DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION

Drugs, Devices and Cosmetics

RULE NOS.: RULE TITLES:
61N-1.001 General Regulations; Definitions
61N-1.012 Records of Drugs, Cosmetics and Devices
61N-1.013 Prescription Drugs; Receipt, Storage and Security

PURPOSE AND EFFECT: The Division proposes the rule amendments to clarify the definitions of terms set forth in Chapter 499, F.S., and the Division’s rules; set forth the records which must be created and maintained by entities in Florida engaging in the possession of limited quantities of prescription drugs, obtained from non-Florida licensed sources, for the purpose of research and development; and set forth the storage requirements for those entities.

SUBJECT AREA TO BE ADDRESSED: Definitions, records, storage requirements.

RULEMAKING AUTHORITY: 499.003, 499.01(3), (4), (6), 499.012(12), 499.0121, 499.0122, 499.013, 499.014 FS.

LAW IMPLEMENTED: 499.028 (6), 499.003, 499.004, 499.005, 499.0054, 499.0057, 499.006, 499.007, 499.008, 499.009, 499.01, 499.012, 499.0121, 499.0122, 499.013, 499.014, 499.015, 499.023, 499.024, 499.025, 499.028, 499.03, 499.033, 499.035, 499.039, 499.04, 499.041, 499.05, 499.051, 499.052, 499.06, 499.063, 499.064, 499.066, 499.067, 499.069, 499.61, 499.62, 499.63, 499.64, 499.65, 499.66, 499.67, 499.71, 499.75 FS.

IF REQUESTED IN WRITING AND NOT DEEMED UNNECESSARY BY THE AGENCY HEAD, A RULE DEVELOPMENT WORKSHOP WILL BE NOTICED IN THE NEXT AVAILABLE FLORIDA ADMINISTRATIVE REGISTER.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE DEVELOPMENT AND A COPY OF THE PRELIMINARY DRAFT, IF AVAILABLE, IS: Dinah Greene, Operations Review Specialist, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 North Monroe Street, Suite 26A, Tallahassee, Florida 32399-1047, (850)488-1802

THE PRELIMINARY TEXT OF THE PROPOSED RULE DEVELOPMENT IS AVAILABLE AT NO CHARGE FROM THE CONTACT PERSON LISTED ABOVE.
61N-1.013 Prescription Drugs; Receipt, Storage and Security.
(1) through (2) No change.
(3)(a) through (c) No change.
(d) Facility requirements for the storage and handling of prescription drugs.
1. through 2. No change.

3. Prescription drugs obtained in "limited quantities" for research and development ("R&D") purposes under Section 499.01(3) and(4)(b), F.S. and paragraph 61N-1.001(2)(a), F.A.C., must be physically segregated from all other products intended for manufacturing, compounding, dispensing, or administration. In a manufacturer’s establishment, these drugs must also be stored and maintained in a separate and clearly designated area.

(4) through (7) No change.

Rulemaking Authority 499.0121(1), 499.05 F.S. Law Implemented 499.004, 499.006, 499.007, 499.0121, 499.028(6), 499.052 F.S.
History–New 7-8-84, Amended 1-30-85, Formerly 10D-45.535, Amended 11-26-86, 7-1-96, Formerly 10D-45.535, Amended 1-26-99, 4-17-01, 1-1-04, 1-19-06, 11-18-07, Formerly 64F-12.013, Amended ______.

NAME OF PERSON ORIGINATING PROPOSED RULE: Dinah Greene, Operations Review Specialist, Division of Drugs, Devices and Cosmetics, Department of Business and Professional Regulation, 1940 North Monroe Street, Suite 26A, Tallahassee, Florida 32399-1047; (850)488-1802

NAME OF SUPERVISOR OR PERSON WHO APPROVED THE PROPOSED RULE: Ken Lawson, Secretary, Department of Business and Professional Regulation

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: May 28, 2013

DATE THE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: May 20, 2013