

By Senator Latvala

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1 A bill to be entitled

2 An act relating to drugs, cosmetics, and certain
3 devices; amending s. 499.01, F.S.; requiring that the
4 Department of Health notify an applicant for an out-
5 of-state prescription drug wholesale distributor
6 permit of the status of its permit application within
7 60 days after receipt of all required documentation;
8 providing an effective date.

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10 Be It Enacted by the Legislature of the State of Florida:

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12 Section 1. Paragraph (e) of subsection (2) of section
13 499.01, Florida Statutes, is amended to read:

14 499.01 Permits.—

15 (2) The following permits are established:

16 (e) *Out-of-state prescription drug wholesale distributor*
17 *permit.*—An out-of-state prescription drug wholesale distributor
18 is a wholesale distributor located outside this state which
19 engages in the wholesale distribution of prescription drugs into
20 this state and which must be permitted by the department and
21 comply with all the provisions required of a wholesale
22 distributor under this part. An out-of-state prescription drug
23 wholesale distributor that applies to the department for a new
24 permit or the renewal of a permit must submit a bond of
25 \$100,000, or other equivalent means of security acceptable to
26 the department, such as an irrevocable letter of credit or a
27 deposit in a trust account or financial institution, payable to
28 the Florida Drug, Device, and Cosmetic Trust Fund. The purpose
29 of the bond is to secure payment of any administrative penalties

16-01645B-11

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30 imposed by the department and any fees and costs incurred by the
31 department regarding that permit which are authorized under
32 state law and which the permittee fails to pay 30 days after the
33 fine or costs become final. The department may make a claim
34 against such bond or security until 1 year after the permittee's
35 license ceases to be valid or until 60 days after any
36 administrative or legal proceeding authorized in this part which
37 involves the permittee is concluded, including any appeal,
38 whichever occurs later.

39 1. The out-of-state prescription drug wholesale distributor
40 must maintain at all times a license or permit to engage in the
41 wholesale distribution of prescription drugs in compliance with
42 laws of the state in which it is a resident.

43 2. The department shall notify an out-of-state prescription
44 drug wholesale distributor that applies for a permit the status
45 of its permit within 60 days after receipt of all documentation
46 required by the application.

47 ~~3.2.~~ An out-of-state prescription drug wholesale
48 distributor permit is not required for an intracompany sale or
49 transfer of a prescription drug from an out-of-state
50 establishment that is duly licensed as a prescription drug
51 wholesale distributor, in its state of residence, to a licensed
52 prescription drug wholesale distributor in this state, if both
53 wholesale distributors conduct wholesale distributions of
54 prescription drugs under the same business name. The
55 recordkeeping requirements of ss. 499.0121(6) and 499.01212 must
56 be followed for this transaction.

57 Section 2. This act shall take effect July 1, 2011.