Ridge Properties, LLC 10/13/17

U.S. FOOD & DRUG ADMINISTRATION

Los Angeles District Office
19701 Fairchild, Irvine, CA 92612-2506
Telephone: 949-608-2900
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WARNING LETTER
VIA SIGNATURE CONFIRMED DELIVERY

October 13, 2017

John Randall Durig, Owner
Ridge Properties, LLC dba Pain Relief Naturally
4995 Ridge Drive NE
Salem, Oregon 97301

Dear Mr. Durig:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Ridge Properties, LLC (FEI: 3011007272) at 4995 Ridge Drive NE, Salem, Oregon, from February 28 to March 16, 2017.

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).

In addition, your firm also manufactures unapproved new drugs in violation of the FD&C Act under section 505(a), 21 U.S.C. § 355(a) and misbranded drugs in violation of the FD&C Act under sections 502(b)(1), 21 U.S.C. § 352(b)(1); and 502(x), 21 U.S.C. § 352(x).

We have not received a written response from your firm that provides corrective actions to the violations identified to you during the inspection.

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

CGMP Violations

1. Your firm failed to perform, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release, and for each batch of drug product required to be free of objectionable microorganisms, appropriate laboratory testing, as necessary (21 CFR 211.165(a) and (b)).

During the inspection, your chief executive officer stated that you do not test any of the topical analgesic drug products that you manufacture. For example, you distributed multiple batches of TAT Balm and Naturally HL products without testing these batches for chemical attributes including, but not limited to, identity and strength of each active ingredient.

FDA testing of your Extra Strength PreTAT Gel (lot 1043) found it to be subpotent. During testing, FDA also observed that the product had separated into two separate phases, and was not uniform in character or quality.

In addition, your firm lacked testing for microbial attributes. Your topical analgesic drug products are indicated for treating bleeding wounds, bedsores, and tattoo procedure pain. It is essential that you test each of your drug product batches for appropriate microbial attributes, including sterility or microbial limits (i.e., total count; absence of objectionable microorganisms), in consideration of its intended use.

2. Your firm failed to establish and follow written procedures describing the handling of all written and oral complaints regarding a drug product (21 CFR 211.198(a)).

You did not adequately investigate more than 50 complaints you received in 2016 regarding your 4% lidocaine TAT Balm products for “ineffectiveness” and “inadequate numbing strength.” These complaints are for the same product line that the FDA analysis showed to be subpotent. When you received complaint samples from your customers, you failed to conduct an adequate investigation including testing quality attributes of each sample. You also received multiple complaints for other drug products you distributed.

3. Your firm failed to establish an adequate quality control unit and procedures applicable to the 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) and (d)).

Your firm does not have a quality control unit. During the inspection, we found that your firm lacked critical procedures to ensure a functional quality unit including, but not limited to, procedures for establishing specifications and complaint handling.

4. Your firm failed to prepare batch production and control records with complete information relating to the production and control of each batch of drug product produced (21 CFR 211.188).

Your firm lacked batch records for all drug products you manufactured from May 2015 to February 2017. You did not document significant production details, including but not limited to the personnel, dates, equipment, raw material identity, and labeling, for each batch. We acknowledge that you created a batch record template during the inspection for your Lidocaine Carbomer Free Gel drug product. However, this batch record template lacked provisions for data on processing, filling, and packaging operations. Such data is necessary to establish that the manufacturing process was followed and is reproducible.

5. Your firm failed to have separate or defined areas or such other control systems necessary to prevent contamination or mix-ups (21 CFR 211.42(c)).

Your firm manufactures drug products in a kitchen. You use household kitchen utensils and cookware, including a steel pot, **(b)(4)** blender, and kitchen spatula to mix ingredients. Our investigator observed conditions and practices that increase the risk of your drug products containing harmful and insanitary contaminants. For example, you had a window open to the outside for ventilation during production. You also stored cleaning equipment near formulation ingredients without adequate controls to prevent contamination.

6. Your firm failed to establish adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess (21 CFR 211.100(a)).

You have not specified or validated manufacturing processes to ensure reproducible batch quality. For example, your procedures for formulation do not include defined process parameters such as mixing times, blending speeds, and bulk hold times. In addition, our investigator noted that you use a kitchen **(b)(4)** blender to mix ingredients.

