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WARNING LETTER

Signature Formulations, LLC

MARCS-CMS 545017 – 31/07/2018

Recipient:

Mr. John R. Rose

Signature Formulations, LLC

5446 W. Roosevelt St., Suite 101

Phoenix, AZ 85043

United States

Issuing Office:

San Francisco District Office

United States

U.S. FOOD & DRUG ADMINISTRATION

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road, Irvine, CA 92612
Telephone: (949) 608-2900
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WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE REQUIRED

July 31, 2018

Mr. John R. Rose
President
Signature Formulations LLC
5446 W. Roosevelt St., Suite 101
Phoenix, AZ 85043

Dear Mr. Rose:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Signature Formulations LLC (FEI 3011368010), at 5446 W. Roosevelt St., Suite 101, Phoenix, AZ from October 24 to November 9, 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 to the CGMP violations, your firm also manufactures unapproved new and/or misbranded drug products. During the inspection, the investigator collected labeling for Herbal Muscle Gel, Herbal Muscle Mist, and CBD Muscle Gel products. FDA also reviewed your websites at www.sigform.com (http://www.sigform.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and www.cbdtechcenter.com (http://www.cbdtechcenter.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) where the products Herbal Muscle Gel; Herbal Muscle Mist; CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and/or CBD Toothpaste are available for purchase. Your products mentioned above are unapproved new drugs in violation of section 505(a) of the FD&C Act, 21 U.S.C. 355(a). Furthermore, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste are also misbranded drugs in violation of section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1). As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act.

We reviewed your December 1, 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 have, 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 (21 CFR 211.165(a)).

Your firm released finished over-the-counter (OTC) topical pain relief drug products (Herbal Muscle Gel, CBD Muscle Gel, and Herbal Muscle Mist) without testing to determine conformance with their assay specifications or active ingredient label claims. In addition, your firm failed to establish product release specifications for your finished drug products.

In your response, you state that you tested retention samples from one distributed lot of each drug product noted above and that each of the tested lots met label claims. Your response is inadequate. You did not provide a scientific rationale for the limited testing you performed. Testing only a single lot of each of these drugs from **(b)(4)** does not demonstrate that all of the lots of these products you manufactured and released met their label claims.

In response to this letter, we request that you provide:

- The quality control test methods and specifications you rely upon to analyze each of your finished OTC drug products before making batch release decisions;
- An action plan and timelines for testing retained samples of all finished OTC drug products distributed and within expiry to determine the identity and strength of active ingredients. If such testing reveals that you released drug products that did not meet specifications for identity or strength of active ingredients, indicate what corrective actions you have taken or will take, such as notifying customers or recalling products.

2. Your firm failed to establish an adequate quality control unit with the responsibility and authority to approve or reject all drug products and with the responsibility for approving or rejecting procedures or specifications impacting on the identity, strength, quality, and purity of the drug products. (21 CFR 211.22(a) and (c)).

Your quality unit released drug products even though it had no assurance that products met specifications or were manufactured under adequate controls. Your quality unit failed to ensure that procedures for numerous drug manufacturing operations, such as production, cleaning, sampling plans, and testing, were drafted and approved. In addition, your quality unit did not approve finished drug product specifications.

In your response, you state that you are in the process of establishing drug product specifications and sampling plans. You state that you have prepared written procedures describing the production process for each of your drug products. We acknowledge your statement that you hired a CGMP consultant and a "**(b)(4)**" to bring your facility into CGMP compliance.

Your response cannot be fully evaluated because you failed to provide documentation and sufficient details about your firm's plan to establish appropriate drug product specifications and manufacturing procedures.

In response to this letter, we request that you provide your plan for establishing adequate quality systems. Include your approved written procedures and drug product specifications.

See FDA's guidance document, *Quality Systems Approach to Pharmaceutical CGMP Regulations*, for help implementing modern quality systems and risk management approaches to meet the requirements of CGMP regulations (21 CFR, parts 210 and 211), at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070337.pdf. (/media/71023/download)

3. Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality. Your firm also failed to establish the reliability of component supplier analyses on which you rely in lieu of certain tests through appropriate validation of the supplier's test results at appropriate intervals (21 CFR 211.84(d)(1)&(2)).

Your firm failed to test incoming components used in manufacturing your finished OTC drug products **(b)(4)**, and your products labeled as homeopathic drug products **(b)(4)** to determine identity, purity, strength, and quality.

