

COMPANY ANNOUNCEMENT

Biota Biosciences Issues Voluntary Nationwide Recall of Cannabidiol (CBD) Complex, Curcumin Complex, and Cannabidiol + Curcumin Injectables Because They Were Marketed Without FDA Approval

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

May 20, 2020

FDA Publish Date:

May 20, 2020

Product Type:

Drugs

Reason for Announcement:

Unapproved new drug

Company Name:

Biota Biosciences, LLC

Brand Name:

Biota Biosciences

Product Description:

Cannabidiol (CBD) Complex, Curcumin Complex, Cannabidiol + Curcumin

Company Announcement

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 our 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)	Multiple Dose Vial Size	Lot	Expiration
Cannabidiol(CBD) Complex	40	10 mL	2H071219P	07/12/2021
	500	10 mL	10102019P	10/10/2021
Curcumin Complex	40	10 mL	2H071219CCD	07/12/2021
	500	10 mL	0712019CCD	07/12/2021
Cannabidiol + Curcumin	500	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 40mg/10m products can be identified by the labels below.

Water Soluble 500mg/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 (<mailto:hq@biotacbd.com>). 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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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.

Company Contact Information

Consumers:

☎ (866) 996-2293

✉ hq@biotacbd.com (<mailto:hq@biotacbd.com>)

Media:

Ben Sinclair

☎ (866) 996-2293

Product Photos

Sterile Cannabidiol (CBD)

4mg / mL

Qty: 10 mL

Lot#:

Expiry:

Sterile Curcumin

4mg / mL

Qty: 10 mL

Lot#:

Expiry:

Sterile Cannabidiol (CBD)+ Curcumin

4mg / mL

Qty: 10 mL

Lot#:

Expiry:

Sterile Cannabidiol (CBD)

50mg / mL

Qty: 10 mL

Lot#:

Expiry:

Sterile Curcumin

50mg / mL

Qty: 10 mL

Lot#:

Expiry:

Sterile Cannabidiol (CBD)+ Curcumin

50mg / mL

Qty: 10 mL

Lot#:

Expiry:

[More Recalls, Market Withdrawals, & Safety Alerts \(/safety/recalls-market-withdrawals-safety-alerts\)](#)

