



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

NOTICE OF MEETING AND AGENDA

Enforcement and Compounding Committee Meeting

June 4, 2013

Contact Person: Laura Hendricks
(916) 574-7918

Note: This is a combined meeting to discuss enforcement and compounding matters.

An E-Pedigree meeting will occur on June 24, 2013, in Sacramento.

This committee meeting is open to the public and is accessible to the physically disabled. A person who needs a disability-related accommodation or modification in order to participate in the meeting may make a request by contacting Laura Hendricks at (916) 574-7918, by emailing laura.hendricks@dca.ca.gov or sending a written request to Ms. Hendricks at the Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. Providing your request at least five business days before the meeting will help to ensure availability of the requested accommodation.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

DATE: June 4, 2013

PLACE: Department of Consumer Affairs / Hearing Room
1625 N. Market Blvd
Sacramento, CA 95834

This meeting may be cancelled without notice. For verification of the meeting, call (916) 574-7900 or access the Board's Web site at www.pharmacy.ca.gov.

Discussion and action may be taken on any item on the agenda. The committee may discuss agenda items in any order. Board members who are not on the committee may attend, but may not vote. Time limitations for discussion and comment will be determined by the committee chair.

Agenda

Call to Order

9:30 a.m.

I. Enforcement Matters:

- a. Enforcement and Compounding Committee Meeting Dates for the Remainder of 2013: September 10 and December 3
- b. Discussion on Whether Emerging Technologies Necessitate Revisions to Title 16, Section 1713 of the California Code of Regulations
- c. Request from California Society of Health-System Pharmacists to Discuss Drug Shortages
- d. Implementation of Penal Code Section 11105 – Board Requirement to Provide Criminal Offender Record Information to an Applicant or Licensee When the Information Is Used as the Basis for an Licensing Decision
- e. National Association of Boards of Pharmacy Report on Sales of Fake and Substandard Medications
- f. NABP Announces Development of Standards for the *.pharmacy* Generic Top Level Domain for Internet Pharmacy Web Sites

II. Compounding Matters

- a. Discussion on Pending California Legislation on Sterile Compounding: Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva)
- b. Discussion of Recent Federal Reports and Articles Relating to Compounding Pharmacies
 - 1. *FDA's Oversight of NECC and Ameridose: A History of Missed Opportunities?*
 - 2. Office of Inspector General Memorandum Report: *High-Risk Compounded Sterile Preparations and Outsourcing by Hospitals That Use Them*, OEI-01-013-00150
 - 3. ASHP Guidelines on Outsourcing Sterile Compounding Services
 - 4. FDA's Guidance for FDA Staff and Industry – Marketed Unapproved Drugs, Compliance Policy Guide
 - 5. U.S. Senate Health, Education, Labor and Pensions Committee Report: *The Case for Clarifying FDA Authority: Large-Scale Drug Compounding and the Ongoing Risk to Public Health*
 - 6. Miscellaneous Articles
- c. Proposed Federal Legislation on Compounding Introduced by the U.S. Senate (S. 959)
- d. Discussion Regarding USP's 797 Standards and Regulation Requirements of the Board of Pharmacy
- e. Discussion Regarding "Batches"
- f. Discussion of the Board of Pharmacy's Questions and Answers Document on Compounding
- g. Outcomes of Recent Sterile Compounding Inspections
- h. Recalls of Compounded Drugs Throughout the United States

III. Closing Comments

IV. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

ADJOURNMENT

4 p.m.