



Being Alive

Evolutions in Being P.O. Box 4008 Chelmsford, MA. 01824 Eibeing.com 978-256-0438

*The FDA When it Does
it's Job*

The FDA When it Does it's Job (although I would argue it is taking too long to resolve)

Toms of Maine Cited for Mold Violations and Required Improvements

Toms of Maine-Palmolive/Tom's of Maine, Inc. MARCS-CMS 687043 -
November 5, 2024

Recipient:

Mr. Noel Wallace
Chief Executive Officer
Colgate-Palmolive/Tom's of Maine, Inc.

300 Park Avenue New York, NY 10022 United States

Warning Letter 320-25-09

November 5, 2024

Dear Mr. Wallace:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Tom's of Maine, Inc., FEI 1218077, at 27 Community Dr., Sanford, ME, from May 7 to 22, 2024.

This warning letter summarizes significant violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations (CFR), parts 210 and 211 (21 CFR parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

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We reviewed your June 13, 2024, response to our Form FDA 483 in detail and acknowledge receipt of your subsequent correspondence.

During our inspection, our investigator observed specific violations including, but not limited to, the following.

1. Your firm failed to follow appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile (21 CFR 211.113(a)).

Microbiological Results in Water Samples and Finished Product

Your firm produced (b)(4) water and used it as a component in your OTC drug products and as a final rinse after equipment cleaning.

A. You recovered *Pseudomonas aeruginosa* in multiple (b)(4) water samples, from June 2021 to October 2022. This water was used to manufacture Tom's Simply White Clean Mint Paste, batch (b)(4), and for the final rinse of numerous equipment cleaning processes. None of these incidents were investigated to assess product impact and water system performance.

B. You also reported multiple incidents where too numerous to count (TNTC) *Ralstonia insidiosa* was recovered from water points of use. Your investigations included testing of new samples collected at least 4 days after the initial sampling. Batches manufactured after these incidents were released based on the microbial testing of the finished OTC product despite the quality of the water used as a component or to clean the equipment.

C. You recovered gram-negative cocco-bacilli *Paracoccus yeei* in your OTC finished product, Wicked Cool! Anticavity Toothpaste, batch 3025UST11B. Your investigation concluded, without sufficient justification, that the growth was due to sample contamination. The batch was released based on retest results.

In your response, you state you are performing a retrospective review of your microbial incidents in water and in OTC products. You also acknowledge that you do not have adequate specifications for the water used for the final rinse of equipment. You also state in your response that the root cause for *P. yeei* was related to a laboratory error even though the initial investigation stated no laboratory errors were identified.

Your response is inadequate. It does not include additional supporting evidence or testing results for the finished products. In addition, you are resampling the water points of use, 4 days after initial sampling, without further evaluation of manufacturing activities or water use during those 4 days that may impact other products.

In response to this letter provide:

- A comprehensive assessment of the design and control of your firm's manufacturing operations, with a detailed and thorough review of all microbiological hazards.
- A detailed risk assessment addressing the hazards posed by distributing OTC drug products with potentially objectionable contamination. Specify actions you will take in response to the risk assessment, such as customer notifications and product recalls.

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- Complete investigations into all batches with potential objectionable microbial contamination or an OOS microbiological result (whether or not later invalidated). The investigations should detail your findings regarding the root causes of the contamination.
- Appropriate microbiological batch release specifications (i.e., total counts, identification of bioburden to detect objectionable microbes) for each of your drug products.
- All chemical and microbial test methods used to analyze each of your drug products.
- A summary of results from testing reserve samples of all drug product batches within expiry. You should test all appropriate quality attributes including, but not limited to, identity and strength of active ingredients and microbiological quality (total counts and identification of bioburden to detect any objectionable microbes) of each batch. If testing yields an OOS result, indicate the corrective actions you will take, including notifying customers and initiating recalls.

Inadequate Water System

You failed to adequately qualify your (b)(4) water system that produced water used for equipment cleaning and in formulating your product. The installation qualification and operational qualification (IQ/OQ) was performed on October 23, 2019, and data collection was completed in September 2022. You did not evaluate this data at the time and presented the performance qualification (PQ) to Quality Assurance for review and approval after our inspection. This qualification was performed using a validation criterion of (b)(4) for total aerobic count but lacked the analysis for total organic carbon (TOC) and conductivity. Also, the absence of gram-negative microorganisms, which is required in your OTC product specifications, was not addressed.

