WARNING LETTER

High Chemical Company, Div of National Generic Distributors

MARCS-CMS 576577 — JUL 02, 2019

Delivery Method:

VIA UPS

Product:

Drugs

Recipient:

Mr. Nalin Parikh

President

High Chemical Company, Div of National Generic Distributors

23 Mantoloking Lane
Waretown, NJ 08758
United States

Issuing Office:

Division of Pharmaceutical Quality Operations I

10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
United States

WARNING LETTER

CMS #576577

07/02/2019

VIA UPS OVERNIGHT

Mr. Nalin Parikh
President
High Chemical Company
23 Mantoloking Lane
Waretown, NJ 08758

Dear Mr. Parikh:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, High Chemical Company, a Division of National Generic Distributors at 3901-A Nebraska Street, Levittown, Pennsylvania, from December 17, 2018 to February 8, 2019.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API 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).

Based on the information your firm submitted to FDA's Drug Registration and Listing System, and the evidence collected during the FDA inspection from December 17, 2018–February 8, 2019, your firm manufactures and distributes Sarracenia Purpurea (Sarapin) Distillate, a misbranded drug in violation of section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

We reviewed your February 26, 2019, response in detail.

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

1. **Failure to ensure that, for each batch of API, appropriate laboratory tests are conducted to determine conformance to specifications.**

Your firm manufactures Sarapin, a non-sterile botanical-derived Active Pharmaceutical Ingredient (API) intended for sterile injectable finished drug products. Our inspection found that you did not perform appropriate quality control testing prior to release. For example, you failed to test for strength by dry weight, residual pesticide, and heavy metals on each batch of Sarapin API before it was released and distributed to customers. These tests ensure that consumers receive drugs with consistent strength and are free of deleterious substances.
Your response stated that the active ingredient has not been identified despite numerous attempts, and that assay testing cannot be performed. However, when the active ingredient cannot be identified, other tests can better characterize the material, as described in FDA's *Botanical Drug Development Guidance for Industry*, which can be found at https://www.fda.gov/media/93113/download (https://www.fda.gov/media/93113/download).
In response to this letter, provide:

- A list of all test methods, both chemical and microbiological, along with their corresponding validation studies, and specifications that capture the active or chemical constituents and purity of your botanical drug substance prior to a lot disposition decision.
- Test results obtained from testing retain samples of all drugs within expiry that have been distributed in the United States. Include test results for strength by dry weight, residual pesticide, heavy metals, and all other appropriate chemical and microbial quality attributes.

2. **Failure to design a documented, on-going stability testing program to monitor the stability characteristics of API and to use the results to confirm appropriate storage conditions and retest or expiry dates.**

You were unable to provide any data to support the two-year expiration date given to Sarapin API distributed in **(b)(4)**.
Your response did not address this deficiency.
In response to this letter, provide a comprehensive assessment and corrective action and preventive action (CAPA) plan to ensure the adequacy of your stability program. Your CAPA plan should include, but not be limited to:

- A SOP describing your stability program
- Stability indicating methods
- Stability studies for Sarapin in its container-closure system used for distributions
- An ongoing stability program in which representative batches are added each year to the program to determine if the shelf-life claims remains valid
- Specific attributes to be tested at each stability station

Misbranded Drugs

During the inspection, your firm's representative stated that Sarracenia Purpurea (Sarapin) Distillate is sold for use as a component of the finished drug product, Sarapin for Injection, which is given intramuscularly and intended to treat pain and reduce inflammation.

As demonstrated by its intended uses, the finished product Sarapin for Injection is a drug as defined in section 201(g)(1)(B) and (C) of the FD&C Act, 21 U.S.C. 321(g)(1)(B) and (C), because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or to affect the structure or function of the body.

According to section 201(g)(1)(D) of the FD&C Act, 21 U.S.C. 321(g)(1)(D), a drug also means an article intended for use as a component of a drug that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or to affect the structure or function of the body. As such, your Sarracenia Purpurea (Sarapin) Distillate is also a drug under section 201(g)(1)(D) of the FD&C Act, 21 U.S.C. 321(g)(1)(D), because it is a component of Sarapin for Injection (the finished drug product).

Your Sarracenia Purpurea (Sarapin) Distillate is a misbranded drug under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), because its labeling fails to bear adequate directions for use. Section 201.122 of Title 21 of the Code of Federal Regulation (CFR) states that a drug in a bulk package … intended for processing … shall be exempt from the section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), if its label bears the statement, "Caution: For manufacturing, processing, or repackaging."

The evidence indicates that the Sarracenia Purpurea (Sarapin) Distillate is sold to compounding pharmacies for further processing. However, the Sarracenia Purpurea (Sarapin) Distillate label does not contain the caution statement described in 21 CFR 201.122. Therefore, the labeling of Sarracenia Purpurea (Sarapin) Distillate fails to bear adequate directions for use and, therefore, is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). The introduction or delivery for introduction into interstate commerce of this misbranded drug violates sections 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Drug Production Ceased

We acknowledge your commitment to "…close the company on or before May 31, 2019." We also acknowledge that your firm **(b)(4)**.

In response to this letter, clarify if you intend to resume manufacturing or distributing any drugs or other API in the future. If you plan to resume manufacturing drugs for the U.S. market, notify this office prior to resuming your operations.

Conclusion

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

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

Until these deviations 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. We may also refuse your requests for export certificates.

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 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.

Send your electronic reply to ORApharm1_responses@fda.hhs.gov (mailto:ORApharm1_responses@fda.hhs.gov). Please identify your response with FEI number 2511349 and Warning Letter number 576577.

If you have any questions, contact Compliance Officer James Mason at james.mason@fda.hhs.gov (mailto:james.mason@fda.hhs.gov) or 570-262-0519.

Sincerely,

/S/

Diana Amador-Toro

Program Division Director/District Director

U.S. Food and Drug Administration

OPQO Division I/New Jersey District

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