WARNING LETTER

Ultra Seal Corporation

MARCS-CMS 624650 — MARCH 14, 2022

Delivery Method:

Electronic Mail

Product:

Drugs

Recipient:

Mr. Dennis P. Borrello

President and CEO

Ultra Seal Corporation

521 Main Street
New Paltz, NY 12561
United States

Issuing Office:

Office of Pharmaceutical Quality Operations

United States

Warning Letter 624650

March 14, 2022

Dear Mr. Borrello:

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The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facilities, ULTRAtab Laboratories Inc., FEI 3003068822, at 50 Toc Drive, Highland, from August 16 to September 14, 2021 ("ULTRAtab Toc Drive" or "Toc Drive"); ULTRAtab Laboratories Inc., FEI 3016117472, at 240 South Riverside Drive, Highland, from August 24 to September 14, 2021 ("ULTRAtab Riverside" or "Riverside"); and Ultra Seal Corporation, FEI 1317759, at 521 Main Street, New Paltz, from November 8 to 19, 2021.

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).

We reviewed your October 5, 2021 response and your December 15, 2021 response to our Form FDA 483(s) in detail, and acknowledge receipt of your subsequent correspondence.

During our inspections, our investigators observed specific violations including, but not limited to, the following.

ULTRAtab Toc Drive

1. Your firm failed to establish and follow adequate written procedures for cleaning and maintenance of equipment (21 CFR 211.67(b)).

Your firm manufactures numerous over-the-counter (OTC) drug products in various dosage forms on non-dedicated equipment including **(b)(4)**, blenders, and tablet presses. FDA investigators observed that the cleaning validation studies for many critical, non-dedicated equipment with direct drug product contact surfaces were incomplete. During the inspection, your

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firm was unable to provide adequate justification that current cleaning procedures adequately remove drug residues and prevent cross-contamination.

Furthermore, your firm's cleaning procedures lacked adequate specificity and detail to be performed consistently and be validated. For example, standard operating procedure (SOP) MF- 22 "Procedure for Cleaning **(b)(4)**," Section 7.3.9 contained instructions to "**(b)(4)**." **(b)(4)** are an example of product contact equipment that is extremely difficult to clean and is therefore usually dedicated to a specific drug product. You did not have scientific data that visibly clean **(b)(4)** do not result in carryover of drug residues from one drug product to another. Additionally, cleaning to remove only visual residue is inadequate. Non-visible residues, including those from the cleaning process itself, must also be adequately removed. Your firm must have adequate and validated cleaning procedures.

This is a repeat observation from the 2020 inspection and was a discussion item during the August 13, 2020, regulatory meeting.

In your response, you stated that you will review and revise cleaning procedures, update cleaning validation protocols, and contract a third party to assist with cleaning validation. Your response is inadequate because it did not consider the impact that your deficient cleaning practices for non-dedicated equipment may have had on drug products that remain on the U.S. market. Additionally, you stated that upon the resumption of manufacturing, you would implement interim equipment cleaning validation protocols. However, you did not provide sufficient details about such protocols.

In response to this letter provide the following:

• 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 of whether cross-contaminated drug products may have been released for distribution. The assessment should identify any inadequacies of cleaning procedures and

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practices and should encompass each piece of manufacturing equipment used to manufacture more than one product.
• Appropriate improvements to your cleaning validation program, with special emphasis on incorporating conditions identified as worst case in your drug manufacturing operation. This should include, but should not be limited to, identification and evaluation of all worst case:
  o Drugs with higher toxicities
  o Drugs with higher drug potencies or drugs of lower solubility in their cleaning solvents
  o Drugs with characteristics that make them difficult to clean
  o Swabbing locations for areas that are more difficult to clean
  o Maximum hold times before cleaning
• A description of the steps that must be taken in your change management system before introduction of new manufacturing equipment or a new product.
• A summary of updated SOPs that ensure an appropriate program is in place for verification and validation of cleaning procedures for drug products, processes, and equipment.
• A commitment to dedicate your **(b)(4)** to individual drug products or provide cleaning validation data to demonstrate your cleaning procedures can adequately remove residues and prevent cross-contamination.

2. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Your firm failed to adequately investigate out-of-specification (OOS) laboratory results and unexplained discrepancies. For example:

• Your investigation into cross-contamination of 22 lots of Pain Aid Extra Strength (ESF) tablets with the active pharmaceutical ingredient (API) guaifenesin, which is not part of the ESF formulation, failed to scientifically identify the root cause of the contamination. Instead of investigating each OOS result, your firm compiled all the OOS results into one investigation, which resulted in no corrective action and preventive action (CAPA). Your firm then proceeded to modify approved analytical method TM-48A to

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retest new sample preparations. Your retesting also produced failing test results for guaifenesin cross- contamination. When you did not obtain favorable results, your firm then used a new and unvalidated test method, TM-149, to test only the failed samples, obtained passing results, and subsequently released the drug product lots for distribution.

