AGENDA DEPARTMENT OF HEALTH BOARD OF PHARMACY FULL BOARD MEETING

November 20, 2012

Renaissance at SeaWorld 6677 Sea Harbor Drive Orlando, FL 32821 (407) 351-5555

PLEASE TURN OFF ALL CELL PHONES, PAGERS, AND BEEPERS DURING THE MEETING. THANK YOU.

Board Members: Cynthia Griffin, PharmD, Chair, Jacksonville Albert Garcia, BPharm, MHL, Vice-Chair, Miami Michele Weizer, PharmD, Boca Raton Gavin Meshad, Consumer Member, Sarasota Jeffrey J. Mesaros, PharmD, Tampa Lorena Risch, Consumer Member, Bradenton DeAnn Mullins, BPharm, Lynn Haven Debra B. Glass, BPharm, Tallahassee Leo J. "Lee" Fallon, BPharm, PhD, The Villages <u>Board Staff:</u> Mark Whitten, Executive Director Tammy Collins, Program Operations Administrator

<u>Board Counsel:</u> David Flynn, Assistant Attorney General

Department of Health Staff: John J. Truitt, Assistant General Counsel William Miller, Assistant General Counsel

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

Tuesday, November 20, 2012 – 9:00 a.m.

TAB 1COMPOUNDING IN PHARMACIES LICENSED AND REGULATED BY
THE FLORIDA BOARD OF PHARMACY AND THE FLORIDA
DEPARTMENT OF HEALTH, (Cynthia Griffin, PharmD, Chair & Mark
Whitten, Executive Director)

- 1. Overview of Pharmacy Compounding
 - a. Chapter 465, Florida Statutes
 - b. Rule 64B16-27.700, Florida Administrative Code, Definition of Compounding
- 2. Compounding of Sterile Preparations
 - a. United States Pharmacopeia (USP) 797
 - b. Rule 64B16-27.797, Florida Administrative Code, Standards of Practice for Compounding Sterile Preparations
 - c. Rule 64B16-28.820, Florida Administrative Code, Sterile Products and Special Parenteral/Enteral Compounding

- 3. Compounding of Non-sterile Preparations
 - a. United States Pharmacopeia (USP) 795
 - b. Rule 64B16-28.450, Florida Administrative Code, Centralized Prescription Filling, Delivering and Returning
- 4. Non-resident Pharmacies

TAB 2 PHARMACY COMPOUNDING SURVEYS, (David Flynn, Assistant Attorney General)

- 1. Florida Pharmacy Compounding Survey, October 2012 Survey
- 2. Proposed Florida Mandatory Pharmacies Compounding Survey

TAB 3DOH PHARMACY INSPECTION PROCESS, (Jeane Clyne, Chief of
Investigative Services Unit)

- 1. Inspection Forms
- 2. Inspector Education and Training

TAB 4 DEPARTMENT OF HEALTH'S PUBLIC PROTECTION CONCERNS, (Cassandra Pasley, BSN, JD, Chief, Bureau of Health Care Practitioner Regulation)

1. Representative from the Department of Health

TAB 5 ADDITIONAL REFERENCE MATERIALS

- 1. Chapter 499, Florida Statutes
- 2. Federal Food, Drug, and Cosmetic Act
- 3. The Committee On Energy And Commerce Briefing Document- Hearing on "The Fungal Meningitis Outbreak: Could It Have Been Prevented?"
- 4. Massachusetts Compounding Survey
- 5. Correspondence, Florida Pharmacy Association