

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661		DATE(S) OF INSPECTION 3/17/2026-3/23/2026* FEI NUMBER 3000717606			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Stephen P. Hossenlopp, Vice President of Finance					
FIRM NAME The Mentholum Company		STREET ADDRESS 707 Sterling Dr			
CITY, STATE, ZIP CODE, COUNTRY Orchard Park, NY 14127-1557		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: OBSERVATION 1 There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed. Specifically, A. Your firm's OOS investigation practices do not conduct a thorough investigation to determine root causes, leading to repeated failures including out-of-specification results for active pharmaceutical ingredients and content uniformity. Currently you are releasing product despite specification failures based on retest results without proper investigation or justification to invalidate the initial OOS failures. Review of your OOS investigation log from the last 3 years revealed at least 25 investigations concluding with "possible" root causes without definitive determination. Examples include: 1. OOS-946-QC concluding "possible root cause may have been sample preparation error" with no verification 2. OOS-0019-QC concluding "Possible root cause may have been incorrect (b) (4) " 3. OOS-0022-QC concluding "Possible root cause may have been standard preparation". Additionally, at least 6 investigations (OOS-0031-QC, OOS-0049-QC, OOS-0051-QC, OOS-0067-QC, OOS-0069-QC, OOS-0107-QC) conclude "Possible root cause could be the age of the material" without assessing potential supplier or storage issues. B. Your OOS files from 2023-2026 revealed investigation root causes without determining effective corrective action, leading to ongoing OOS failures for the same assays. There are 8 OOS investigations for (b) (4) and Content Uniformity OOS results your firm has experienced over the last 3 years for (b) (4) formulas (OOS-0008-QC, OOS-0026-QC, OOS-0054-QC, OOS-0056-QC, OOS-0058-QC, OOS-0087-QC, OOS-0092-QC, OOS-0110-QC). These investigations covered (b) (4) Product Lots for both stability and finished product release testing with no corrective actions implemented. For example: 1. OOS-0008-QC opened on 2/08/2023 for low (b) (4) in Lots (b) (4) & (b) (4) noted "there have					
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been two other previous OOS investigations for this formulation" and concluded "R&D will evaluate corrective actions" with no evidence of completion or improved results. 2.OOS-0054-QC opened on 7/24/2024 for low/high (b) (4) in release and stability Lots (b) (4), (b) (4), and (b) (4) noted "there have been four previous OOS investigations relating to this test method" and identified analyst error, but no investigation of training deficiency. The test method (TM-0007) was finally revised in August 2025 however, OOS results are still ongoing according to OOS-0110-QC which concludes "Possible root cause could be sample (b) (4)". Subsequently, at least (b) (4) Product Lots were released for sale into the US market without conclusive investigation or invalidation of initial OOS results including (b) (4), and (b) (4).					
OBSERVATION 2 Laboratory records do not include the quantity of the sample. Specifically, During live evaluation of raw material release testing of (b) (4) (Batch # (b) (4)) performed on 3/19/2026, your analyst was observed performing method Q-1045, (b) (4) Assay determination by Gas Chromatography, Version 1.0, Effective Date: 5/18/2022. The analyst was observed: 1. Weighing USP Reference Standard material with weights recorded it Notebook Number 861, Page 51 (weight (b) (4), weight (b) (4)) 2. (b) (4) volumetric flask 3. Assuming (b) (4) volume without measuring or recording the actual volume added 4. Entering the unconfirmed concentration of (b) (4) into the GC software without written verification of calculations The test method requires to "accurately weigh standard known sample to (b) (4)" which necessitates precise measurement and documentation of both weight and volume to calculate concentration. However, no written calculation was recorded to confirm the known standard solution concentration ((b) (4)) prior to entry into the GC system. When questioned, the analyst stated: "I always add exactly (b) (4)." Additionally, historical data review of the analysts Laboratory notebook and raw data from the same method performed by the same analyst on April 2, 2025, for (b) (4) Lot # (b) (4) recorded in Notebook # 833, Page 25, confirmed this is an established practice, showing the same documentation practice which lacked (b) (4) volume added, and no standard concentration calculated.					
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The (b) (4) raw material Lot # (b) (4) released based on this testing was used in the manufacture of (b) (4) batches of finished OTC drug products between August 2025-February 2026.			
