VIRGINIA BOARD OF VETERINARY MEDICINE
USP AD HOC COMMITTEE
MEETING MINUTES
October 2, 2019

TIME AND PLACE:	The Board of Veterinary Medicine's (Board) United States Pharmacopeia (USP) Ad Hoc United States Pharmacopeia (USP) Committee (Committee) meeting was called to order at 12:00 p.m., at the Department of Health Professions (DHP), Perimeter Center, 9960 Mayland Drive, 2nd Floor, Board Room 1, Henrico, Virginia and Virginia-Maryland College of Veterinary Medicine, 205 Duck Pond Drive, Room 131, Blacksburg, VA 24061.
PRESIDING OFFICER:	Autumn Halsey, LVT, Committee Chair
COMMITTEE MEMBERS:	Ellen Hillyer, DVM, Board Member Jason Bollenbeck, DVM, Virginia Medical Association of Virginia (VVMA) Nathaniel Burke, DVM, VVMA Sammy Johnson, Pharmacist, Deputy Executive Director, Virginia Board of Pharmacy Maureen Perry, Pharmacist, Pharmacy Supervisor, Virginia-Maryland College of Veterinary Medicine (participated from Blacksburg, Virginia location)
OTHER MEMBERS PRESENT:	Steve Karras, DVM, Board Member (participated from Blacksburg, Virginia location)
STAFF PRESENT:	Leslie L. Knachel, Executive Director Anthony C. Morales, Licensing/Operations Manager Elaine Yeatts, Senior Policy Analyst, (Joined the meeting at 12:25p.m.) Laura Paasch, Administrative Assistant Kelly Gottschalk, Veterinary Review Coordinator
OTHERS PRESENT:	Gigi Davidson, Pharmacist, Chair, USP Compounding Expert Committee Susan Seward, VVMA Robin Schmitz, VVMA Ed Fallin, DVM, Veterinary Referral and Critical Care (VRCC) Kim Gemeinhardt, DVM, North Carolina Board of Veterinary Medicine (participated from Blacksburg, Virginia location) John Wilson, DVM, West Virginia Board of Veterinary Medicine, (participated from Blacksburg, Virginia location)
ORDERING OF AGENDA:	Ms. Knachel identified that Ms. Autumn Halsey would be handling "Public Comment."
PUBLIC COMMENT:	There was no public comment from either site.
INTRODUCTIONS:	Ms. Halsey asked Committee and Board Staff to introduce themselves.
DISCUSSION ITEMS:	**Presentation on the USP Compounding Requirements – Gigi Davidson** Ms. Davidson provided a PowerPoint presentation on the current USP Compounding Requirements, (See Attachment 1). **Compounding in Virginia Veterinary Practices**

Ms. Knachel and Ms. Yeatts provided information on the Virginia laws related to veterinary compounding and options for going forward. The Committee discussed the issue and requested that staff draft a document for the full Board's consideration of frequently asked questions (FAQs) related to USP as an educational tool. The consensus of the Committee was to take no further, other than the FAQs, until the Virginia Board of Pharmacy determines its course of action.

NEW BUSINESS: No new business was presented.

NEXT MEETING: No new meeting was scheduled at this time.

ADJOURNMENT: With all business concluded, the meeting adjourned at 2:11 p.m.

Autumn Halsey, LVT
Chair
3/5/2020
Date

Leslie L. Knachel, M.P.H
Executive Director
March 5, 2020
Date

Attachment 1

USP Compounding Standards and Veterinary Practice

Who is USP?