• Your investigation into cross-contamination of four lots of 3-Component Cold Tabs tablets with the API, caffeine, which is not part of the formulation, failed to scientifically identify the root cause of the contamination. Based on assumptions, your firm then retested the failed lots **(b)(4)** times with unvalidated test methods and without identifying a root cause for the repeat OOS results until passing results were obtained, and subsequently released the drug product for distribution.

In both instances of cross-contamination, you disregarded all previous failing test results without providing adequate scientific justification to invalidate the original OOS or identify a root cause. Instead, your firm resampled and retested failing lots with invalidated and unverified test methods until passing results were obtained.

In your response, you indicated that you have recalled product, but you have not performed a review of all OOS investigations of product within expiry that may warrant additional market action. Your response is inadequate because it fails to recognize and address systematic failings of your quality unit (QU) that allow repeated testing into compliance.

In response to this letter, provide the following:
• A retrospective, independent, review of all invalidated OOS (including in-process and release/stability testing) results for U.S. drug products, irrespective of whether the batch was ultimately distributed in the United States, and a report summarizing the findings of the analysis, including the following for each OOS:
  o Determine whether the scientific justification and evidence relating to the invalidated OOS result conclusively or inconclusively demonstrates causative laboratory error.
  o For investigations that conclusively establish laboratory root cause, provide rationale, and ensure that all other laboratory methods vulnerable

to the same (or a similar) root cause are identified for remediation.
  o For all OOS results found by the retrospective review to have no root cause or an inconclusive root cause identified in the laboratory, include a thorough review of production (for example, batch manufacturing records, adequacy of the manufacturing steps, suitability of equipment/facilities, variability of raw materials, process capability, deviation history, complaint history, batch failure history). Provide a summary of potential manufacturing root causes for each investigation and any manufacturing operation improvements.
• A comprehensive review and remediation plan for your OOS result investigation systems. The CAPA should include, but not be limited to addressing, the following:
  o QU oversight of laboratory investigations
  o Identification of adverse laboratory control trends
  o Resolution of causes of laboratory variation
  o Initiation of thorough investigations into potential manufacturing causes whenever a laboratory cause cannot be conclusively identified
  o Adequate scoping of each investigation and its CAPA
  o Revised OOS investigation procedures with these and other remediations
• A comprehensive, independent assessment of your overall system for investigating deviations, discrepancies, complaints, OOS results, and failures. 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, QU oversight, and written procedures. Address how your firm will ensure that all phases of the investigations are appropriately conducted.
• Your action plan to address any product quality or patient safety risks for all your drug products in U.S. distribution, including potential customer notifications and recalls.

For more information about handling failing, OOS, out-of-trend, or other unexpected results and documentation of your investigations, see FDA's guidance document *Investigating Out-of- Specification (OOS) Test Results*

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for Pharmaceutical Production at https://www.fda.gov/media/71001/download (https://www.fda.gov/media/71001/download).

ULTRAtab Riverside

1. Your firm failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed (21 CFR 211.192).

Your Riverside facility conducts analytical testing of drug products manufactured at your ULTRAtab Toc Drive facility.

Your firm did not adequately investigate OOS laboratory results and unexplained discrepancies. You failed to appropriately justify potential root causes, expand investigations to all potentially affected lots, and implement CAPA.

Specifically, you obtained OOS test results for assay and **(b)(4)** impurities observed in the 25℃ ± 2℃, 60% ± 5% relative humidity stability program for numerous batches of acetaminophen 250 mg/aspirin 250 mg/caffeine 65 mg tablets at **(b)(4)** and **(b)(4)**.
During your investigation, you tested reserve samples stored under the less-stressed condition of **(b)(4)**, and without controlled relative humidity. After obtaining passing results, you concluded that 60% ± 5% humidity storage condition was the cause for the aspirin sub-potency and **(b)(4)** impurities without scientific justification, maintaining that the OOS results "may not represent condition of typical lot 18J024 consumer goods in the marketplace." At the time, your firm took no market action.

In your response, you stated that you hired a third-party consultant, have ceased manufacturing and distribution, and initiated a voluntary recall of acetaminophen 250 mg/aspirin 250 mg/caffeine 65 mg tablets. Additionally, you stated you will conduct a review of testing operations and develop and implement CAPAs. Your response did not address the 60% ± 5% humidity storage condition.

