STATE AND CONSUMER SERVICES AGENCY DEPARTMENT OF CONSUMER AFFAIRS Arnold Schwarzenegger, GOVERNOR

California State Board of Pharmacy 400 R Street, Suite 4070, Sacramento, CA 95814-6237 Phone (916) 445-5014 Fax (916) 327-6308 www.pharmacy.ca.gov

## LICENSING COMMITTEE WORKGROUP ON COMPOUNDING

Ken Schell, Pharm.D. John Tilley, R.Ph.

Hilton Oakland Airport One Hegenberger Road Oakland, CA 94621 (510) 635-5000

September 22, 2004 1:30 p.m. – 4:00 p.m. *Empire Room, Building 5* 

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 days prior to the meeting.

## A. Call to Order

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1:30 p.m.

#### **B.** Introductions and Meeting Format

#### C. Discussion of Compounding Issues

- Law Manufacturing/Compounding Efficacy Label on "unit of use" containers Definition Central Fill Veterinary Anticipatory OTC
- Quality Standards
  Non-sterile (USP 795/1075)
  Equipment Quality/Process Validation
- Sterile Compounding USP797/Pending California Regulations Environmental Control Definition of inhalation drugs, otics, and ophthalmic Oils/suspensions
- General Compounding Proposal

# D. Next Meeting – December 1, 2004

#### Adjournment

4:00 p.m.

Meeting materials will be available on the board's Web site by September 17, 2004.