In your response, you provide the PQ report approved in June 2024. You also acknowledge that the validation criteria are insufficient for formulating OTC drug products and for rinsing final equipment when the OTC finished product specification requires the absence of gram-negative microorganisms. You commit to start a new validation in the (b)(4) and plan to (b)(4) the water system by the (b)(4).

Water is a major ingredient in many of your OTC drug products. It is essential that you employ a water system that is robustly designed, and that you effectively control, maintain, and monitor the system to ensure it consistently produces water suitable for pharmaceutical use.

In response to this letter, provide:

- A comprehensive remediation plan for the design, control, and maintenance of the water system.
- (b)(4) water system validation report. Also include the summary of any improvements made to system design and to the program for ongoing control and maintenance.
- Your total microbial count limits to monitor whether this system is producing water suitable for the intended uses for each of your OTC products.
- A detailed risk assessment addressing the potential effects of the observed water system failures on the quality of all drug product lots currently in U.S. distribution or within expiry. Specify actions that you will take in response to the risk assessment, such as customer notifications and product recalls.

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2. Your firm failed to maintain buildings used in the manufacture, processing, packing, or holding of drug products in a good state of repair (21 CFR 211.58).

Our investigator observed a black mold-like substance at the base of the hose reel and behind the water storage tank in the (b)(4) clean out of place (b)(4) room. The black substance was within one foot of stainless-steel pails and other product-contact equipment used for OTC drug production. The base of the wall behind the water tank in the (b)(4) room was also observed to have an uneven surface that contained a similar-appearing black mold-like substance.

Our investigator also observed powder residues at a stainless-steel tray adjacent to the (b)(4) used to compound Tom's Silly Strawberry Anticavity, batch (b)(4). These residues were observed prior to the addition of any solid raw materials.

It is essential that your facility is in a good state of repair and sanitary conditions are maintained to protect drug products from potential routes of contamination.

In your response, you state the (b)(4) room was thoroughly cleaned to remove the black substance which was located at a non-smooth surface transition susceptible to moisture accumulation and in a hard-to-clean area that missed some cleaning activities. You also state the powder observed in the (b)(4) was immediately cleaned prior to adding any solids. You identify that a final check of the area where the powder residues were observed was not part of the (b)(4) required to be completed prior to starting a batch, and the (b)(4) was modified.

Your response is inadequate because it only addresses the equipment and manufacturing areas cited during the inspection and does not include a comprehensive evaluation of the clean and sanitary condition of your facility and equipment used to manufacture OTC drug products.

In response to this letter provide:

- A corrective and preventive action (CAPA) plan and status to implement routine, vigilant operations management oversight of facilities and equipment. This plan should ensure, among other things, prompt detection of equipment/facilities performance issues, effective execution of repairs, adherence to appropriate preventive maintenance schedules, timely technological upgrades to the equipment/facility infrastructure, and improved systems for ongoing management review.
- A comprehensive, independent retrospective assessment of your cleaning effectiveness to evaluate the scope of cross-contamination hazards. Include the identity of residues, other manufacturing equipment that may have been improperly cleaned, and an assessment whether cross-contaminated products may have been released for distribution. The assessment should identify any inadequacies of cleaning procedures and practices and encompass each piece of manufacturing equipment used to manufacture more than one product.

3. Your firm failed to establish and follow adequate written procedures describing the handling of all written and oral complaints regarding a drug product, including provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with 21 CFR 211.192 (21 CFR 211.198(a)).

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Your complaint procedure is inadequate because not all quality related issues are investigated. You only investigate complaints related to adverse event, foreign matter, and incorrect product. For example, approximately 400 complaints related to odor, color, and taste in your toothpaste products, including those for children, were not investigated. These complaints are not investigated because your procedure requires an investigation only if a trend is identified.

Although you state complaint investigations were not required because there was no trend identified, you did not provide a documented evaluation determining the lack of trend for the quality issue specific to each complaint. Instead, you included a general statement from the procedure in each of the complaint's documentation.

In your response, you state that due to the high number of complaints received, you use a risk-based approach and that an individual complaint by itself is not sufficient to implicate a failure of a drug product to meet any of its specifications. You also state you trend your complaints by (b)(4) global quality managers to determine the need for an investigation.

