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Via FedEx & E-Mail

Dane Fredericksen (CEO)
Republic Registered Agent Inc.
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Re: Forever Young Pharmacy's Promotion and Sale of "Tirzepatide"

Dear Mr. Fredericksen:

I write because Eli Lilly and Company is deeply concerned that Forever Young Pharmacy ("Forever Young") is selling research-grade "Tirzepatide" that poses serious risks to the American public. Research-grade product has not been purified to pharmaceutical-grade levels and is not approved for or appropriate for human use. Nonetheless, you are actively promoting and/or selling research-grade tirzepatide for the purpose of human consumption, as evidenced by your sales and/or promotional practices. Your products also do not require a prescription from a healthcare provider, even though the U.S. Food and Drug Administration prohibits the selling of tirzepatide products for human consumption without a valid prescription and a determination by a medical provider that the drug is medically necessary. Forever Young practices are unlawful and dangerous. Forever Young's use of Lilly's marks—including its clinical trials for Mounjaro® and Zepbound®—is also improper, deceptive, and likely to cause confusion.

We therefore demand that Forever Young Pharmacy cease—no later than July 5, 2024—the promotion and sale of its "Tirzepatide" or any other tirzepatide product and the improper and confusing use of Lilly's marks.

Lilly's FDA-Approved Medicines

Lilly is a medicine company. We have pioneered life-changing discoveries for nearly 150 years. We manufacture Mounjaro®, which is FDA-approved to treat Type-2 diabetes. We also manufacture Zepbound®, which is FDA-approved to help adults with obesity—or those with excess weight who also have weight-related medical problems—lose weight and keep it off; it should be used with a reduced-calorie diet and increased physical activity. Mounjaro® and Zepbound® are the only FDA-approved therapies to target both GIP and GLP-1 hormone

receptors. Both medicines require a prescription and should only be used as directed by and under the care of a licensed healthcare professional.

The active pharmaceutical ingredient in Mounjaro® and Zepbound® is tirzepatide. Lilly's tirzepatide medicines are injectables; they are administered via under-the-skin injections. Lilly is the only lawful supplier of FDA-approved tirzepatide. We do not provide tirzepatide API to compounding pharmacies or other manufacturers. Lilly does not know where compounding pharmacies or others are obtaining what they claim is tirzepatide API.

FDA approved Mounjaro® and Zepbound® following its multi-year New Drug Application ("NDA") process, which is designed to develop, study, and bring safe medicines to patients so that "American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world."[1] Our tirzepatide medicines are the result of billions of dollars of investments in research and development. Since 2017, Lilly has completed 37 studies and trials for these medicines, including three Phase 2 clinical trials, three biopharmaceutical studies, 12 Phase 3 clinical trials, and 10 clinical pharmacology studies. Lilly also completed more than 40 FDA product label reviews for these medicines. FDA approval for Mounjaro® and Zepbound® was based on almost a dozen clinical trials involving over 10,000 patients; after reviewing the data from these trials, including the safety and efficacy of these medicines, the FDA approved them both. Approval for Zepbound® and Mounjaro® involved review from 45 and 49 FDA officials, respectively.

At Lilly, specialized personnel ensure our medicines meet our quality and safety standards. We manufacture our medicines under strict controls in state-of-the-art facilities. Transforming API into finished injectable doses is a complex, methodical, and science-based process. We follow Good Manufacturing Practices (GMP). Lilly's processes to manufacture our tirzepatide medicines—from sourcing and chemical synthesis of the API to sterile filling and device assembly and packaging and shipping—require extensive testing, controls, and specialized equipment. Lilly's medicines must be, and always are, accompanied with important, FDA-approved labels, instructions, and warnings.

Selling Research-Grade Drugs For Human Use Is Illegal

The FDA regulates precisely when and how prescription drugs can be sold for human consumption. Absent narrow exceptions not applicable here, a "new drug"—which includes drugs that have not been clinically tested and proven to be safe and effective—may not be legally sold for human consumption within the United States without an approved application from the FDA. 21 U.S.C. §§ 321(p), 331(d), 355(a). As described above, Lilly complied with the FDA's New

[1] FDA, *Development & Approval Process | Drugs*, https://www fda.gov/drugs/development-approval-process-drugs.

Drug Application process in connection with gaining approval of Mounjaro® and Zepbound®. "Research-grade tirzepatide" is, by definition, a new drug. It is untested and unproven, has never been the subject of a New Drug Application, and has never been approved by the FDA as safe and effective. The sale of that untested, unproven, and unapproved product to patients for human consumption violates the FDCA, including 21 U.S.C. §§ 331(d), 355(a).

In addition, the use of tirzepatide for weight loss is an indication that requires a prescription because it is not amenable to self-diagnoses and self-treatment by a layperson. A tirzepatide product is "misbranded" if it is sold directly to patients for weight loss. *See* 21 U.S.C. §§ 352(f)(1), 353(b)(1)(A).

