

# State Regulations and Product Disclosures

The following information is provided pursuant to applicable state law.

## **CALIFORNIA: STATEMENT REGARDING COMPLIANCE WITH CALIFORNIA HEALTH AND SAFETY CODE § 119402**

Last Updated: December 1, 2025

The following information is provided pursuant to the requirements of California Health and Safety Code, Section 119402, which requires pharmaceutical companies doing business in California to make available their Compliance Program and annual written declaration of compliance with the Compliance Program.

California Health and Safety Code, Sections 119400-119402, ("California Compliance Law") requires pharmaceutical companies to adopt a compliance program in accordance with the April 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Compliance Guidance") developed by the United States Department of Health and Human Services Office of Inspector General ("OIG") and policies for compliance with the Pharmaceutical Research and Manufacturers of America ("PhRMA") "Code on Interactions with Health Care Professionals" ("PhRMA Code") within six months of any update or revision of the PhRMA Code. Revisions to the PhRMA Code were implemented in January 2009, October 2019 and January 2022.

Botanix SB Inc. (the "Company") has established a Compliance Program in accordance with the OIG Compliance Guidance and has policies in place to foster compliance with the PhRMA Code for its pharmaceutical business. For purposes of compliance with the requirements of the California Compliance Law and as part of the Compliance Program, the Company has established a specific annual aggregate dollar limit of \$2,000 on gifts, promotional materials, or items or activities that the Company may give or otherwise provide to an individual medical or healthcare professional licensed in California on an annual basis from January 1st to December 31st each year. Such items or activities primarily include: modest meals associated with a substantive discussion of a Company product or a disease state; medical textbooks and other items that principally entail a patient benefit or are related to the healthcare professional's practice; and other items or activities permitted under the PhRMA Code, and/or the OIG Compliance Guidance. These items and activities are primarily directed to the dissemination or communication of medical and scientific information as a resource for healthcare professionals to assist in making clinical or other medical judgments. This limit may be revised from time to time, in which case the revised limit will be published in this section of the Company website. This limit represents a spending cap, not a goal or average; in many cases, the amount spent per physician may be substantially less than the cap amount. The Company has established an internal monitoring system designed to help ensure compliance with the annual spending limits in California and is working to establish additional monitoring processes.

The annual limits do not include the following:

- Drug samples given to physicians and healthcare professionals
- Financial support for continuing medical education program
- Financial support for educational scholarships
- Payments for bona fide professional services made pursuant to a contract, and any meals or expenses associated with the provision of such services
- Items of nominal value with a retail value of less than \$10 (e.g., visual aids, reprints of medical journal articles)
- Patient educational materials provided to patients by their physician with the purpose of educating the patient or enhancing the patient's understanding or management of the condition

### Annual Declaration

As stated in its Compliance Program description, the Company is committed to conducting its business ethically and in compliance with all applicable laws. To the best of its knowledge and based on a good faith

understanding of the statutory requirements, the Company has established a Compliance Program that meets the requirements set forth in California Health and Safety Code, Sections 119400-119402. The Company has tailored its Compliance Program to meet the specific needs of the Company and continuously assesses the effectiveness of the Compliance Program. The Company has established an internal monitoring system designed to help ensure compliance with its respective annual spending limits in California and is working to establish additional corporate tracking and monitoring processes. Thus, subject to the limitations described above, the Company declares that, based upon current tracking and monitoring systems, the Company is, in all material respects, in compliance with the Compliance Program and with the respective established annual spending limits.

As recognized by the OIG Compliance Guidance, even an effective compliance program cannot eliminate the possibility that one or more individual employees engage in conduct that would be considered improper. Accordingly, this declaration is not intended and should not be construed to imply that the Company has not identified any individual instances in which an employee has or may have violated one or more provisions of its Compliance Program. In such situations, the Company takes reasonable and appropriate remedial or corrective action in a manner consistent with its Compliance Program.

Annual Declaration (December 15, 2025)

For a written copy of the Compliance Program description or this declaration, call 1-445-300-3403 and select option “4” or by email at [compliance@botanixpharma.com](mailto:compliance@botanixpharma.com).

**COLORADO:** Colorado HB 19-1131 – HCP Price Disclosure

Last Updated: November 1, 2025

Information for Colorado Prescribers of Prescription Drugs

**Sofdra® (sofpironium)**

The following information is being provided to Colorado prescribers pursuant to Colorado law HB 19-1131. The price listed below represents the Wholesale Acquisition Cost (“WAC”) as made available to the public by a third-party publisher. WAC does not reflect discounts, rebates and other reductions in price. The actual price paid by patients may differ and is dependent upon the individual patient’s insurance.

MARKETED PRODUCT	WAC PRICE
Sofdra 72 mg sofpironium/0.67 mL gel/pump (50 mL) bottle, 30 2-pump daily doses	\$990.72/bottle

**Generic Drugs in Same Therapeutic Class\*: N/A**

**Data as of November 1, 2025**

Sofdra is a registered trademark of Botanix SB Inc.

\*Colorado law requires manufacturers to provide the names of generic prescription drugs from the same “therapeutic class” as the marketed drug. Colorado defines “therapeutic class” as “a group of similar drugs that have the same or similar mechanisms of action and are used to treat a specific condition.”

Last Updated: November 1, 2025

Information for Connecticut Prescribers of Prescription Drugs

**Sofdra® (sofpironium)**

The following information is being provided to Connecticut prescribers pursuant to CT House Bill 6669. The price listed below represents the Wholesale Acquisition Cost (“WAC”) as made available to the public by a third-party publisher. WAC does not reflect discounts, rebates and other reductions in price. The actual price paid by patients may differ and is dependent upon the individual patient’s insurance.

MARKETED PRODUCT	NDC	WAC PRICE
Sofdra 72 mg sofpironium/0.67 mL gel/pump (50 mL) bottle, 30 2-pump daily doses	83723-0010-50	\$990.72/bottle

Data as of November 1, 2025

Sofdra is a registered trademark of Botanix SB Inc.