Tuesday, February 17, 2015

Task Force

Agenda minutes

Meeting began 7:00 AM

- FOU
  - Letter to Utah delegates sent out Jan 12th, 2015.
  - Outsourcing pharmacies can compound FOU.
- FDA advisory board.
  - Meeting has been set (2/23-2/24). Board members have been selected. There will be a webinar or audio files available.
  - The board members chosen are a diverse group representing the various compounding fields.
- Prescriber Rx Pads/Blanks
  - DOPL was going to discuss and provide feedback but recent issues delayed their presentation. However they answered several questions. There can not be controlled substances on pad. The patient must be given the right to choose the pharmacy. This must be documented on the bland Rx pad with language reads similar to "Patient has the right to choose where to compound Rx." It is also allowable to list a few pharmacies where a Rx may be compounded.
  - There was discussion about whether controlled substances can be allowed to be printed on Rx pad. Koby thinks the DEA won't allow controlled substances regardless who makes/prints them .
  - Discussion about the indications of list of compounds. According to court case (Dean) you are allowed to put claims on rx pad.
- Sample Label/Batched Labeling
  - Nick Cox presented on this topic. See attachment.

- DOPL- If you are compounding in other states or sending compounds to other states you must be in compliance with other state(s) guidelines. Utah investigators will investigate upon request of other state agencies.

- Christine Jacobson made motion to change drafted language to pharmacy practice R156-17b section 614a section F:

  - Strike f) (vi and x)

  - i. To be revised to "a complete list of active ingredients"

  - v. To be revised to "name"

- Seconded by Jennifer Jeppsen

- Unanimous approval

- Domperidone

  - Per discussion the board was advised by Trip Hoffman and DOPL that domperidone can only be compounded under certain circumstances. It can only be used for prescribers who have IND and only for gastropareisis. It was asked that emails be sent to Trip and he will make recommendations to the board of pharmacy about what actions the task force feels DOPL should take at this time. Domperidone is currently in line to be considered by FDA for inclusion on FDA's approved compounding ingredients. USP is also in process of writing a monograph for domperidone. If either of these actions take place then it will become compliant with FDA regulations and approved compounding ingredient.

- Inspections.

  - There is a inspection list on how to prepare for inspections on DOPL website. There is a newsletter that DOPL will send out to educate pharmacies on process and how to prepare. It will also list common violations. DOPL investigators said currently they see pharmacies in violation of compounding ingredients stored on the floor. Koby updated task force on pharmacies in St George about recent inspections. One of his main concerns war regarding question 1 and 2 of inspection from which states "Are you in compliance with USP 795". No pharmacies in Utah are compliant with USP 795 because one violation results in

noncompliance. He would like to see DOPL not ask pharmacies whether they are compliant. DOPL investigators agree.

- Jacob Corsi made a motion to strike question 1 and 2 of inspection form used by DOPL investigators.
- Second by Dean Jolley
- Unanimous agreement.

- USP 800
  - Can make suggestions until 5/31/15 and there is a webinar Feb 20th.
- USP 795-797 meeting in D.C. There is possible funding for pharmacists, technicians, and interns from DOPL to attend meeting.
- Class B Concerns- inspection forms.
  - DOPL is considering revising forms.
  - Setup education meeting between DOPL and several class B pharmacies. Kavish Choudary to run point.
- Meeting adjourned 8:50

State of Utah
Utah Board of Pharmacy
Compounding Task Force

January 8, 2015

The Honorable Orrin G. Hatch
104 Hart Building
United States Senate
Washington, D.C. 20510

Re: Maintaining Utah Patient Access to Compounded Drugs

Dear Senator Hatch:

The Utah Compounding Task Force on behalf of the Utah State Board of Pharmacy would like to bring an important issue to your attention that is affecting our health care here in Utah. This issue, associated with the Drug Quality and Security Act (DQSA) HR 3204 signed into law in November 2013, is impacting our medical and pharmacy communities as well as individual patients.