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Your response is inadequate. Standard stability storage for the United States is at conditions with a relative humidity of 60% ± 5%.1 Additionally, the analytical testing operations were transferred from your Toc Drive facility to your Riverside facility. However, the manager of Riverside still reports to Toc Drive's QU, which was notified of similar issues during 2018 and 2020 FDA inspections at Toc Drive. Your response lacked sufficient information on actions taken between 2018 and the current inspection to remediate your QU oversight of laboratory operations.

Furthermore, your response lacked sufficient detail:
• To address potential impact of inadequate OOS investigations on other drug products currently on the market
• To identify the root cause of continued inadequate investigations and inadequate QU oversight
• To evaluate the effectiveness of your quality system with respect to investigations and associated CAPAs

In response to this letter, provide the following:
• A retrospective, independent review of all invalidated OOS (including in-process and release/stability testing) results for U.S. drug products, irrespective of whether the batch was ultimately distributed in the United States, and a report summarizing the findings of the analysis, including the following for each OOS:
  o Determine whether the scientific justification and evidence relating to the invalidated OOS result conclusively or inconclusively demonstrates causative laboratory error.
  o For investigations that conclusively establish laboratory root cause, provide rationale, and ensure that all other laboratory methods vulnerable to the same (or a similar) root cause are identified for remediation.
  o For all OOS results found by the retrospective review to have no root cause or an inconclusive root cause identified in the laboratory, a thorough review of production (for example, batch manufacturing records, adequacy of the manufacturing steps, suitability of equipment/facilities, variability of raw materials, process capability, deviation history, complaint history, batch failure history). Provide a summary of potential manufacturing root causes for each investigation and any manufacturing operation

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improvements.
• A comprehensive review and remediation plan for your OOS result investigation systems. The CAPA should include, but not be limited to addressing, the following:
  o QU oversight of laboratory investigations
  o Identification of adverse laboratory control trends
  o Resolution of causes of laboratory variation
  o Initiation of thorough investigations into potential manufacturing causes whenever a laboratory cause cannot be conclusively identified
  o Adequate scoping of each investigation and its CAPA
  o Revised OOS investigation procedures with these and other remediations
• A comprehensive, independent assessment of your overall system for investigating deviations, discrepancies, complaints, OOS results, and failures. 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, QU oversight, and written procedures. Address how your firm will ensure that all phases of the investigations are appropriately conducted.
• Your action plan to address any product quality or patient safety risks for all your drug products in U.S. distribution, including potential customer notifications and recalls.

For more information about handling failing, OOS, out-of-trend, or other unexpected results and documentation of your investigations, see FDA's guidance document *Investigating Out-of- Specification (OOS) Test Results for Pharmaceutical Production* at https://www.fda.gov/media/71001/download (https://www.fda.gov/media/71001/download).

2. Your firm failed to establish and follow required laboratory control mechanisms. (21 CFR 211.160(a)).

You did not adequately validate numerous test methods utilized in drug product testing. According to CAPA-2020-034, of your **(b)(4)** test methods, approximately 60 test methods were reported as deficient, and 75 test method validation or verification reports were missing. These deficient

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or potentially unvalidated or unverified test methods continued to be used for the in- process testing of pharmaceutical blends, as well as for the release and stability testing of bulk drug and finished drug products. For example, method TM-19, "Analysis of Phenylephrine HCL," was not validated, but was used for the release of at least **(b)(4)** batches of 5 mg phenylephrine HCl tablets currently on the market. Additionally, your Excel workbooks used for calculations did not produce reliable results, as demonstrated by numerous errors.

In your response, you stated that you temporarily suspended release and stability testing operations and would finish method validation or verification by November 1, 2021. You indicated that you obtained a CGMP consultant to assist with performing a review of all test methods and associated validation and verification reports for potential impact on drug products. In your subsequent response, dated November 5, 2021, you stated that you contracted **(b)(4)** to conduct chemical and product stability testing and cleaning validation chemical testing.

Your response is inadequate because it lacked sufficient detail:
• To evaluate the effectiveness of implementing the remediation of the systemic laboratory issues
• To evaluate the effectiveness of retrospective assessment of potential quality concerns for drug products currently on the market
• To demonstrate how you qualified **(b)(4)** as the CGMP contract testing lab for your stability samples
• To address the validation status and comparability of the test methods used by your CGMP contract laboratories, including **(b)(4)**

In response to this letter, provide the following:
• A comprehensive, independent assessment of your laboratory practices, procedures, methods, equipment, documentation, and analyst competencies. Based on this review, provide a detailed plan to remediate and evaluate the effectiveness of your laboratory system.
• A retrospective review and comprehensive assessment of the impact on safety, identity, strength, quality, and purity of your drug products on the market.

