numbering, and Lifecycle Management at Tom's of Maine" is inadequately followed. GEN-1000-13 states that each active SOP will be reviewed every (b) (4) (maximum) to ensure it is current. The most recent version of SOP 10000009011 "Annual Stability Testing Program for FDA" was last reviewed on 9/5/2018 and GEN-2000-08 "Training Program for Full Time Personnel" was last reviewed on 3/25/2020.

***DATES OF INSPECTION**
5/07/2024(Tue), 5/08/2024(Wed), 5/09/2024(Thu), 5/10/2024(Fri), 5/15/2024(Wed), 5/16/2024(Thu), 5/17/2024(Fri), 5/22/2024(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."