

Secretary of State
STATEMENT OF NEED AND JUSTIFICATION
A Certificate and Order for Filing Temporary Administrative Rules accompanies this form.

Board of Pharmacy
Agency and Division

OAR 855
Administrative Rules Chapter Number

In the Matter of: **Rules for Pharmaceutical Manufacturers and Wholesale Drug Outlets**

Rule Caption: **Revise registration rules for drug manufacturers and wholesalers.**

Statutory Authority: ORS 689.205

Other Authority:

Stats. Implemented: ORS 689.155

Need for the Temporary Rule(s): Since the Board last revised the administrative rules for the registration of manufacturers and wholesalers, the industry has evolved and a number of new business models have developed that do not fit easily or cleanly into any existing definitions. The FDA now regulates manufacturers much more stringently and state rules can reflect that oversight without adverse effect on public safety. In addition, there has been a significant increase in the number of entities that, while intrinsically involved in the drug distribution process, do not ever actually possess or take title to any drug products. A new category is necessary to enable them to register with the Board without having to undergo the more stringent procedures that are required of companies that actually make, store and distribute drugs.

Documents relied upon, and where they are available:

None

Justification of Temporary Rule(s):

The Board finds that pursuing permanent rulemaking procedures will delay the implementation of these rules and cause serious prejudice to the public interest in that:

- 1) The annual registration renewal cycle for drug manufacturers and wholesalers begins in August and without these changes, many companies will not know in which category they should register. This would generate a large amount of additional work for the Board's licensing staff and cause delays in the registration process for applicants.
- 2) Without this temporary rule, a number of companies would be forced into either undergoing the more stringent registration process as wholesalers or simply not qualify to be registered as a wholesale drug outlet in Oregon. This rule allows a simpler process that will now be available to companies that are already registered with the FDA as manufacturers and do not actually possess any drug product.


Authorized Signer

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06/17/2009
Date