- Founded in 1820 by 11 physicians, nonprofit, private, independent and self-funded
- Values-driven organization focused on quality standards to protect the public's health
- More than 1,000 employees worldwide
- Headquarters in Rockville, MD near Washington, DC, NIH and FDA
- Laboratory facilities in U.S., India, China, Brazil and Ghana
- Offices in Switzerland, Ethiopia, Indonesia, the Philippines and Nigeria
- Work with more than 900 scientists, practitioners and regulators to develop standards that help protect public health
- International, recognized and globally focused
- USP Standards adopted in 140+ countries

Role of USP Quality Standards and Law

- As an independent nonprofit organization, USP has shared a close relationship and collaborative history with the FDA and states for more than a century
- USP standards are recognized in federal law
  - 1938 Federal Food, Drug, and Cosmetic Act
  - 1997 FDA Modernization Act
  - 2013 Drug Quality and Security Act
    - FDA Guidance: *Pharmacy Compounding of Human Drug Products under Section 503A of the Federal Food, Drug, and Cosmetic Act.*
    - *Draft Guidance for Industry #230: Compounding Animal Drugs*
- USP standards are also recognized in many state laws

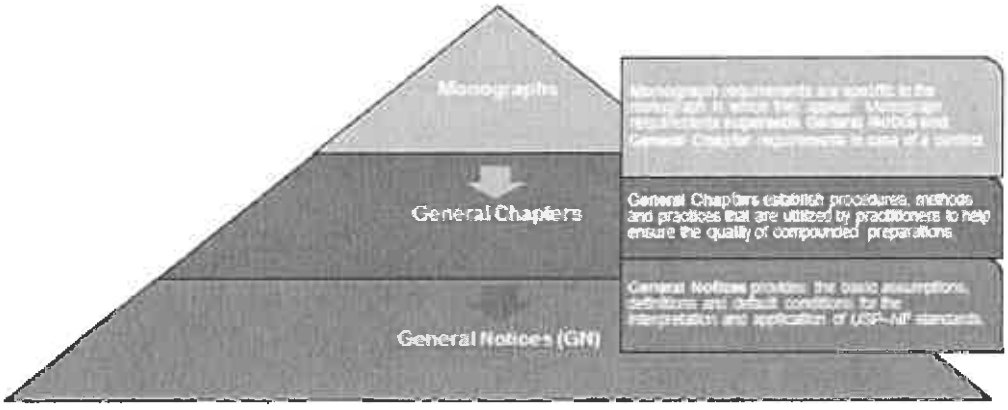
USP Council of Experts

Healthcare Quality & Safety Standard-Setting Process

USP Education

USP–NF

- USP Monographs, General Chapters and General Notices



USP Compounding Standards

USP provides 3 types of public standards for compounding

USP General Chapters

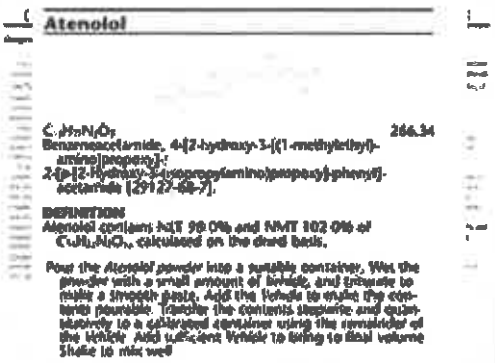
- establish practice standards to help ensure the quality of compounded preparations.

USP Compounded Preparation Monographs

- contain formulations for specific preparations for which there is no suitable commercially available product.

USP Monographs for Bulk Substances and Other Ingredients

- provide standards for identity, quality, purity, strength, packaging and labeling for bulk substances and other ingredients that may be used in compounded preparations.



Atenolol

$C_{14}H_{22}N_2O_3$ 266.34

Benzeneacetamide, 4-[2-hydroxy-3-[(1-methylethyl)-amino]propoxy]-; 2-(p-[2-Hydroxy-3-(isopropylamino)propoxy]phenyl)-acetamide [29122-68-7].

DEFINITION

Atenolol contains NLT 99.0% and NMT 102.0% of $C_{14}H_{22}N_2O_3$, calculated on the dried basis.