OBSERVATION 3 Determinations of conformance to appropriate written specifications for acceptance are deficient for drug products. Specifically, Your firm changed batch release specifications in response to out-of-specification (OOS) results without providing adequate scientific rationale, and without following formal change control procedures. Review of the OOS log identified at least (b) (4) specification changes made in response to OOS results over 3 years (OOS-0002, OOS-0005-QC, OOS-0009-QC, OOS-0021-QC, OOS-0024-QC, OOS-0030-QC, OOS-0041-QC, OOS-0053-QC, OOS-0055-QC, OOS-0080-QC) allowing substandard batches to be released to the market. For example: A. OOS-0021-QC - (b) (4), Lot (b) (4) - Deficiencies in OOS-0021-QC Investigation: Your firm explicitly states "no root cause for the high (b) (4) values has been determined" yet proceeded to change the specification and release the batch. However, the specification was widened from (b) (4) % to (b) (4) % specifically to accommodate the 107.3% failing result. No scientific rationale was provided for why (b) (4) % (b) (4) is acceptable when (b) (4) % was previously the upper limit, or what quality attributes are affected by higher (b) (4) levels. The investigation committed to "review of stability data providing proof that the (b) (4) analysis is stable throughout the expiry" yet the batch was released prior to completion of PHASE (b) (4) : Follow-up Completion which remains blank. On, 11/27/2023, the batch was released as "acceptable and safe for consumer use" based on the assertion it "is expected to pass all stability requirements" - an assumption, not verified data. B. OOS-0024-QC - (b) (4) Process Validation, Lots (b) (4) - Deficiencies in OOS-0024-QC Investigation: Your firm changed specifications to accommodate the failing process validation batch without investigating why the process cannot meet specifications, modifying the process, or repeating validation with successful batches. Rather than investigating why viscosity exceeded specifications and correcting the process, your firm eliminated the specification without justification for why viscosity is not critical to quality. Your firm justified high (b) (4) (0.176% vs. (b) (4) % specification) by stating it is "within the USP tolerance of (b) (4) % amount max"; however, the batch failed your firm's established specification. USP maximum is a safety limit, not a quality target. All results being above specification indicates an			
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unaddressed process problem. No investigation was conducted into why the process cannot consistently meet specifications for (b) (4), viscosity, and homogeneity. On 01/08/2024 Lot # (b) (4) was released for distribution.					
OBSERVATION 4 Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures. Specifically, Your firm's Annual Product Review (APR) procedures and execution are inadequate to identify trends and drive continuous improvement. For example: A. Deficiencies in 2024 APR for Formula (b) (4) 1. The 2024 APR states "no significant trends on assay results for (b) (4), and (b) (4)" despite three documented OOS investigations (OOS-0012-QC at (b) (4) stability, OOS-0017-QC at (b) (4) stability and OOS-0064 for finished product) all involving (b) (4) degradation and low OOS. OOS-0017-QC noted "historically, there have been various OOS investigations for this formulation container closure system (b) (4)," yet there is no mention to corrective actions taken to address recurrence. 2. The APR states "no trends were noted" in deviations despite documenting 10 deviations where 50% were labeling/packaging issues, 30% were process control issues, and 20% were material accountability failures - clear patterns that were not identified or addressed. 3. The APR identified that (b) (4) has a Cpk of 0.91 (below the (b) (4) specification, indicating the process is not in control) and states "assay results for (b) (4) are at the upper end of the specification range" but took no corrective action. No CAPA was documented to center the process, and no determination as to why (b) (4) trends high. 4. For OOS-0017-QC (Lot # (b) (4), (b) (4) stability failure with 81.7% (b) (4) and 87.3% (b) (4)), the APR provides only one sentence: "The retest values are all within specification range, refer to OOS-0017-QC" with no discussion of root cause, impact assessment, CAPA, or whether the (b) (4) expiration date remains appropriate after a (b) (4) failure.					
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B.Deficiencies in SOP M-0050 (Annual Product Reviews) Your APR procedure lacks specific requirements for: CAPA documentation, Trending methodology, Management review, Process validation status review, Cleaning validation status review, Supplier performance review, and Training program effectiveness review Also, Section 5.3 states specifications and processes are "<i>updated as needed</i>" with no criteria for when updates are needed, no CAPA documentation requirements, no timelines, and no management approval requirements. The APR functions as a compliance exercise rather than a quality improvement tool, with issues identified but not acted upon and no evidence of continuous improvement.			
*DATES OF INSPECTION 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon)			
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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."