



Clifton Health Department Food Recall Notification



Public Health
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Food/Drug/Pet Recall: Biota Biosciences

Biota Biosciences is voluntarily recalling the following lots in the table below of Cannabidiol (CBD) Complex, Curcumin Complex, and Cannabidiol + Curcumin Injectables to the customer level. These injectable products are being recalled because they were marketed without FDA approval. The products claims on the firm's website make these products unapproved new drugs. Further, the products are misbranded because the labeling fails to bear adequate directions for use.

| Product Name | Strength(mg) | (mg/mL) | Multiple Dose | Vial Size | Lot | Expiration |
|--------------------------|--------------|---------|---------------|------------|-----|------------|
| Cannabidiol(CBD) Complex | 4 | 10 mL | 2H071219P | 07/12/2021 | | |
| | 50 | 10 mL | 10102019P | 10/10/2021 | | |
| Curcumin Complex | 4 | 10 mL | 2H071219CCD | 07/12/2021 | | |
| | 50 | 10 mL | 0712019CCD | 07/12/2021 | | |
| Cannabidiol + Curcumin | 50 | 10 mL | 10102019PC | 10/10/2021 | | |

Risk Statement: Unapproved new drugs injected into the bloodstream for which safety and efficacy have not been established could pose a serious risk of harm to users because they bypass many of the body's natural defenses against toxic ingredients, toxins, or dangerous organisms that can lead to serious and life-threatening conditions such as septicemia or sepsis. Biota Biosciences has not received any reports of adverse events related to this recall.

Cannabidiol (CBD) Complex was marketed to suppress pain and aid in the detoxification processes as a promising therapeutic for a wide array of disorders such as epilepsy, including many challenging neuropathy conditions. Curcumin Complex was marketed as a potent anti-inflammatory and antioxidant that may also help improve symptoms of depression and arthritis. Cannabidiol + Curcumin was marketed as a more efficient therapeutic effect. The product was sold to certified practitioners who further administer to customers. The product is packaged in 10 mL sterile vials. Products were distributed Nationwide in the USA and one consignee in New Zealand.

Water Soluble 4mg/10m products can be identified by the labels below.

Water Soluble 50mg/10m products can be identified by the labels below.

Biota Biosciences is notifying its distributors and customers by email and is arranging for return of all recalled products. Practitioners or consumers that have product which is being recalled should stop using product and return to place of purchase.

Consumers with questions regarding this recall can contact Biota Biosciences by phone number at (866) 996-2293 Monday to Friday 8:00 am to 4:00 pm PST or by e-mail at hq@biotacbd.com.



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Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- . Complete and submit the report Online
- . Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.