As a result of the tragic events from the aftermath of the New England Compounding Center (NECC), the regulation of prescription drug compounding has been undergoing drastic changes to ensure this does not happen again. The DQSA introduces increased oversight and tighter regulation, which we applaud. Our point of contention pertains to *non-sterile* compounded products provided by a pharmacy to a practitioner's office for "office use only." Specifically, DQSA HR 3204 prohibits "for office use" compounding and delineates that any compounded drug product prepared and dispensed without a prescription for an identified individual patient is adulterated and misbranded.

The practice of *non-sterile* compounding for "office use only" occurs when a practitioner orders non-sterile compounded medications that are not commercially available, to administer to their patients in the office. It has been a common practice among compounding pharmacies for decades. These products are utilized by all practices in the medical field, but dermatological, dental and critical care sites are finding the new regulations most restrictive to their daily practices.

Some examples of *non-sterile* "for office use only" compounds that are now prohibited are topical agents such as cantharidin plus, Dinitrochlorobenzene, and trichloracetic acid solutions that dermatologists use every day; or numbing agents that contain tetracaine, lidocaine, and prilocaine used by that dentists on patients; or lidocaine, epinephrine, and tetracaine (LET) gels that critical care sites depend on for numbing and stitching wounds. These medications are often necessary to administer in critical emergency situations to better treat patients. In some cases, the prescribing practitioner may want to carefully monitor a patient after administration for potential side effects. Additionally, all too often, manufactured medications that need to be used in the office are in short supply and thus can only be compounded. To be clear, the *sterile*

products compounded by the NECC were extremely complex intrathecal corticosteroid *sterile* injections. Necessary actions to ensure appropriate safety measures were delayed until it was too late.

The *non-sterile* medications we are referring to are vastly different than the *sterile* medications produced at NECC. *Non-sterile* products such as topical creams and ointments pose minimal risk when compared to *sterile* products.

There are two main points that are problematic with this new regulation. First, as the events were unfolding with the DQSA, numerous times compounding stakeholders and several professional pharmacy organizations were told traditional compounding, which included "office use only" compounding, would not be affected and would remain under state regulation. Ultimately, this was not the case.

Second, the Utah State Board of Pharmacy and the Utah Department of Commerce, Division of Occupational and Professional Licensing (DOPL) drafted rules to address concerns regarding "office use only" compounding. After the Utah Legislature passed S.B. 77 in 2014 that allowed "office use only" compounding, Utah was prepared to implement these rules. Unfortunately, upon further inquiry of the FDA and the Utah Office of Attorney General, DOPL determined under the DQSA and the Federal Drug Cosmetic Act (FDCA), Utah compounding pharmacies are prohibited from "office use only" *sterile* and *non-sterile* compounding. As a result, DOPL proposed a rule that complied with the federal law.

Practitioners in Utah are frustrated that they are unable to obtain *non-sterile* medications that they previously could compound and have used safely for many years. DQSA has drastically changed their practice and the way they provide treatment to their patients. While the FDA does allow practitioners to obtain "for office use" medications from the 40 outsourcing facilities across the country which are regulated by the FDA, there is no such facility in Utah. Even if this were not the case, the practice of outsourcing has multiple issues which are of concern. These include outsourcing facilities that are relatively new and practitioners are not familiar with them or their standards of safety. In addition, practitioners are finding it very difficult to get necessary *non-sterile* products at outsourcing facilities, since outsourcing facilities primarily produce *sterile* products. Most importantly, there is no evidence to show improved safety with *non-sterile* medications obtained at outsourcing facilities compared to those compounded by traditional compounding pharmacies "for office use."

Not allowing "for office use" compounding also denies commerce to Utah businesses. The DQSA is denying the practitioner the right to make the best medical decisions for their patients by preventing them access to the correct medications as well as access as to the best place to receive the medications.

