Cerno Pharmaceutical 5/15/18

Office of Pharmaceutical Quality Operations,
Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204

May 15, 2018

CMS Case #546921

WARNING LETTER

VIA UPS Overnight

Juan J. Hernandez, Owner and President
Cerno Pharmaceuticals, LLC
6714 NW 72nd Ave.
Miami, Florida 33166-3045

Mr. Hernandez:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Cerno Pharmaceuticals, LLC at 6714 NW 72nd Ave., Miami, Florida, from November 13 to 17, 2017.

This warning letter summarizes significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals. See 21 Code of Federal Regulations (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).

Additionally, your drug products are misbranded. Specifically, as formulated and labeled, Verruguin Wart Remover is misbranded under section 502(c) of the FD&C Act, 21 U.S.C. 352(c). Both Verruguin and Stamapro are misbranded under section 502(x) of the FD&C Act, 21 U.S.C. 352(x).

We reviewed your December 13, 2017, response in detail.

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

CGMP Violations

1. Your firm failed to withhold from use each lot of components, drug product containers, and closures until the lot had been sampled, tested, or examined, as appropriate, and released for use by the quality control unit (21 CFR 211.84(a))

Your firm manufactured an over the counter (OTC) wart remover drug product, Verruguin Wart Remover. You produced this drug using a raw material, salicylic acid, lot **(b)(4)**, before the component was tested and before it was released for use by the quality unit. During the inspection, you stated that you sent the raw material for testing and the test result was still pending. You also stated that you manufactured the wart remover “at risk” and would take appropriate actions should the raw material not meet its specifications.

In your response, you stated that you were creating a deviation report for using raw material before final release. You also stated you would train your staff on deviation reporting.

Your response is inadequate. It is unacceptable as a matter of CGMP to manufacture drugs from components that have not been tested or examined prior to use, and released for use by the quality unit. Reporting such incidents as deviations will not mitigate the failure to ensure that raw materials are withheld from use until they have been tested or examined, and then released by the quality unit.

In your response to this letter, provide analytical results of testing performed on components that you used to manufacture drugs before those components were released for use by the quality unit. Include measures you will take to prevent the use of untested, unexamined, or unreleased raw materials in the future.

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

You did not follow your own procedures for cleaning your equipment. Your firm’s cleaning procedure, CP-QA-015, Room/Equipment Cleaning and Release, states wet (major) equipment cleaning will be performed when it has been more than **(b)(4)** days from the previous cleaning. However, your filling room records show a minor (dry) equipment cleaning was performed on July 31, 2017. The immediately-preceding entry shows a major (wet) cleaning on May 26, 2017, more than two months earlier. You acknowledged that a wet clean should have been performed on July 31, 2017, and not a dry clean as documented.

In your response, you stated that you would revise your procedures to ensure that a major cleaning will take place prior to production if the equipment has not been used for an extended period of time, and that you would train employees on cleaning.

Your response is inadequate because you failed to assess the effect of this deficiency on product quality. You also did not include your plan for how you will prevent this deficiency in the future. In addition, your response is inadequate because you failed to define “extended period of time.” Adequate equipment cleaning is crucial to prevent your drugs from being contaminated by other materials or products that are manufactured using shared equipment.

In your response, provide your revised cleaning procedure, and details on how you will effectively train employees and enforce your cleaning procedures.

3. Your firm failed to maintain adequate written records of major equipment maintenance and use (21 CFR 211.182).

You do not have equipment use logs for the blender and filler you use for manufacturing liquid products. Your firm uses combined “Room/Equipment Cleaning and Use Logs” to document equipment cleaning and use, but the logs do not contain adequate information to document who performed what operations and when. For example, our investigator asked you whether the log entries “**(b)(4)**” on May 26, 2017, and “**(b)(4)**” on July 31, 2017, indicated cleaning of the mixer, filler, or room. You did not know. Furthermore, multiple fields in the logs were blank.

In your response, you provided the same combined room and equipment cleaning and use logs for Suites **(b)(4)**, **(b)(4)**, and **(b)(4)** that our investigator collected at the inspection. These combined logs are unacceptable because they do not show, for each piece of equipment, the date, time, product, and lot number of each batch processed, with signatures.

In your response, provide copies of your revised equipment logs demonstrating how your will account for all the information for each piece of equipment. Also, provide the controls you are putting into place to ensure your operators use the logs correctly and maintain them properly.

CGMP consultant recommended

Based upon the nature of the violations we identified at your firm, we strongly recommend engaging 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 fully resolving all deficiencies and ensuring ongoing CGMP compliance.

Misbranding Violations
Verruguin and Stamapro

Examples of claims observed on your product labels for Verruguin and Stamapro that establish the intended uses of the products include, but may not be limited to, the following.
• Verruguin: “Wart Remover . . . for the removal of common warts.”
• Stamapro: “Male Genital Desensitizer . . . helps in the prevention of premature ejaculation.”

Based on the above claims, Verruguin and Stamapro are “drugs” as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. 321(g)(1)(B), because they are intended for the diagnosis, cure, mitigation, treatment, or prevention of disease, and/or under section 201(g)(1)(C) of the FD&C Act, 21 U.S.C. 321(g)(1)(C) because they are intended to affect the structure or any function of the body.

As OTC drugs, Verruguin and Stamapro must comply with all of the requirements of section 502 of the FD&C Act and all pertinent regulations found in Title 21 of the Code of Federal Regulations (21 CFR). However, they do not for the reasons described below.

Verruguin is misbranded under section 502(c) of the FD&C Act, 21 U.S.C. 352(c) because it is not labeled in accordance to 21 CFR 201.15. Specifically, 21 CFR 201.15 describes the conditions that must be met to have an OTC drug label contain both English and a foreign language, and it states that “all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language” … and “if the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.” Although claims on Verruguin’s Principal Display Panel are in Spanish, the information contained in the product’s Drug Facts panel only appears in English and does not also contain the Spanish translation.

Verruguin and Stamapro are misbranded under Section 502(x) of the FD&C Act, 21 U.S.C. 352(x) because the products’ labels fail to disclose a domestic address or domestic telephone number through which the responsible person may receive a report of a serious adverse event with such drug. Please note that Section 201(k) of the FD&C Act defines the term “label” as “... a display of written, printed, or graphic matter upon the immediate

container of any article; and a requirement made by or under the authority of the FD&C Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such…also appears on the outside container…" Therefore, the domestic address or domestic telephone number must appear on your products' immediate container labels and on the outside container labels. However, the outside container labels for Verruguin and Stamapro do not list a domestic address or telephone number.

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.

Until these violations are corrected, we may withhold approval of pending drug applications listing your facility. 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. Please identify your response with FEI 3012306417. Your written notification should refer to the Warning Letter Number above (CMS Case #546921).

Please address your reply to John W. Diehl, Director, Compliance Branch at the FDA address provided on the first page of this letter. In addition, please submit a signed copy of your response on your firm's letterhead to **orapharm2_responses@fda.hhs.gov (mailto:orapharm2_responses@fda.hhs.gov)**.

If you have questions regarding the contents of this letter, you may contact Rebecca Asente via (504) 846-6104 or **Rebecca.asente@fda.hhs.gov (mailto:Rebecca.asente@fda.hhs.gov)**.

Sincerely,
/S/

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