Our findings demonstrate that you lack understanding of the basic elements of a compliant manufacturing operation, such as suitable facilities and equipment, trained personnel, appropriate components, a well-defined process, and written procedures. These and other elements supporting process validation are outlined in FDA's guidance document, *Process Validation: General Principles and Practices*, available at **https://www.fda.gov/downloads/drugs/guidances/ucm070336.pdf (https://www.fda.gov/downloads/drugs/guidances/ucm070336.pdf)**.

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.

Your poor manufacturing practices increase the likelihood of producing inconsistent and poor quality drug products. It is imperative that drug products be consistently manufactured to ensure that each batch meets appropriate quality standards and specifications. Concerning the drugs that you have distributed, your written response to this letter should specify actions you will take, such as notifying customers and recalling products.

Unapproved New Drugs

Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine

Examples of claims observed on your product label for "Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine" and your websites, painreliefnaturally.co and naturallyhl.com that establish the intended uses of the product include, but may not be limited to, the following:

Claims found on product label:

> "Uses: Temporarily relieves pain"

Claims found on product website:

> "Kill your hemorrhoids Fast – Powered by NatureCaine An Unrivaled Special Blend of Nature's Strongest Anorectal numbing and healing treatments . . . Naturally HL provides the Legal Maximum Of Over The

> Counter Lidocaine Numbing Treatment for Hemorrhoids . . . Cuts Healing Time of Hemorrhoid Related Wounds & Abrasions By More Than Half – Improvements Often Seen In only Minutes With Our Powerful Deep Penetrating Antiseptics & Healing Ingredients . . . Stops Hemorrhoid Itching Almost Immediately with Fast Acting, Natural Numbing & Soothing Ingredients Designed To Go To Work Fast & Soak In For Hours Of Much Needed Relief . . . Our powerful natural ingredients attack healing in a variety of different ways. We start by reducing swelling & bleeding. Then our natural infection resistant ingredients make a protective barrier to harmful bacteria & stimulate the healing process. The brown color in our creams is thanks to an unrivaled organic healing agent called Propolis, a must have for any recovery."

Based on the above claims, "Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine" is a "drug" as defined by section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B), because it is 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 it is intended to affect the structure or any function of the body. Specifically, this product is intended as an anorectal external analgesic.

OTC drug products intended as anorectal external analgesics, such as "Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine," are subject to the final rule for Anorectal Drug Products for Over-the-Counter Use, see 21 CFR Part 346. However, this product is not labeled or formulated in accordance with the final rule for the reasons explained below.

The label for "Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine" identifies lidocaine hydrochloride 4% as the active ingredient. The final rule for Anorectal Drug Products (21 CFR 346) does not include lidocaine hydrochloride as an active ingredient for any anorectal drug product indications.

Additionally, your product websites claim Propolis is an "unrivaled organic healing agent … a must have for any recovery." According to 21 CFR 201.66(b)(2), an "active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Although your firm does not specifically list Propolis as an active ingredient, your website claim for this specific ingredient that is described above demonstrates that this is an "active ingredient" as defined in 21 CFR 201.66(b)(2) because the ingredient is intended to furnish pharmacological activity. Propolis is not recognized as an active ingredient in the Anorectal final rule.

"Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine" is not labeled in accordance with the Anorectal final rule. As indicated above, your product includes labeling claims specifically intended for healing hemorrhoids and preventing infection. These claims are not indications set forth in the Anorectal final rule.

Thus, as formulated and labeled, "Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine" does not conform to the final rule described above. Furthermore, we are not aware of sufficient evidence to show the product as formulated and labeled is generally recognized as safe and effective and therefore, your product is a "new drug" under section 201(p) of the FD&C Act, 21 U.S.C. § 321(p). New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from the FDA, as described in sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. § 331(d), 355(a). "Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine" is not the subject of an FDA-approved application, and therefore, the current marketing of this product violates section 505(a) of the FD&C Act, 21 U.S.C. § 355(a). Introduction of such products into interstate commerce is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. § 331(d).

Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine" and "Extra Strength PreTAT Gel With Added Lidocaine"

Examples of claims observed on your product labels for “Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine” and “Extra Strength PreTAT Gel With Added Lidocaine” and your websites, painreliefnaturally.co, naturallyhl.com, and tatbalm.net that establish the intended uses of the products include, but may not be limited to, the following:

“Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine”
Claims found on product label:

> “Uses: Temporarily relieves pain”

Claims found on product website:

> “Kill your Bedsore’s Fast – With Unrivaled Healing Speed!!! . . . Cut Bedsore Healing By More Than Half the Time – You’ll Often See Improvements in only Minutes with Powerful Deep Penetrating Antiseptics & Healing solutions . . . Stop Bedsore Itching Almost Immediately with Fast Acting Numbing + Several Natural Anti-itch Agents . . . Great All Natural Healing Agents for Bedsores & Related Abrasions that are Jam Packed in our Specially Formulated Blend! . . . Numbs Bedsore Pain Fast with Nature’s Most Powerful Numbing Agents Plus Chock Full Of The Legal Maximum Amount Of Lidocaine . . . Our powerful natural ingredients attack healing in a variety of different ways. We start by reducing swelling & bleeding. Then our natural infection resistant ingredients make a protective barrier to harmful bacteria, & stimulate the healing process. The brown color in our creams is thanks to an unrivaled organic healing agent called Propolis, a must have for any recovery.”

“Extra Strength PreTAT Gel With Added Lidocaine”
Claims found on product label:

> “Uses: Temporarily relieves pain during tattoos”

Claims found on product website:

> “Fast Acting Tattoo Numbing Power – The Deep Penetrating Numbing & Healing Blend That Kills The Many Types Of Tattoo Pain . . . TAT Balm Gel Provides The Legal Maximum Of Over The Counter Lidocaine Numbing – It Will Numb Your Tattoo Pain Within FDA Compliance . . . Supercharges Your Tattoo Natural Healing Time, Reducing It By Over Half – Our Numbing & Healing Blend Will Not Only Numb, But Also Begins Repairing Your Skin In only Minutes With Powerful Deep Penetrating Numbing, Antiseptic & Healing Ingredients . . . Our TAT Balm Numbing Agents Immediately Relieve Tattoo Itching With Fast Acting, Soothing Ingredients Designed To Numb Fast & Soak In For Hours Of Much Needed Pain, Itch, & Irritation Relief . . . Our powerful natural ingredients will reduce swelling, bleeding, infection, and will even tone the skin making it easier to tattoo, solving many problems caused by chemical based products. We don’t stop at just providing a great natural base, we also jam pack it with the highest percentage of Lidocaine allowed by the FDA and we are FDA compliant.”

Based upon the above claims, “Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine” and “Extra Strength PreTAT Gel With Added Lidocaine” are drugs within the meaning of section 201(g)(1)(B) of the FD&C Act, 21 U.S.C. § 321(g)(1)(B), because they are intended for use in the diagnosis, 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 function of the body. Specifically, they are intended for use as external analgesics.

Drug products such as “Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine” and “Extra Strength PreTAT Gel With Added Lidocaine” intended for external analgesic indications such as the temporary relief of pain are being evaluated as part of the OTC Drug Review. They have been proposed to be classified as generally recognized as safe and effective and not misbranded under the Tentative Final Monograph (TFM) for External Analgesic Drug Products for Over-the-Counter Human Use (48 FR 5852, February 8, 1983) if they meet each condition in the TFM and each general condition in 21 CFR 330.1. Pending a final rule, the agency does not

intend to pursue unapproved new drug or misbranded drug violations against firms that market products consistent with the conditions proposed in the TFM and each general condition in 21 CFR 330.1. Such marketing, however, is subject to the risk that a final rule may require reformulation and/or relabeling or FDA approval through the "new drug" procedures of the FD&C Act (section 505). The labeling for such drugs, like all OTC drugs, must comply with all of the requirements of section 502 of the FD&C Act and all pertinent regulations found in 21 CFR. However, these products are not labeled or formulated in accordance with the TFM for the reasons explained below.

Your product websites claim that "Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine" contains propolis, an "unrivaled organic healing agent," and that "Extra Strength PreTAT Gel With Added Lidocaine" contains aloe juice, witch hazel, konjac root, and pickling lime, ". . . powerful natural ingredients will reduce swelling, bleeding, infection . . ." According to 21 CFR 201.66(b)(2), an "active ingredient" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Although your firm does not specifically list propolis, aloe juice, witch hazel, konjac root, or pickling lime as active ingredients, your website claims for these specific ingredients described above demonstrates that they are "active ingredients" as defined in 201.66(b)(2) because these ingredients are intended to furnish pharmacological activity. Propolis, aloe juice, witch hazel, konjac root, and pickling lime are not proposed as active ingredients in the TFM.