Instead, your firm used results from your suppliers' certificates of analysis (COA) without establishing the reliability of your suppliers' analyses through appropriate validation, and without conducting at least one specific identity test on each incoming lot of components. Under 21 CFR 211.84(d)(2), you may not rely on your suppliers' COA to verify the identity of your components.

In your response, you state that you have validated your suppliers' COA. You also state that you will conduct identity testing of active ingredients prior to approving them for use in drug manufacturing.

Your response cannot be fully evaluated because you did not provide sufficient details regarding the validation of your suppliers' COA. You did not address your failure to test all components, including both active *and* inactive ingredients, for identity and other appropriate specifications prior to use. Also, you did not address the effect of this deficiency on the quality of all your drug products.

In response to this letter, provide:

- A retrospective review for all drug product lots, within expiry and in distribution, manufactured using components that were not adequately tested and controlled. Based on your review, indicate any corrective actions and preventive actions you have taken, including a recall of affected products, if appropriate.
- Your procedure to test incoming components.
- A detailed description of how you plan to test each component for conformity with all appropriate written specifications for identity, purity, strength, and quality. Explain how you intend to perform at least one identity test for all incoming components used in your drug product. If you accept your suppliers' COA in lieu of testing components for purity, strength, and quality, specify how you plan to establish the reliability of your suppliers' test results through validation at appropriate intervals.

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

You do not have cleaning procedures for the equipment you use to manufacture multiple drug products. You have not validated the methods you use to clean your equipment. Your firm manufactures both oral and topical products, and some of these products contain **(b)(4)**. Inadequate removal of residues from manufacturing equipment during cleaning can lead to cross-contamination of products subsequently manufactured on the non-dedicated equipment.

In your response, you state that you will draft procedures for cleaning the manufacturing equipment and validate your cleaning procedures.

Your response is inadequate because you failed to assess the risk of potential cross-contamination and its effects on product quality.

In response to this letter, we request that you provide:

- Your equipment cleaning procedures and cleaning validation report to demonstrate the adequacy of your cleaning procedures.
- Your evaluation of all drug product lots, within expiry and in distribution, identifying the effects of any cross-contamination that may have occurred.

5. Your firm failed to establish and follow a written testing program designed to assess the stability characteristics of drug products and to use results of such stability testing to determine appropriate storage conditions and expiration dates (21 CFR 211.166(a)).

You do not have stability data to support your firm's two-year expiration date for your OTC drug products, Herbal Muscle Gel, CBD Muscle Gel, and Herbal Muscle Mist. You failed to demonstrate that the chemical and physical properties of your drug products remain acceptable throughout the labeled two-year expiry period. Therefore, there is no assurance that your drug products can meet their label claims through their expiration period.

In your response, you state that you conducted informal testing or observation to support the expiration date of your OTC drug products, and that you have now established a formal stability plan to evaluate and verify the stability characteristics of your formulation and container-closure system.

Your response cannot be fully evaluated because you did not include your stability test results to demonstrate that each of your drug products met its specifications at the end of the labeled expiration period.

In response to this letter, you should provide an adequate written stability testing program and results to support your assigned expiration dates.

Unapproved New Drug Violations for OTC Drug Products

Herbal Muscle Gel and Herbal Muscle Mist are drugs within the meaning of Section 201(g)(1)(B) of the FD&C Act because they are intended for use in 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. Specifically, these products are intended for use as external analgesics and for the treatment of other diseases (including but not limited to gout, cold, and flu).

Examples of claims observed on your products' labels and on your website, www.sigform.com (http://www.sigform.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), include the following claims that demonstrate the intended uses for Herbal Muscle Gel and Herbal Muscle Mist as drugs, as defined in section 201(g). This list is not inclusive of all claims demonstrating the products' intended uses.

Herbal Muscle Gel

Statements that appear on the product label:

- Helps reduce...Inflammation...Arthritis...Back Pain...Muscle Aches...Joints
- Try it on: • Fibromyalgia Pain • Carpal Tunnel • Sciatica • Tendonitis • Muscle Cramps • Sports Injuries • Heel Spurs • Sore/Achy Feet • Tired Legs • Gout
- Directions...Rub into temples to help with headaches, and chest to relieve cold and flu. Apply prior to a workout or sports activity.

