

Secretary of State
Certificate and Order for Filing
TEMPORARY ADMINISTRATIVE RULES
A Statement of Need and Justification accompanies this form.

I certify that the attached copies* are true, full and correct copies of the TEMPORARY Rules adopted on 06-09-2009 by the _____
Date prior to or same as filing date

Oregon Board of Pharmacy _____ 855
Agency and Division Administrative Rules Chapter Number

Karen MacLean _____ 800 NE Oregon St, Portland, OR 97232 _____ 971-673-0001
Rules Coordinator Address Telephone

to become effective 06-26-2009 _____ through 12-23-2009
Date upon filing or later A maximum of 180 days including the effective date.

RULE CAPTION

Change and clarify registration rules for drug manufacturers and wholesalers.
Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.

RULEMAKING ACTION
List each rule number separately, 000-000-0000.

ADOPT: 855-060-0003T, 855-062-0003T, 855-062-0005T, 855-062-0020T, 855-062-0030T, 855-062-0040T, 855-062-0050T, 855-110-0003T.

AMEND: 855-065-0001, 855-065-0005, 855-065-0006, 855-110-0007, 855-110-0010.

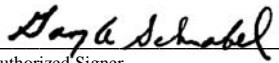
SUSPEND:

ORS 689.205 _____
Stat. Auth. Other Authority

ORS 689.155 _____
Stats. Implemented

RULE SUMMARY

The new rules in Division 60 and 62, and the amended rules in Division 65 define more clearly which entities must register as drug manufacturers and as drug wholesalers. A new category of Drug Distribution Agent is created in Division 62 to accommodate entities that are involved in the drug manufacturing and distribution industry but that do not ever take ownership or possession of actual product and are not licensed with the FDA as manufacturers. Division 65 is further amended to eliminate confusion over the status of repackagers and brokers, and to eliminate the requirement for a surety bond for a wholesale drug outlet that is accredited by the National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program. The fee schedule in Division 110 is amended to include the new category of Drug Distribution Agent.

 _____ Gary S. Schnabel _____ 6/18/2009
Authorized Signer Printed name Date