While lidocaine hydrochloride, the labeled active ingredient in both of the products, is an active ingredient included in the TFM, the proposed allowable indications for lidocaine hydrochloride are limited to the temporary relief of pain and/or itching, which can be followed by "associated with minor burns, sunburn, minor cuts, scrapes, insect bites, and/or minor skin irritations" (48 FR 5852 at 5868, February 8, 1983). Indications related to tattooing, bedsores, and preventing infection are not proposed under the TFM.

Thus, as formulated and labeled, "Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine" and "Extra Strength PreTAT Gel With Added Lidocaine" do not conform to the TFM described above. Furthermore, we are not aware of sufficient evidence to show "Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine" and "Extra Strength PreTAT Gel With Added Lidocaine" as formulated and labeled, are generally recognized as safe and effective. Therefore, these products are new drugs within the meaning of section 201(p) of the FD&C Act, 21 U.S.C. § 321(p), because they are not generally recognized among scientific experts as safe and effective for their labeled uses. As new drugs, "Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine" and "Extra Strength PreTAT Gel With Added Lidocaine" may not be legally marketed in the United States absent approval of applications filed in accordance with section 505 of the FD&C Act, 21 U.S.C. § 355(a). "Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine" and "Extra Strength PreTAT Gel With Added Lidocaine" are not the subject of FDA-approved applications, and therefore, the current marketing of these products violate section 505(a) of the FD&C Act, 21 U.S.C. § 355(a)). Introduction of such products into interstate commerce are prohibited under Section 301(d) of the FD&C Act, 21 U.S.C. § 331(d).

Misbranded Drugs

Additionally, "Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine," "Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine," and "Extra Strength PreTAT Gel With Added Lidocaine" are misbranded within the meaning of section 502 of the FD&C Act, 21 U.S.C. § 352, because the labeling of the drugs do not comply with several specific requirements for nonprescription drug labeling.

"Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine," "Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine," and "Extra Strength PreTAT Gel With Added Lidocaine" are misbranded under section 502(b)(1) of the FD&C Act, 21 U.S.C 352(b)(1), because the product labels fail to bear the name and place of business of the manufacturer, packer, or distributor on the product label as required under 21 CFR 201.1.

“Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine,” “Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine,” and “Extra Strength PreTAT Gel With Added Lidocaine” are misbranded under section 502(x) of the FD&C Act, 21 U.S.C 352(x), because the product labels fail to disclose a domestic address or domestic phone 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….”

Additionally, “Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine,” “Extra Strength Naturally HL Bed Sore Relief Cream With Added Lidocaine,” and “Extra Strength PreTAT Gel With Added Lidocaine” are misbranded within the meaning of section 502 of the FD&C Act, 21 U.S.C. § 352, because the labeling of the drugs do not comply with several specific requirements for nonprescription drug labeling. The “For external use only” warning is not in bold type as required for topical drug products under 21 CFR 201.66(c)(5)(i). “Extra Strength Naturally HL Hemorrhoid Numbing With Lidocaine,” “Extra Strength Naturally HL Bed, Sore Relief Cream With Added Lidocaine,” and “Extra Strength PreTAT Gel With Added Lidocaine” fail to highlight the general “Keep out of reach of children” warning statement in bold type and include the complete accidental overdose warning statement “If swallowed, get medical help or contact a Poison Control Center right away” as required under 21 CFR 330.1(g). The introduction of these misbranded products into interstate commerce is prohibited under section 301(a) of the FD&C Act, 21 U.S.C. § 331(a).

Conclusion

Violations 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. 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 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.
Send your reply to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
United States Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2506

If you have any questions regarding any issues in this letter, please contact Maria P. Kelly-Doggett, Compliance Officer, via email to **maria.kelly-doggett@fda.hhs.gov (mailto:maria.kelly-doggett@fda.hhs.gov)** or by phone at (425) 302-0427 and reference unique identifier **525794**.

Sincerely,