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See FDA's guidance document *Analytical Procedures and Methods Validation for Drugs and Biologics* for general principles and approaches that FDA considers appropriate elements of method validation at https://www.fda.gov/media/87801/download (https://www.fda.gov/media/87801/download).

3. Your firm failed to exercise appropriate controls over computer or related systems to assure that only authorized personnel institute changes in master production and control records, or other records (21 CFR 211.68(b)).

Your firm did not have adequate oversight and control of its electronic data and software systems. During the inspection, our investigators observed that your analysts ran single injections on high performance liquid chromatography (HPLC) equipment without justification and saved the associated data in a folder entitled "single runs," without a documented purpose. Our investigators also observed multiple actions such as "Deleted Methods," "Aborted Runs," "Deleted Manual Integrations," and "Stop Data Acquisition" in the HPLC audit trails, also without a documented purpose. Additionally, your analysts have the privileges to modify approved test methods in HPLC equipment. Your inadequate control over electronic record- keeping systems did not ensure that data is reliable and accurate.

In your response, you stated that you would install and qualify the **(b) (4)** software, revise your SOP to include routine review of single injection runs, and establish policies and procedures to govern laboratory testing for investigative purposes. Additionally, you assigned a quality assurance professional to the laboratory.

Your response is inadequate because you did not provide details or clarity on when single injection runs may be used. Additionally, it did not include a retrospective evaluation of impact on product on the market, nor did it include a description of how you plan to remediate your firm's oversight of the electronic record-keeping system and relevant data.

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In response to this letter, provide the following:
• A list of all laboratory instruments and software identifying which have activated audit trails.
• A list of all software configurations, details of all user privileges up to and including administrator rights, and oversight roles for each of your laboratory systems. Regarding user privileges, specify user roles and associated user privileges for all staff who have access to the laboratory computer systems, with their organizational affiliation and title. Describe in detail how you will ensure that administrative privileges are fully segregated and completely independent of QU laboratory personnel.
• Your action plan, with timelines, describing your interim controls and when audit trails at all appropriate levels will be enabled for all applicable laboratory instruments and electronic data systems, as well as when procedures will be implemented for the review of audit trails before the release of analytical results subject to CGMP.
• A retrospective review and risk assessment on all manual integration events in your audit trails. Include written procedures to define the conditions and circumstances when manual integration would be allowed and predefine manual integration procedures based on scientific justification. Provide procedures to document, track, and investigate such events.

Responsibilities of a Contract Testing Lab

Your Riverside facility also conducts testing for other drug manufacturers. FDA considers contractors as extensions of the manufacturer's own facility. Your failure to comply with CGMP may affect the quality, safety, and efficacy of the drugs you test for your clients. It is essential that you understand your responsibility to operate in full compliance with CGMP, and that you inform all your customers of any out-of-specification results or significant problems encountered during the testing of these drugs.

For additional information, refer to FDA's guidance document *Contract Manufacturing Arrangements for Drugs: Quality Agreements* (https://www.fda.gov/media/86193/download (https://www.fda.gov/media/86193/download)).

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Ultra Seal Corporation

1. Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging materials, labeling, and drug products (21 CFR 211.22(a)).

Ultra Seal Corporation oversees both facilities above in addition to its own operations and is responsible for releasing drug products into interstate commerce. Your QU did not provide adequate oversight of the manufacture of your drug products manufactured at your multiple facilities, including oversight of cleaning, investigations, and laboratory operations.

Your firm's QU failed to adequately exercise its responsibility for finished drug product release. Your QU makes decisions on drug product release based on the test results obtained from ULTRAtab Riverside. As noted above, you failed to ensure adequate testing for your drug products' identity, strength, quality, and purity, because the test methods used for drug release and stability testing at your laboratory facility were not verified or validated. Yet, since at least early 2021, your QU continued to release numerous drug product batches based on test results obtained from these unvalidated test methods.

Your firm failed to adequately exercise its responsibility to ensure that stability samples were tested at designated time points according to your SOP QA-65, "Stability System Procedure." As a result, you lacked adequate data to ensure that drug products currently on the market maintain their identity, strength, quality, purity, and safety throughout their labeled shelf-lives.

In your response, you stated that the test methods are based on USP monographs that require verification only and that you will determine the root cause for releasing drug product batches using unverified test methods. You also stated that you have contracted a third-party laboratory to conduct method verification and to test the stability samples.