Pour the *Atenolol powder* into a suitable container. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents gradually and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

General Chapters Numbering and Legal Significance

General Chapters can:

- **Be state requirements and be compendially required if:**
  - Numbered below<1000> **AND are;**
  - **Made applicable through reference in *General Notices*, a monograph, or another applicable chapter numbered below<1000>**
- **Be Informational:**
  - Numbered <1000> to <1999>
- **Be specific for dietary supplements:**
  - Numbered above <2000>

Terminology

- **Must** ——— **Requirements**
- **Should** —— **Recommendations**

Compendial Applicability of USP Compounding Standards to Veterinary Practice

- FD&C Acts 1906, 1938
  - Defined a "drug" as anything listed in USP
  - Defined adulteration and misbranding as anything not complying with USP standards
- 1997 Food and Drug Modernization Act Section 503A
  - Required that compounding comply with USP standards (monographs and General Chapters)
- Statutory reference to USP Compounding Chapters (797 and 795) in DQSA
  - DQSA applies only to compounding for humans
- 797 and 795 are called out in the USP General Notices as applicable to compounding
- 797 and 795 are currently postponed due to appeals by stakeholders
- 800 will become "official" December 1, 2019

Overview of 795—Non-sterile compounding

- Scope: all persons and all places where compounding occurs
- Standards for:
  - Personnel training and competency
  - Compounding garb and hygiene
  - Compounding spaces and equipment
  - Cleaning and sanitizing
  - Documentation (SOPs, Recordkeeping, and labeling)
  - Assigning beyond-use-dates and packaging
  - Complaints, recall, and adverse events

Overview of 797—Sterile compounding

- Scope: all persons and all places where compounding occurs
- Standards for:
  - Personnel training and competency
  - Compounding garb and hygiene
  - Compounding spaces and equipment
  - Cleaning and disinfecting
  - Sterilization methods and testing
  - Documentation (SOPs. Recordkeeping, and labeling)
  - Assigning beyond-use-dates and packaging
  - Complaints, recall, and adverse events

Overview of 800—Handling Hazardous Drugs in Healthcare Settings

- Scope: all persons and all places where hazardous drugs are handled
- Standards for:
  - Types of exposure and list of hazardous drugs
  - Personnel training, competency, and responsibilities
  - Hazardous drug receipt, storage, and disposal
  - Hazardous drug engineering controls
  - Manipulation of hazardous drugs and assessment of risk
  - Deactivation, decontamination, cleaning and spill control
  - Documentation (SOPs, recordkeeping, labeling)

Impact of USP Standards on Veterinary Practice

- 797 and 795 declare **administration** to be not compounding and "out of scope"
  - E.g. drawing up a dose to give to a single patient
- 797 allows for compounding for **immediate use**
  - Mixing 3 or fewer sterile drugs to administer to a patient within 4 hours
  - Not subject to full requirements of 797
- Compounding activities that are subject to full requirements of 795 and 797:
  - Preparing compounds for more than one patient
  - Preparing compounds with beyond-use-dates of longer than 4 hours

Compliance vs. Best Practices

- 795 and 797 postponed indefinitely
  - Pharmacy practice now reverts back to "old" 795 and 797 (ca. 2008)
  - "old" 797 and 795 make no mention of 800—disconnect
  - Compounding quality is directly attributable to patient outcomes
  - Veterinarians may not associate poor drug response with compound quality
- 800 becomes official December 1, 2019
  - Hazardous drugs do not become hazardous on December 1, 2019—they have always been hazardous
- Enforcement of standards in pharmacy and medical practice–up to the states
- FDA could move in to regulate compounding if USP standards are frozen in time and states do not step up to regulate

Potential Next Steps?

- Survey stakeholders for extent of compounding in their practices
  - Compounds purchased from pharmacies
  - Compounds prepared by veterinary practice
- Evaluate use of "administration" and "immediate use" to meet practice needs
- Identify best compounding and hazardous drug handling practices for veterinarians
- Consider inspection checklist/inspector training

Discussion