



**California State Board of Pharmacy**

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**PROPOSAL TO ADD A NEW SECTION 1747.2 OF DIVISION 17 OF  
TITLE 16 OF THE CALIFORNIA CODE OF REGULATIONS**

During the board meeting a regulation hearing will be conducted on a Proposal to Add a New Section 1747.2 of Division 17 of Title 16 of the California Code of Regulations.

At the conclusion of the hearing the board will consider all comments received during the 45 day comment period as well as those provided orally during the regulation hearing. As of October 24, 2013, the board has received one written comment during the comment period. If additional comments are received, the comments will be brought to the board meeting

Attached are the proposed language and the one comment received.

**Title 16. Board of Pharmacy  
Proposed Language**

**Proposal to Add a New Section 1747.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1747.2 Drop Shipments.**

For the purposes of Business and Professions Code section 4163.1, when a manufacturer utilizes the “drop shipment” method of sale as defined by that section, the data elements pertaining to transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery thereby, may be omitted from the pedigree, in which case the manufacturer shall convey the pedigree directly to the pharmacy or other person authorized by law to dispense or administer the dangerous drug prior to or contemporaneous with delivery of the corresponding dangerous drug.

Note: Authority cited: Sections 4005, 4034, and 4163.1, Business and Professions Code.

Reference: Sections 4034, 4037, 4163, 4163.1, 4170, 4180, and 4190, Business and Professions Code.

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October 24, 2013

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**VIA E-MAIL [Debbie.Damoth@dca.ca.gov]**  
**FOLLOWED BY U.S. MAIL**

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**Re: Support for Board of Pharmacy Proposed Regulation 1747.2 "Drop Shipments"  
Notice Published September 13, 2013**

On behalf of our client, Millennium Pharmaceuticals, Inc. ("Millennium"), we are pleased to submit comments in support for the California State Board of Pharmacy ("Board") adoption of its proposed new regulation at Title 16, California Code of Regulations, Section 1747.2 – "Drop Shipments."

Millennium has worked closely with the Board to encourage its focus on a unique distribution model in the prescription drug supply chain, and one for which customized rulemaking is authorized in the state's electronic pedigree ("e-pedigree") statute at Section 4163.1(b) of the California Business and Professions Code.

Millennium supports the Board's proposal to specify that when a manufacturer utilizes the "drop shipment" method of distribution for a dangerous drug, the manufacturer may omit data elements from the pedigree showing transfers of ownership to and from the wholesale distributor, including any certifications of receipt and delivery of the drug by the wholesaler. Pedigree would then be required to be conveyed directly from the manufacturer or its designated distributor to the authorized purchaser prior to or contemporaneously with the delivery of the dangerous drug.

As the Board knows from our previous testimony and written submissions on this question, Millennium utilizes a "drop-shipment" distribution model that provides treating physicians and their patients with timely and efficient access to critical and time-sensitive therapies for cancer. This

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Drop Shipment Regulation Coordinator  
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model allows our client to facilitate the direct shipment of medications to a healthcare provider's office, and ultimately to the patient, within a day of placing an order.

In this model, wholesalers place orders for the product and consequently take title to the ordered product, but never take possession or physical control of the product. The role of the wholesaler in this model is thus limited to facilitating administrative services, such as the processing of orders and payments.

Section 4163.1(b) of the California Business and Professions Code expressly permits the Board to establish an alternative process to convey the pedigree information for drugs that are distributed by drop shipment. The intent of the drug pedigree requirements in California law is to provide the capability to track and trace drug shipments. As a result, only those stakeholders that actually take possession or physical control of the drugs are best positioned to satisfy the objectives of the law's pedigree requirements.

In the context of a drop shipment distribution model, pedigree information should include records of any shipments directly from manufacturers (or their designated distributors) to dispensers, as well as any returns. However, pedigree requirements need not apply to wholesale distributors who take only legal title of a drug product, but take neither possession nor physical control. Ensuring entities that *never* physically handle the product are not subject to the reporting requirements will allow companies, like Millennium, to maintain important efficiencies in its distribution system without subjecting its wholesalers to unnecessary regulation. All the while, the accurate tracking of pharmaceutical products throughout this unique chain of physical custody is ensured.

On behalf of Millennium, we wish to express our thanks to the Board and its staff for its sustained focus, and proposed action, on this important aspect of "e-pedigree." Millennium reiterates its support for the adoption of this regulation.

Should the Board require any additional information, please don't hesitate to contact me at (916) 441-2430.

Respectfully submitted,



JOHN R. VALENCIA

JRV:mb  
Enclosures: Exhibits "A" & "B"  
1020420.1

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Exhibit "A"

## **“Drop Shipment” Distribution Process Summary**

A variety of pharmaceutical manufacturers use a “drop-shipment” distribution model that provides treating physicians and their patients with timely and efficient access to drugs. By using a drop-ship model, the manufacturer can facilitate a direct shipment of its drug to a healthcare provider’s office. In this model, wholesalers place orders with the manufacturer or a designated distributor for the product and consequently take title to the ordered product, but never take possession or physical control of the product. Instead, the manufacturer or designated distributor ships directly to the physician upon receipt of the order. The role of the wholesaler in this model is thus limited to facilitating drug distribution by providing administrative services, such as the processing of orders and payments.

Exhibit "B"

**A 'DROP-SHIPMENT' DRUG DISTRIBUTION MODEL**