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Your response is inadequate because you failed to address the impact of using unvalidated and unverified methods on the identity, strength, quality, and purity of the drug products currently on the market, regardless of whether the drug products have USP monographs.

Significant findings in this letter indicate that your QU is unable to fully exercise its authority and/or responsibilities. Your firm must provide the QU with the appropriate authority and sufficient resources to carry out its responsibilities and consistently ensure drug quality.

In response to this letter, provide the following:
• A comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to function effectively. The assessment should also include, but not be limited to:
  o A determination of whether procedures used by your firm are robust and appropriate
  o Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices
  o A complete and final review of each batch and its related information before the QU disposition decision
  o Oversight and approval of investigations and discharging of all other QU duties to ensure identity, strength, quality, and purity of all drug products
  o A description of how top management supports quality assurance and reliable operations, including but not limited to the timely provision of resources, to proactively address emerging manufacturing and quality issues and to ensure a continuing state of control.
• An independent investigation for deviation from your Quality Manual to release drug products using unverified or unvalidated test methods.
• Your plan or procedures to ensure that only test data from validated or verified test methods are used to make batch release decisions.
• Your action plan to address any product quality or patient safety risks for all your drug products in U.S. distribution, including potential customer notifications and recalls.

Repeat Observations at Multiple Sites

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FDA cited similar CGMP observations at facilities in your company's network. These repeated failures at multiple sites demonstrate that your management's oversight and control over the manufacture of drugs is inadequate.

• On June 29, 2018, Ultra Seal Corporation, FEI 1317759, was cited for, among other items, inadequate stability program, inadequate OOS investigations, and inadequate equipment cleaning procedures and validations.
• On January 31, 2020, ULTRAtab Laboratories Inc., Toc Drive, FEI 3003068822, was cited for, among other items, inadequate OOS investigations, inadequate equipment cleaning procedures and validations, and inadequate controls over computer or related systems.

Your executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance. You should immediately and comprehensively assess your company's global manufacturing operations to ensure that systems, processes, and the drug products manufactured conform to FDA requirements.

Drug Product Production and Testing Suspended

We acknowledge your commitment to suspend production and testing of drugs at the Toc Drive and Riverside facilities, respectively, until remediation is completed. In response to this letter, provide an estimate of when you will resume manufacturing operations at these facilities. Additionally, notify this office before resuming your operations.

Data Integrity Remediation

Your quality system does not adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you test. See FDA's guidance document *Data Integrity and Compliance with Drug CGMP* for guidance on establishing and following CGMP compliant data integrity practices at https://www.fda.gov/media/119267/download (https://www.fda.gov/media/119267/download).

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We acknowledge that you are using a consultant to audit your operation and assist in meeting FDA requirements. In response to this letter, provide the following:

A. A comprehensive investigation into the extent of the inaccuracies in data records and reporting, including results of the data review for drugs distributed to the United States. Include a detailed description of the scope and root causes of your data integrity lapses.

B. A current risk assessment of the potential effects of the observed failures on the quality of your drugs. Your assessment should include analyses of the risks to patients caused by the release of drugs affected by a lapse of data integrity, and analyses of the risks posed by ongoing operations.

C. A management strategy for your firm that includes the details of your global corrective action and preventive action plan. The detailed corrective action plan should describe how you intend to ensure the reliability and completeness of all data generated by your firm, including microbiological and analytical data, manufacturing records, and all data submitted to FDA.

Conclusion

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

Correct any violations promptly. Failure to promptly and adequately address this matter may result in regulatory or legal action without further notice including, without limitation, seizure, and injunction. Unresolved violations may also prevent other Federal agencies from awarding contracts.

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

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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.

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 ORAPHARM1_RESPONSES@fda.hhs.gov. Your written notification should refer to the Warning Letter and include FEI number's 1317759, 3003068822, and 3016117472.

If you have questions regarding the content of this letter, please contact us through ORAPHARM1_RESPONSES@fda.hhs.gov, and "cc" Compliance Officers, Emmanuel Ramos (Emmanuel.Ramos@fda.hhs.gov), Lisa Orr (Lisa.Orr@fda.hhs.gov) and Jose Hernandez- Guzman (jose.hernandez-guzman@fda.hhs.gov).

Sincerely,
/S/
Alonza E. Cruse

Program Director
Office of Pharmaceutical Quality Operations

Office of Regulatory Affairs

/S/
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cc:
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1 The relative humidity of 60% ± 5% corresponds to climatic zone II. See FDA's guidance document 1A(R2) Stability Testing of New Drug Substances and Products at https://www.fda.gov/media/71707/download (https://www.fda.gov/media/71707/download).

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