Statements that appear on the website, www.sigform.com (http://www.sigform.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer):

- MSM (methylsulfonylmethane) provides sulfur and methy [sic] groups that are used for healing and repair by our joints and connective tissue. Clove Oil and Sweet Birch Oil may help to stimulate

circulation and reduce tension and spasms in muscles. Also included are the essential oils of peppermint and eucalyptus to help reduce inflammation and soothe aching feet and irritated nerves.

Herbal Muscle Mist

Statements that appear on the product label:

- Try it on: • Fibromyalgia Pain • Carpal Tunnel • Sciatica • Tendonitis • Muscle Cramps • Sports Injuries
- Restores Blood Flow
- DIRECTIONS: Rub into temples to help with headaches. Spray onto chest to relieve cold and flu. Apply prior to a workout or sports activity.

Statements that appear on the website, www.sigform.com: (http://www.sigform.com:) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

- Included in the Herbal Muscle Mist formula are menthol and camphor for pain relief, invigoration of tired muscles and joints, and cramps. MSM (methylsulfonylmethane) provides sulfur and methy (sic) groups that are used for healing and repair by our joints and connective tissue. Clove Oil and Sweet Birch Oil may help to stimulate circulation and reduce tension and spasms in muscles. Also included are the essential oils of peppermint and eucalyptus to help reduce inflammation and soothe aching feet and irritated nerves.

Drug products intended for external analgesic indications such as the temporary relief of minor aches and pains of muscles and joints are being evaluated under the developing monograph for Over-the-Counter (OTC)External Analgesic Drug Products for Over-the-Counter Human Use ("External Analgesic TFM" or "TFM") (48 FR 5852, February 8, 1983). Pending the promulgation of a final monograph, the agency generally does not intend to object to the marketing of products that meet both the proposed formulation and labeling conditions outlined in the TFM and each general condition in 21 CFR 330.1 unless a particular product poses a public health concern. 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 formulation and labeling for Herbal Muscle Gel and Herbal Muscle Mist are not consistent with the conditions proposed in the External Analgesic TFM (see 48 FR 5852 at 5868). 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 of humans. Although your firm does not specifically list MSM (methylsulfonylmethane), clove oil, sweet birch oil, and essential oils of peppermint and eucalyptus as active ingredients in your products, the claims on your website pertaining to these specific ingredients, as described above, demonstrate that they are active ingredients as defined in 201.66(b)(2) because the ingredients are intended to furnish pharmacological activity.

MSM (methylsulfonylmethane), sweet birch oil, eucalyptus oil, and clove oil are not proposed as active ingredients in the External Analgesic TFM. Eucalyptus oil is not included as an active ingredient in the OTC Drug Review for the indications intended for your product, and it is explicitly not permitted as an active ingredient in an OTC external analgesic drug product for counterirritant use without an FDA-approved new drug application (*see* 21 CFR 310.545(a)(10)(ii)).

Lastly, while camphor, a labeled active ingredient in both of your products, is an active ingredient included in the External Analgesic TFM, the proposed allowable dosage range for camphor in the TFM is 3-11% (48 FR 5862 at 5868). Your products' label identifies camphor at a dosage of 2%, which is outside the range which FDA proposed to be generally recognized as safe and effective for use in an external analgesic product Further, the external analgesics TFM does not propose that camphor is generally recognized as safe and effective to treat fibromyalgia pain, carpal tunnel, sciatica, tendonitis, heel spurs, gout, headaches, or cold and flu, which are included in the labeling for Herbal Muscle Gel, or fibromyalgia pain, carpal tunnel, sciatica, tendonitis, headaches, cold and flu, or restoring blood flow, which are included in the labeling for Herbal Muscle Mist.

Your products are also labeled for the treatment of gout, cold, and flu. Treatment of gout is not a condition that is included in the OTC Drug Review. Although FDA has established an OTC monograph for indications related to cold and flu (see 21 CFR Part 341), the active ingredients in your products are not included in the relevant monograph.

Furthermore, we are not aware of any adequate and well controlled clinical trials in the published literature that support a determination that Herbal Muscle Gel and Herbal Muscle Mist are generally recognized as safe and effective for their labeled indications.

Herbal Muscle Gel and Herbal Muscle Mist, as labeled, are therefore new drugs within the meaning of section 201(p) of the FD&C Act because they are not generally recognized among scientific experts as safe and effective for the drug uses described in their labeling. "New drugs" may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FD&C Act is in effect for the drug. Herbal Muscle Gel and Herbal Muscle Mist are not the subjects of approved new drug applications; therefore, marketing these products in the United States is prohibited under section 301(d) of the FD&C Act, 21 U.S.C. 331(d) and violates section 505 of the FD&C Act.

