WARNING LETTER

Results RNA, LLC

MARCS-CMS 578997 — JUL 29, 2019

Delivery Method: VIA SIGNATURE CONFIRMED DELIVE
Product: Drugs

Recipient:

Mr. David L. Larson
CEO and President
Results RNA, LLC
1272 S 1380 W
Orem, UT 84058
United States

Issuing Office:

Division of Pharmaceutical Quality Operations IV
19701 Fairchild
Irvine, CA 92612-2506
United States

WARNING LETTER

VIA UPS SIGNATURE CONFIRMED DELIVERY

July 29, 2019

Mr. David L. Larson
CEO and President
Results RNA, LLC
1272 S 1380 W
Orem, Utah 84058

Dear Mr. Larson:

The U.S. Food and Drug Administration (FDA) conducted an inspection at Results RNA, LLC, FEI 3009469622, at 1272 S 1380 W, Orem, Utah, from December 3 to 18, 2018.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 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 January 16, 2019, response in detail and acknowledge subsequent responses. While you stated that you will no longer manufacture drug products, you do not adequately address the impact of poor manufacturing practices and inadequate quality unit (QU) oversight for the manufacture of drug products that remain on the market and within expiry.

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

1. Your firm's quality control unit failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity (21 CFR 211.22).

During the inspection, our investigator observed that your QU did not provide adequate oversight for the manufacture of your over-the-counter (OTC) drug products, including drugs required to be sterile. For example, your QU failed to ensure that all testing was performed and reviewed prior to batch release; batch records were adequate; validation was performed; and a stability program was established to support product shelf life.

In response to this letter, provide a retrospective assessment of your drug products on the U.S. market within expiry to identify and take appropriate action on any product quality or patient safety risks. This assessment should include but not be limited to testing of retains of all drug product batches that remain on the market for all appropriate chemical and microbiological attributes. Provide a timeline that ensures prompt initiation and completion of this testing. Specify what actions you will take, such as notifying customers and recalling products, if your assessment indicates that any drug product batch may be compromised.

2. Your firm failed to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes (21 CFR 211.113(b)).

Your filling suite is not suitable for filling sterile drugs, whether aseptically filled or **(b)(4)** sterilized. For example, you lacked the following:
• an area that is suitable for sterile product manufacturing
• process validation for Lubrisine eye drops
• manufacturing processes designed and controlled to prevent contamination and reliably render your Lubrisine eye drops sterile
• sterility testing on finished drug product batches of Lubrisine eye drops
• adequate written procedures and practices for environmental monitoring during manufacturing

Drug Production Ceased and Product Recalled

We acknowledge your commitment to cease production of drugs at this facility for the U.S. market. Additionally, during the inspection, you initiated a recall of all Lubrisine eye drop batches after investigators identified you did not have suitable processes designed to reliably render your Lubrisine eye drops sterile.

In response to this letter, clarify whether you intend to resume manufacturing any drugs at this facility in the future. Provide the response on company letterhead signed by the top official at your firm. If you plan to resume manufacturing drugs, notify this office in writing to arrange for a meeting to discuss required remediation prior to resuming operations.

CGMP Consultant Recommended

While you indicated in your response that your firm will cease drug manufacturing, you did not provide information on how you will ensure that none of the products you continue to manufacture are drug products. We recommend that you engage a consultant qualified to help you identify which products are drugs, so you can meet your commitment to cease all drug product manufacturing.

Additionally, if you intend to resume manufacturing drugs for the U.S. market in the future, we strongly recommend engaging a consultant qualified as set forth in 21 CFR 211.34 to assist your firm in meeting CGMP requirements. The consultant should aid you to address all the above issues systemically and assist with comprehensive corrective actions and preventive actions before you resume any drug product manufacturing.

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

Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations.

Correct the violations cited in this letter promptly. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved violations in this warning letter may also prevent other Federal agencies from awarding contracts.

FDA may also withhold approval of requests for export certificates and approval of pending new drug applications or supplements listing your facility as a supplier or manufacturer until the above violations are corrected. We may re-inspect to verify that you have completed your corrective actions.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your violations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Specify what you have done since our inspection to correct your deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Please send your electronic reply to ORAPHARM4_Responses@FDA.HHS.GOV or mail your reply to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild Road
Irvine, California 92612-2506

Please identify your responses with the unique identifier: **CMS 578997**.

If you have questions regarding the contents of this letter, please contact Mariza Jafary, Compliance Officer via email at Mariza.Jafary@fda.hhs.gov or by telephone at 949-608-2977.

Sincerely,
/S/
CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

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