WARNING LETTER

Medinatura Inc

MARCS-CMS 596269 — JUNE 11, 2020

Product:

Drugs

Recipient:

Cathy Raish

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United States

WARNING LETTER

June 11, 2020

RE: 596269

Dear Ms. Raish:

This letter is to advise you that the United States Food and Drug Administration (FDA) has reviewed your product labeling, including your website at http://hcp.medinatura.com/, from which you take orders for your injectable products "Zeel Injection Solution," "Traumeel Injection Solution," "Engystol Injection Solution," "Neuralgo Rheum Injection Solution," "Lymphomyosot X Injection Solution," and "Spascupreel Injection Solution." Based on our review, these injectable products are unapproved new drugs under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355. Introducing or delivering these products for introduction into interstate commerce violates section 301 of the FD&C Act, 21 U.S.C. 331.

These products are especially concerning from a public health perspective because injectable drug products can pose risks of serious harm to users; these risks are less likely to occur with topical or ingested products, i.e., those applied to the skin or taken by mouth. Injectable products are delivered directly into the body, sometimes directly into the bloodstream, and therefore, bypass some of the body's key defenses against toxins and microorganisms that can lead to serious and life-threatening conditions. Your injectable products are further concerning because they are labeled to contain potentially toxic or otherwise harmful ingredients, such as "mercurius solubilis" (mercury) and "embryo totalis suis," thereby presenting additional risk of serious harm to patients when delivered directly into the body.

Statements on your product inserts, as well as your firm's website, that establish the intended uses of your products include, but are not limited to, the following:

"Zeel Injection Solution"

• "[A] homeopathic drug product indicated for the treatment of arthrosis/osteoarthritis, and/or rheumatic joint diseases and for the relief of symptoms such as pain and joint stiffness."
• "[I]n combination with Traumeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness."

“Traumeel Injection Solution”
• “[A] homeopathic drug product indicated for the treatment of injuries, inflammatory and degenerative conditions of the musculoskeletal system and for the relief of associated symptoms such as pain.”
• “[I]n combination with Zeel® Injection Solution, for the treatment of inflammatory and degenerative conditions of the musculoskeletal system, such as arthrosis/osteoarthritis and/or rheumatic joint diseases, and for the relief of symptoms including pain, swelling, and joint stiffness.”

“Engystol Injection Solution”
• “[A] homeopathic drug product indicated for the support of the immune system to reduce severity and duration of symptoms in viral infections, particularly in the early stages of colds and influenza-like illnesses.”
• “Further in vitro studies have demonstrated that Engystol® significantly increases the expression of interferon-y producing T-lymphocytes. Therefore, it appears likely that there is an immunological stimulation caused by Engystol®, that is mediated by the activation of T-lymphocytes. Using Engystol®, therefore, enhanced the Th_1 response, this being an antiviral pathway in the body.”

“Neuralgo-Rheum Injection Solution”
• “[A] homeopathic drug product indicated for the treatment of nerve pain, soft tissue rheumatism and symptoms of disc protrusion.”

“Lymphomyosot X Injection Solution”
• “[A] homeopathic drug product indicated for the improvement of lymphatic drainage, the non-specific immune defense, and conditions such as benign hypertrophy of lymph nodes, chronic tonsillitis, tonsillar hypertrophy and lymphatic edema.”

“Spascupreel Injection Solution”
• “[A] homeopathic drug product indicated for the relief of spasms of the smooth musculature of the gastrointestinal and urogenital tract as well as general muscle spasms.”
• “[I]t is thought that its individual constituents act on the brain-gut axis to relax muscle cramps and restore bowel function.”
• “[A]cts as a powerful antispasmodic”
• “Reduces susceptibility to diarrhea and abdominal bloating”

In addition, on the “Education” section of your website at http://hcp.medinatura.com/portfolio/education-2/, you provide several videos regarding the use of your products for indications such as:
• “Tennis Elbow”
• “Back Pain”
• “Rotator Cuff Syndrome”
• “Fibromyalgia”

Further, on your “Protocols” section of your website, you provide a summary of treatment approaches using your products for indications such as:
• “PRP – AC Ligament, OA, and Other Inflammatory Diseases”
• “Ankle Sprains”
• “Back Pain”
• “Bursitis”
• “Carpal Tunnel Syndrome”
• “Fibromyalgia”
• “Hemarthrosis”
• “Joint Injuries & Arthritis”
• “Morton’s Neuroma”
• “Muscle Strains and Hematomas”
• “Musculoskeletal pain, Tendinopathies, Osteoarthritic pain”
• “Osteoarthritis”
• “Plantar Fasciitis”
• “Rotator Cuff Syndrome”
• “Tendinopathies”

On your “Office Resources” page at http://hcp.medinatura.com/pages/office-resources/, you also provide numerous materials, including, but not limited to the following:
• A “Traumeel Patient Booklet,” that states, “Pain Relief Without the Risks of Steroids, Opioids or NSAIDs”
• A “Traumeel & Zeel Injections Solutions Patient Brochure” that states, “Looking for a different treatment for your osteoarthritis knee pain?”

The above claims for “Zeel Injection Solution,” “Traumeel Injection Solution,” “Engystol Injection Solution,” “Neuralgo Rheum Injection Solution,” “Lymphomyosot X Injection Solution,” and “Spascupreel Injection Solution” demonstrate that they are drugs, as defined by section 201(g) of the FD&C Act, 21 U.S.C. 321(g), because they are intended to cure, mitigate, treat, or prevent disease and/or intended to affect the structure or function of the body of man or other animals. Moreover, these products are “new drugs,” as defined by 201(p) of the FD&C Act, 21 U.S.C. 321(p), because they are not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Under section 505(a) of the FD&C Act, 21 U.S.C. 355(a), new drugs may not be introduced or delivered for introduction into interstate commerce without prior approval from FDA. No approved application pursuant to section 505 of the FD&C Act, 21 U.S.C. 355, is in effect for these products. Accordingly, the introduction or delivery for introduction into interstate commerce of these products violates sections 301(d) and 505(a) of the FD&C Act, 21 U.S.C. 331(d) and 355(a).

We recognize that “Zeel Injection Solution,” “Traumeel Injection Solution,” “Engystol Injection Solution,” “Neuralgo Rheum Injection Solution,” “Lymphomyosot X Injection Solution,” and “Spacrupreel Injection Solution” are labeled as homeopathic drugs with active ingredients measured in homeopathic strengths. Under section 201(g)(1) of the FD&C Act, 21 U.S.C. 321(g)(1), the term “drug” includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the FD&C Act exempts homeopathic drugs from any of the requirements related to adulteration, misbranding, or approval.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your marketed products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of 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. In addition, please note that unapproved new drugs are subject to refusal of admission into the United States, and such products may be subject to detention without physical examination. For more information about detention without physical examination, see Import Alert 66-41.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. Your response should be sent by email to FDAADVISORY@fda.hhs.gov.

Sincerely,
/S/

Carolyn E. Becker
Director
Office of Unapproved Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

cc:
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