Unapproved New and Misbranded Drug Violations for Products Purporting to Contain Cannabidiol (CBD)

The Agency reviewed the product label of CBD Muscle Gel obtained during the FDA inspection of your facility. In addition, we reviewed your website www.cbdtechcenter.com (http://www.cbdtechcenter.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) where you market and take orders for your products CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste. You promote these products as containing cannabidiol (CBD). The claims on your website establish that the products are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and because they are intended to affect the structure or any function of the body. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the FD&C Act. You can find the FD&C Act and FDA regulations through links on FDA's home page at www.fda.gov (http://www.fda.gov/).

Although you market CBD Oil 100mg, 250mg, 500mg, and 1000mg, and CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg as dietary supplements, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act, 21 U.S.C. 321(ff)(3)(B)(ii). Under that provision, if an article (such as CBD) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD.

The existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex **[1]**. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act. FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act, but you may present FDA with any evidence that has bearing on this issue.

Claims on your website www.cbdtechcenter.com (http://www.cbdtechcenter.com) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) that document the intended use of your products as drugs include, but are not limited to, the following:

- "For hundreds of years, people have used preparations made from C. Sativa, including CBD for a variety of disorders, including gout, rheumatism, malaria, pain, and fever."
- "[P]eople have reported reduced pain or positive results from taking CBD as a dietary supplement for ailments and neurological disorders such as . . . Alzheimer's Disease . . . Cancer . . . Crohn's Disease . . . Diabetes . . . Fibromyalgia . . . Glaucoma . . . Gout . . . HIV Dementia . . .. . . Parkinson's Disease . . . Rheumatism . . . Schizophrenia . . . Stress Disorders like PTSD . . ."
- In the product description for CBD Muscle Gel: "Fast absorbing gel reduces inflammation and pain quickly with triple active ingredients. Our gel combines the natural anti-inflammatory power of CBD with the soothing effects of Camphor and Menthol. CBD Gel helps relieve arthritis pain and sore, overworked muscles."

Claims on the label of CBD Muscle Gel that demonstrate its intended use as a drug:

- "Hand crafted with the most effective herbal ingredients for rapid relief of aching, painful joints, muscles and tissues."

- "Uses: For the temporary relief of minor aches and pains at muscles and joints associated with sore muscles, strains, joint discomfort & arthritis."

The claims on your website establish that the products are drugs under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and because they are intended to affect the structure or any function of the body.

Your products, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste, are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" 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). FDA approves a new drug on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the FD&C Act, 21 U.S.C. 352(f)(1), if the drug fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the FD&C Act, 21 U.S.C. 353(b)(1)(A), can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your products, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste, are intended for treatment of one or more diseases that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, CBD CreamLeaf Cream; CBD Muscle Gel; CBD Muscle Mist; Temporary Pain Relief Kit; CBD Oil 100mg, 250mg, 500mg, and 1000mg; CBD Oil Espresso flavor 100mg, 250mg, 500mg, and 1000mg; CBD Salve 50mg and 100mg; and CBD Toothpaste fail to bear adequate directions for their intended uses and, therefore, the products are 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 these misbranded drugs violates section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

Conclusion

Violations cited in this letter are not intended as an all-inclusive list of violations that exist in connection with your marketed products. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction.

We acknowledge your plan to cease drug manufacturing until you implement appropriate CGMP controls. If you resume drug manufacturing, please notify the FDA in advance so that we may verify your firm's compliance with CGMP prior to product distribution. Notify this office in writing of the specific steps that you have taken to correct violations and prevent recurrence. Provide supporting documentation.

Until the CGMP violations are corrected and we confirm your compliance, 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, you should 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 believe that your products are not in violation of the Act, include your reasoning and any supporting information for our consideration. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Please reference unique identifier CMS 545017 on all correspondence.

Send your written response to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road
Irvine, CA 92612

If you have questions regarding any issues in this letter, please contact Mr. William V. Millar, Compliance Officer, at (510) 337-6896, or william.millar@fda.hhs.gov (mailto:william.millar@fda.hhs.gov).

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

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[1] See "Sativex Commences US Phase II/III Clinical Trial in Cancer Pain," available at https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-... (https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and "GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome," available at https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-inves... (https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

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