For these reasons, the FDA recently took action against a seller who attempted to bypass the rules that apply to prescription drugs with a perfunctory declaration that the tirzepatide products were for "research purposes only." On February 7, 2024, the FDA sent a letter to Synthetix Inc., a seller of "research" grade tirzepatide, stating, "[d]espite statements on your product labeling marketing your products for 'research use only' and 'not for human consumption,' evidence obtained from your website establishes that your products are intended to be drugs for human use."[2] As a result, the seller's tirzepatide products were unapproved new drugs and were misbranded, in violation of the FDCA. The FDA warned that "[f]ailure to adequately address this matter may result in legal action including, without limitation, seizure and injunction," and it ordered the seller to respond in writing within 15 days and identify "the specific steps [] taken to address any violations," among other things.

The FDA similarly warned US Chem Labs, a seller of "research" tirzepatide products, stating, "[FDA] reviewed your website," and found that, "[d]espite statements on your product labeling marketing your products as 'research chemicals only' and 'not for human consumption,' evidence obtained from your website establishes that your products are intended to be drugs for human use."[3] FDA determined that the tirzepatide product constituted an unapproved new drug and that the product was misbranded, in violation of the FDCA. It also warned that failure to address this issue could result in "legal action" and ordered the seller to remedy its violations within 15 days. *See also,* FDA Warns of Use of Selective Androgen Receptor Modulators

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[2] FDA, Warning Letter re Synthetix Inc. DBA Helix Chemical Supply (Feb. 7, 2024), https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/synthetix-inc-dba-helix-chemical-supply-668918-02072024

[3] FDA, Warning Letter re US Chem Labs (Feb. 7, 2024), https://www fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/us-chem-labs-669074-02072024

(SARMs) Among Teens, Young Adults, FDA (April 26, 2023)[4] (warning that "dietary supplement" sold for "research" purposes was an unapproved new drug and violated the FDCA).

Forever Young's Promotion and Sale of Research-Grade "Tirzepatide"

Against this backdrop, we believe Forever Young is violating the law. Forever Young offers to sell research-grade "Tirzepatide," which it claims causes "weight loss" and "lowers blood sugar levels."[5] The sale of research-grade tirzepatide for human consumption is unlawful and violates state and federal law, including the FDCA.

Forever Young states that its "Tirzepatide" product is for "research purposes only," but your website indicates that this research-grade product is sold for human use for the purpose of causing weight loss. For example, on your website's blog, you posted an article entitled "Tirzepatide: The Peptide Phenomenon Reshaping Modern Medicine," which falsely states, "[c]linical trials have shown that Tirzepatide can significantly aid in weight loss. In the SURMOUNT-4 Randomized Clinical Trial, continued treatment with Tirzepatide resulted in significant weight reduction in adults with obesity."[6] The blog post also states, "The FDA has approved Tirzepatide for chronic weight management in adults with obesity or overweight with at least one weight-related condition."[7] This blog post also contains an image of a person injecting a substance via injector pen into their stomach.[8] Additionally, on the sale page for "Tirzepatide 15mg," you note that bacteriostatic water, alcohol prep pads, and syringes—all materials required for human use of the product—are "frequently bought together" with your "Tirzepatide" product.[9]

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4 FDA Warns of Use of Selective Androgen Receptor Modulators (SARMs) Among Teens, Young Adults (April 26, 2023), https://www fda.gov/consumers/consumer-updates/fda-warns-use-selective-androgen-receptor-modulators-sarms-among-teens-young-adults

5 https://www foreveryoungpharmacy.com/product/tirzepatide-15mg/2?cp=true&sa=true&sbp=false&q=false

6 https://www foreveryoungpharmacy.com/s/stories/tirzepatide-the-peptide-phenomenon-reshaping-modern-medicine

7 https://www foreveryoungpharmacy.com/s/stories/tirzepatide-the-peptide-phenomenon-reshaping-modern-medicine

8 https://www foreveryoungpharmacy.com/s/stories/tirzepatide-the-peptide-phenomenon-reshaping-modern-medicine

9 Id. at fn. 5

This is precisely the type of conduct that FDA has warned other sellers is unlawful and should be ceased immediately.

Additionally, as described above, Forever Young uses the clinical trials for Lilly's medications to suggest that the compounded "Tirzepatide" sold by Forever Young is safe and effective. Your use of Lilly's marks, including but not limited to Lilly's clinical trials, are deceptive, misleading, and constitute false advertising. Forever Young's statements are likely to deceive patients into believing that the "Tirzepatide" promoted and/or sold by Forever Young is the same clinically tested product that is manufactured by Lilly.

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Forever Young's sale of "research only" drugs pose urgent safety issues. We believe you are violating the law and demand that Forever Young immediately (and no later than July 5, 2024,) cease and desist the promotion and sale of "Tirzepatide" or any other tirzepatide product and the improper and confusing use of Lilly's marks. Lilly reserves its rights.

Sincerely,

/s/ Melanie MacKay

Melanie MacKay