Your response is inadequate. You provide results for an organoleptic flavor evaluation of reserve samples for non-expired batches; however, this evaluation did not include color, odor, or microbial results. Your proposed modification of the complaint procedure does not ensure all complaints will be investigated.

In response to this letter, provide:

A comprehensive assessment of your overall system for investigating complaints. Provide a detailed action plan to remediate this system. Your action plan should include, but not be limited to, significant improvements in investigation competencies, scope determination, root cause evaluation, CAPA effectiveness, quality unit oversight, and written procedures. Address how your firm will ensure all complaint investigations are appropriately conducted.

CGMP Consultant Recommended

Based upon the nature of the violations we identified at your firm, you should engage a consultant qualified as set forth in 21 CFR 211.34 to assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for resolving all deficiencies and systemic flaws to ensure ongoing CGMP compliance.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

Failure to address violations may also cause FDA to withhold issuance of Export Certificates. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any violations are completely addressed and we confirm your compliance with CGMP. We may re-inspect to verify that you have completed corrective actions to address any violations.

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This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done to address any violations and to prevent their recurrence. In response to this letter, you may provide additional information for our consideration as we continue to assess your activities and practices. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 1218077 and ATTN Vilmary Negrón Rodríguez.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

The Column: A Thanksgiving “fireside chat”

In this May 17, 2005 hundreds of gay couples and supporters looked up while streamers fell at the conclusion of a group photo in front of the State House in Boston, one year after Massachusetts became the first U.S. state to recognize same-sex marriages.

UPDATED: November 24, 2024 at 5:03 AM EST

THE SO-CALLED culture wars have a long and ignoble, but influential, role in the history of American politics. The culture wars of 2004 are what brought this reporter to Massachusetts from Michigan, then a bastion of conservatism and lawful discrimination that paled in comparison to the commonwealth’s embrace of human rights and dignity.

During the presidential election of 2004, almost 60% of Michigan voters approved an [amendment to the state’s constitution](#) supporting the “definition of marriage or any similar union” as “the union of one man and one woman.”

First, my partner Snip and I voted at the ballot box and lost; then we voted with our feet. We packed up our jobs and lives, and moved 800 miles away to Massachusetts, which was the first state to legalize same-sex marriage in May 2004. We’ve never looked back.

Wanting to live without looking over your shoulder – and being legally protected – is a powerful motivator for a making a personal diaspora.

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By 2015, the Supreme Court ruled that same-sex couples in the United States, no matter where they live, have the same legal right to marry as different-sex couples. Thanks to that Obergefell v. Hodges ruling, the nation finally caught up to Massachusetts' principled stand that it took way back in May 2004.

We didn't have to wait for marriage equality to prevail; Snip and I were already married and raising three kids, proving every day that love wins.

The new-old culture wars threaten this country's hard-won gains to rise above the fear and scarcity – or the boogey-man – narrative that animates the current divisive political rhetoric.

Whether it's Black Americans using the same restrooms as white Americans, or transgendered people using the bathroom that best matches their [gender identity](#), these human rights issues are repackaged as "culture war" fights by politicians suggesting that bigotry is an American value worth fighting for.

And it's been shockingly effective.

In contrast to President Franklin Delano Roosevelt, whose inaugural address in 1933 spoke to a nation in the throes of a world depression to not fear fear, today's mantra across the national spectrum is to be afraid, to be very afraid.

It's worth quoting the 32nd president's words to remember what it means to be both inspired and committed to be our best selves by the nation's highest elected leader.

"The only thing we have to fear is fear itself – nameless, unreasoning, unjustified terror, which paralyzes needed efforts to convert retreat into advance," Roosevelt said in his 20-minute address from the East Portico of the Capitol. "In every dark hour of our national life, a leadership of frankness and of vigor has met with that understanding and support of the people themselves which is essential to victory. And I am convinced that you will again give that support to leadership in these critical days."

In today's political discourse, Roosevelt, a presidential GOAT, would be considered a woke loser.

This Thanksgiving, I am thankful for people who are not afraid to lead with conviction *and* compassion.

I am thankful for living in the great state of Massachusetts, No. 1 in the country for education and health care.

I am thankful that we make space for [people fleeing](#) unrest and violence in their home countries.

I am thankful for reproductive freedoms enshrined in the state Constitution.

I am thankful for the Healey-Driscoll administration's work on climate change, universal access to free school meals, and free tuition at community colleges, among many other groundbreaking policies and programs.

