

By the Committee on Regulated Industries

580-02164-21

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1                   A bill to be entitled  
2       An act relating to a review under the Open Government  
3       Sunset Review Act; amending s. 499.051, F.S., which  
4       relates to an exemption from public records  
5       requirements for trade secrets contained within  
6       complaints or pursuant to an investigation of such  
7       complaints obtained by the Department of Business and  
8       Professional Regulation, which are submitted by  
9       permittees relating to the manufacture, repackaging,  
10      or distribution of a drug or for a permit or product  
11      registration or for the renewal of such permit or  
12      product registration; removing the scheduled repeal of  
13      the exemption; providing an effective date.

14  
15 Be It Enacted by the Legislature of the State of Florida:

16  
17       Section 1. Section 499.051, Florida Statutes, is amended to  
18      read:

19       499.051 Inspections and investigations.—

20       (1) The agents of the department and of the Department of  
21      Law Enforcement, after they present proper identification, may  
22      inspect, monitor, and investigate any establishment permitted  
23      pursuant to this chapter during business hours for the purpose  
24      of enforcing this chapter, chapters 465, 501, and 893, and the  
25      rules of the department that protect the public health, safety,  
26      and welfare.

27       (2) In addition to the authority set forth in subsection  
28      (1), the department and any duly designated officer or employee  
29      of the department may enter and inspect any other establishment

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30 for the purpose of determining compliance with this chapter and  
31 rules adopted under this chapter regarding any drug, device, or  
32 cosmetic.

33 (3) Any application for a permit or product registration or  
34 for renewal of such permit or registration made pursuant to this  
35 chapter and rules adopted under this chapter constitutes  
36 permission for any entry or inspection of the premises in order  
37 to verify compliance with this chapter and rules; to discover,  
38 investigate, and determine the existence of compliance; or to  
39 elicit, receive, respond to, and resolve complaints and  
40 violations.

41 (4) Any application for a permit made pursuant to s.  
42 499.012 or s. 499.831 and rules adopted under those sections  
43 constitutes permission for agents of the department and the  
44 Department of Law Enforcement, after presenting proper  
45 identification, to inspect, review, and copy any financial  
46 document or record related to the manufacture, repackaging, or  
47 distribution of a drug as is necessary to verify compliance with  
48 this chapter and the rules adopted by the department to  
49 administer this chapter, in order to discover, investigate, and  
50 determine the existence of compliance, or to elicit, receive,  
51 respond to, and resolve complaints and violations.

52 (5) The authority to inspect under this section includes  
53 the authority to access, review, and copy any and all financial  
54 documents related to the activity of manufacturing, repackaging,  
55 or distributing prescription drugs.

56 (6) The authority to inspect under this section includes  
57 the authority to secure:

58 (a) Samples or specimens of any drug, device, or cosmetic;

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59 or

60 (b) Such other evidence as is needed for any action to  
61 enforce this part and the rules adopted under this part.

62 (7) (a) The complaint and all information obtained pursuant  
63 to the investigation by the department are confidential and  
64 exempt from s. 119.07(1) and s. 24(a), Art. I of the State  
65 Constitution until the investigation and the enforcement action  
66 are completed.

67 (b) Information that constitutes a trade secret, as defined  
68 in s. 812.081, contained in the complaint or obtained by the  
69 department pursuant to the investigation must remain  
70 confidential and exempt from s. 119.07(1) and s. 24(a), Art. I  
71 of the State Constitution as long as the information is held by  
72 the department. ~~This paragraph is subject to the Open Government  
73 Sunset Review Act in accordance with s. 119.15 and shall stand  
74 repealed on October 2, 2021, unless reviewed and saved from  
75 repeal through reenactment by the Legislature.~~

76 (c) This subsection does not prohibit the department from  
77 using such information for regulatory or enforcement proceedings  
78 under this chapter or from providing such information to any law  
79 enforcement agency or any other regulatory agency. However, the  
80 receiving agency shall keep such records confidential and exempt  
81 as provided in this subsection.

82 Section 2. This act shall take effect October 1, 2021.