December 15, 2023

VIA UPS EXPRESS MAIL

Maryam Amiri
Co-Founder
Hadaf LLC (dba Brillia)
3306 N 27th Ave.
Unit 3306D
Phoenix, AZ 85017

Dear Ms. Amiri:

The Office of Compliance and Biologics Quality in the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) has reviewed your website, discoverbrillia.com. On this website (last visited on December 15, 2023), you and your firm sell the products "Brillia For Children" and "Brillia For Adults," which you collectively refer to as "Brillia" or "Brillia Products" (hereinafter, "your products"), labeled as containing various dilutions of Lapine S-100 immune globulin as active ingredients, to treat diseases or conditions in humans, including attention deficit/hyperactivity disorder (ADHD), autism, and anxiety. Examples of claims on your website include the following:

- "Brillia is the safe, impactful option to help reduce anxiety, stress, hyperactivity and irritability and to improve focus, attention and emotional regulation. Brillia stands apart from prescription pharmaceuticals, supplements and other products with a unique targeted active ingredient and proven results…"

- "Brillia is an impactful and safe non-prescription alternative to prescription pharmaceuticals…Brillia is able to be used by children, teen [*sic*] and adults with a variety of diagnoses, or no official diagnoses at all, as long as they suffer from anxiety or hyperactivity."

Brillia For Children

- A review featured on your website from the family of a six-year-old girl "diagnosed with ADHD" with "extreme, unmanageable symptoms" states, "The doctor said there was no way we were going to get around medicating her. I saw an ad for Brillia and thought let's try it and see. She was on it for about 2 weeks and within that timeframe the change I saw in her was absolutely amazing."

- “My son (6) has ASD [autism spectrum disorder], ODD [oppositional defiant disorder], ADHD, anxiety and we used it for 3 months. We saw improvement…He’s doing great!”

- A review featured on your website from the family of a 12-year-old girl described as having anxiety and panic attacks states, “My daughter was on prescribed medication...and she actually started having increased suicidal thoughts. After switching to Brillia, I feel like we're getting our real daughter back."

Brillia For Adults

- A review featured on your website and titled “Brillia for Adults: ADHD” states, “I have been on ADHD prescription meds before. I’m off them now because of side effects. I took the whole (Brillia) package…I recently realized how much good it really was doing. I just re-ordered.”

- “Brillia for Adults worked just as promised. . . I noticed a big change in my anxiety.”

Additionally, a page on your website described as a blog post is titled, “How Brillia Can Help Children & Adults with Autism,” and states, “An alternative to prescription medication is Brillia…” under the header “How Brillia Can Help Autism Symptoms.”

Based on our review of your websites, your products are drugs as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 321(g)], because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans. Your products are also biological products as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 U.S.C. 262(i)] because they are applicable to the prevention, treatment, or cure of a disease or condition of human beings.

In order to lawfully market a drug that is also a biological product, a valid biologics license must be in effect [42 U.S.C. 262(a)]. Such licenses are issued only after a showing that the product is safe, pure, and potent. While in the development stage, such products may be distributed for clinical use in humans only if the sponsor has an investigational new drug application (IND) in effect [21 U.S.C. 355(i); 42 U.S.C. 262(a)(3); 21 CFR Part 312]. Your products are not the subject of an approved biologics license application (BLA), nor is there an IND in effect for your products.[1] Based on this information, your actions violate the FD&C Act and the PHS Act.

[1] We recognize that the “Brillia For Children” and “Brillia For Adults” labeling describes the products as being “homeopathic.”

First, we note that 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 drug products are subject to the same statutory requirements as other

This letter addresses certain issues regarding your products and is not intended to be an all-inclusive review. You and your firm are responsible for ensuring that all your products fully comply with the FD&C Act, the PHS Act, and all applicable regulations. We request a written response within 30 days of your receipt of this letter. If you do not believe there is a basis for the regulatory issues raised in this letter, include your reasoning and any supporting information for our consideration.

Your response should be sent to the following address: U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, 10903 New Hampshire Avenue, Bldg. 71, Silver Spring, MD 20993. In addition, you may also email a copy of your official, written response to CBERDCMRecommendations@fda.hhs.gov. If you have any questions regarding this letter, please contact the Division of Case Management, CBER at (240) 402-9156.

Sincerely,

Melissa J. Mendoza
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

---

drugs; nothing in the FD&C Act exempts homeopathic drugs from any of the requirements related to adulteration, misbranding, or FDA approval.

In addition, FDA issued a guidance in December 2022 that describes how the Agency intends to prioritize enforcement and regulatory actions for homeopathic drug products marketed in the United States without the required FDA approval. *See* Homeopathic Drug Products: Guidance for FDA Staff and Industry, available at https://www.fda.gov/media/163755/download. For purposes of this guidance, FDA defines a "homeopathic drug product" as "a drug product that is labeled as 'homeopathic,' and is labeled as containing only active ingredients and dilutions (e.g., 10X, 20X) listed for those active ingredients in the Homeopathic Pharmacopeia of the United States (HPUS)." We recognize that images of your products on your website show the active ingredient in Brillia is measured in homeopathic strengths. However, the active ingredient in your products, "Lapine S-100 immune globulin," is not recognized in the Homeopathic Pharmacopeia of the United States (HPUS) and thus your products fall outside the scope of products addressed in this guidance. Notwithstanding, even if your above listed products were considered "homeopathic drug products" under this guidance, your "Brillia for Children" product would fall under the guidance's categories of homeopathic drug products marketed without the required FDA approval that FDA views as potentially posing higher risks to public health, and thus intends to prioritize for enforcement and regulatory actions.

cc:

Roland Kiskis
General Manager
Santonika UAB
Veiveriu G.134B
Kaunas
LT-46353
Lithuania

Keyvan Taheri
Manager
Hadaf LLC
6929 N Hayden Rd
Ste C4-469
Scottsdale, AZ 85250