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I am thankful for nonprofits like [Community Teamwork](#), [Vinfen](#), [Eliot Church](#) and many other advocates who care for Lowell's homeless population.

I am thankful for the city of Lowell's relentless and [creative promotion](#) of the [cultural richness](#) of the Mill City.

I am thankful for the investment taking place in this Gateway City, from [LINC](#) to individual [developers](#), to state and [federal funding](#) of infrastructure projects that will immeasurably improve the lives of all residents.

I am thankful for being a reporter at a free press like The Sun.

And I am thankful for all our readers.

There's more that connects us than divides us – despite what the cultural warriors say – and that's something to be thankful for.

Happy Thanksgiving.

Bank Fraud Prevention

Established in 2000 by the Association of Certified Fraud Examiners (ACFE), International Fraud Awareness Week is a time dedicated to promoting fraud awareness and education.

Here's a breakdown of some common types of fraud to watch out for:

Account Takeover - Account takeover (ATO) fraud occurs when a cybercriminal takes over another person's legitimate online accounts without permission. It can involve stealing banking and credit card information, email accounts, or other sensitive data such as social media logins.

Phishing/Social Engineering - Phishing and Social Engineering scams are manipulation techniques that aim to trick an individual into giving up their sensitive data. This data can include passwords, social security numbers, bank records, or other personal or private information. The request usually appears to be from a familiar person, organization, or company and often contains links to malicious websites.

Check Fraud - While not as common, check fraud happens when a scammer knowingly writes a bad check, alters a check, or fraudulently forges a check. If your checks are not stored in a secure location, they can be stolen by burglars, service workers, and even trusted houseguests, or even straight from your mailbox.

Card Fraud - Have you ever stumbled upon a website you've never shopped at before that has deals that seem too good to be true? Scammers will set up a legitimate looking website in hopes of capturing your credit card information at check-out if you try to make a purchase.

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Impersonation - Impersonation scams are a type of fraud initiated by a person who pretends to be someone you can trust to get your sensitive data. These scams may target an individual or seek to capture sensitive information about a company. They are often elaborate and may target you via email, text messages, social media, or phone calls.

Identity Theft - Identity theft happens when someone other than you uses your personal information to impersonate, and often steal from you. This personal information can include your Social Security number, bank account or credit card information, and even physical identification like your mail, driver's license, or passport.

Now that you understand these common types of fraud, here are some ways you can protect yourself from falling victim to these scams:

Fraud Prevention Tips:

- Use strong, unique passwords and leverage multi-factor authentication (MFA).
- Instead of following the links in an email or text message, contact companies or people using a phone number or website you know is real.
- Don't open attachments or click on links if you don't know the sender or you didn't request the information.
- Make sure your devices are up to date from a security standpoint and have anti-virus protection installed.
- Always mail checks using a secure envelope, and whenever possible hand the envelope directly to your mail carrier or drop it in a secure location or mail processing facility.
- Look for the "s" in https and the key and lock icon in your browser window to confirm a website's legitimacy and proper security.

1 in 5 Americans Get News from Digital Influencers

About one in five Americans - and a virtually identical share of Republicans and Democrats - regularly get their news from digital influencers who are more likely to be found on the social media platform X, according to a report released Monday by the Pew Research Center.

The findings, drawn from a survey of more than 10,000 U.S. adults and an analysis of social media posts posted this summer by influencers, provide an indication of how Americans consumed the news during the height of the U.S. presidential campaign that President-elect Donald Trump ultimately won.

The study examined accounts run by people who post and talk regularly about current events - including through podcasts and newsletters - and have more than 100,000 followers on Facebook, Instagram, YouTube, X or TikTok. They include people across the political spectrum, such as the progressive podcast host Brian Tyler Cohen and conservative podcaster Ben Shapiro, as well as non-partisan personalities like Chris Cillizza, a former CNN analyst who now runs his own newsletter.

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The report found that news influencers posted mostly about politics and the election, followed by social issues like race and abortion and international events, such as the Israel-Hamas war. Most of them - 63% - are men and the majority - 77% - have no affiliation, or background, with a media organization. Pew said about half of the influencers it sampled did not express a clear political orientation. From the ones that did, slightly more of them identified as conservative than as liberal.

During the campaign, both parties and presidential campaigns had courted influencers, including creators who weren't very political, to compete for voters who are increasingly getting most of their news from non-traditional sources.

The Republican and Democratic national conventions had credentialed influencers to cover their events this past summer. Vice President Kamala Harris sat down with Alex Cooper for her "Call Her Daddy" podcast and talked a little Bay Area basketball with the fellows on "All the Smoke." Meanwhile, Trump hung out with the bros on the "Bussin' With the Boys," "Flagrant" and the popular podcaster Joe Rogan as part of a series of appearances targeting young male voters.

"These influencers have really reached new levels of attention and prominence this year amid the presidential election," Galen Stocking, senior computational social scientist at Pew Research Center, said in a statement. "We thought it was really important to look at who is behind some of the most popular accounts - the ones that aren't news organizations, but actual people."

Even though 85% of news influencers have a presence on X, many of them also have homes on other social media platforms, such as Facebook, Instagram, YouTube and TikTok.

Racial minorities, young adults and adults with a lower income were more likely to get their news from news influencers, according to the report. Most of the people surveyed by Pew said news influencers have helped them better understand current events, while roughly a quarter say what they hear has not made much of a difference. A small share - 9% - say influencers have confused them more.

Media analysts have long been concerned about how influencers - most of whom don't have to abide by editorial standards - could fuel misinformation, or even be used by America's adversaries to churn out content that fits their interests. On social media, though, some influencers have positioned themselves as figures presenting neglected points of view.

Pew, which is doing the study as part of an initiative funded by the Knight Foundation, said 70% of the survey respondents believe the news they get from influencers is somewhat different than what they hear elsewhere. Roughly a quarter said it was "extremely or very different."

The report found TikTok is the only one of the major platforms where influencers who identify as right-leaning do not outnumber those who are more liberal. **Pew said news influencers on the short-form video app were more likely than those on other sites to show support for LGBTQ+ rights or identify as part of the LGBTQ+ community.** The platform also had the smallest gender gap for news influencers.

Reported in Boston Globe by Hallelula Hadero- Associated Press

https://www.bostonglobe.com/2024/11/18/business/news-influencers-social-media/?rss_id=section_rss_full&s_campaign=bg:full:rss:section&et_rid=1876204030&s_campaign=businessheadlines:newletter

10 Ways to Keep Your Hair Strong and Healthy (and Reduce Hair Loss) as You Age

Crista McKay Published July 31, 2024 · 16 min read

Summary

Ever wondered why your hair changes as you get older? From graying to thinning, our hair goes through significant transformations with age. But what triggers these changes, and how can we nurture our hair to keep it looking its best? In this article, we uncover the hair growth cycle, the main causes of hair loss, and effective strategies to maintain healthy hair through the years.

https://foodrevolution.org/blog/hair-loss-anti-aging-hair-care/?frn_source=sfmc&frn_medium=email-blo&frn_campaign=blo-24&frn_content=10-ways-to-keep-your-hair-strong-and-healthy-as-you-age&j=307659&sfmc_sub=60681478&l=137_HTML&u=4743670&mid=514008241&jb=683

The Top 10 Public Elementary Schools in Massachusetts

U.S. News researchers based the 2025 ranking of the nation's [best public elementary schools](#) on publicly available data from the U.S. Department of Education. Elementary schools are considered K-6 in the analysis.

The top 10 public elementary schools in Massachusetts are:

- [Woodland](#), Weston
- [Mary Lee Burbank](#), Belmont
- [Swallow/Union School](#), Dunstable
- [John D. Hardy](#), Wellesley
- [Benjamin G Brown](#), Somerville
- [John Ward](#), Newton
- [Mason-Rice](#), Newton
- [Hunnewell](#), Wellesley
- [Spring Street School](#), Shrewsbury
- [Albert S. Woodward Memorial School](#), Southborough

The methodology for the rankings focused on state assessments of students who were proficient or above proficient in math and reading/language arts, while also accounting for students' background and their achievements in core subjects. Student-teacher ratios were applied to break ties.

Edgar Cayce

Friday, December 21

"Know your ideal; not as to what you would like others to be, but what you would be YOURSELF to others - that they might be the same to you!"

ECRL 2409-1

Saturday, December 14

"KNOW the spirit with which you do a thing is the spirit that will respond to you!"

ECRL 1688-1

Monday, December 16

"There is more to life than to live, and a success must be one in which the individual may grow in understanding and in knowledge."

ECRL 1901-1

Evolutions in Being

P.O. Box 4008

Chelmsford, MA 01824