We have two important objectives to accomplish. First, there will be new federal legislative initiatives forthcoming in 2015 to correct this issue within the DQSA. We want to express our

concerns at this time so you are aware and informed of the desires and concerns of your Utah stakeholders.
Second, we would like to entertain any questions you may have and would be happy to meet for further discussion at your convenience, to include all stakeholders you see fit, and within a forum that would best meets your needs. **You may contact Dr. Trip Hoffman, Chair of the Utah Compounding Task Force, with any questions. Dr. Hoffman can be reached at trip@universitypharmacy.com.**

We are truly concerned about the deleterious effects of this new regulation on our State. We would like to see *non-sterile* "for office use" compounding resume in Utah early this year. We strongly believe that not only is this a safe and effective practice in the State of Utah, but to continue to deny the practice will have a significant detrimental impact on patients. We would value your help and guidance in bringing this practice back in the realms of traditional compounders in Utah and allowing our practitioners to choose the appropriate medications to best treat their patients.

Sincerely,

Utah Compounding Task Force Committee

Utah Board of Pharmacy

Drafted Language to be Added to:
Pharmacy Practice Act Rule - R156-17b
Section: 614a (Operating Standards – General Operating Standards, Class A and B Pharmacy)

(3) Facilities engaged in simple, moderate or complex non-sterile or any level of sterile compounding activities shall be required to maintain proper records and procedure manuals and establish quality control measures to ensure stability, equivalency where applicable and sterility. The following requirements shall be met:

a) shall follow USP-NF Chapter 795, compounding of non-sterile preparations, and USP-NF Chapter 797 if compounding sterile preparations;
b) may compound in anticipation of receiving prescriptions in limited amounts;
c) bulk active ingredients shall:
   i. be procured from a facility registered with the federal Food and Drug Administration; and
   ii. not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness;
d) a master worksheet sheet shall be developed and approved by a pharmacist for each batch of sterile or non-sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master worksheet sheet shall be used as the preparation worksheet sheet from which each batch is prepared and on which all documentation for that batch occurs. The master worksheet sheet shall contain at a minimum:
   i. the formula;
   ii. the components;
   iii. the compounding directions;
   iv. ~~a~~ sample label information that contains, in addition to legally required information:~~;~~
      A. generic name and quantity or concentration of each active ingredient;
      B. assigned beyond-use-date;
      C. storage conditions; and
      D. prescription or control number;
   v. evaluation and testing requirements;
   vi. sterilization methods, if applicable;
   vii. specific equipment used during preparation such as specific compounding device; and
   viii. storage requirements;
e) a preparation worksheet sheet for each batch of sterile or non-sterile pharmaceuticals shall document the following:
   i. identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;
   ii. manufacturer lot number for each component;
   iii. component manufacturer or suitable identifying number;
   iv. container specifications (e.g. syringe, pump cassette);
   v. unique lot or control number assigned to batch;
   vi. beyond use date of batch prepared products;
   vii. date of preparation;
   viii. name, initials or electronic signature of the person or persons involved in the preparation;
   ix. names, initials or electronic signature of the responsible pharmacist;
   x. end-product evaluation and testing specifications, if applicable; and
   xi. comparison of actual yield to anticipated yield, when appropriate;
~~f) the label of each batch prepared of sterile or non-sterile pharmaceuticals shall bear at a minimum:~~
   ~~i. the unique lot number assigned to the batch;~~
   ~~ii. all solution and ingredient names, amounts, strengths and concentrations, when applicable;~~
   ~~iii. quantity;~~
   ~~iv. beyond use date and time, when applicable;~~
   ~~v. appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning labels where appropriate; and~~
   vi. ~~device specific instructions, where appropriate;~~
f) preparations compounded in excess in anticipation of a prescription prior to receiving a valid prescription shall be properly labeled bearing at a minimum:
   i. a complete list of ingredients ~~or preparation name and reference or established name or distinct common~~ name;
   ii. dosage form;
   iii. strength;
   iv. preparation date;
   v. ~~name and address of compounder;~~ name of compounder
   vi. inactive ingredients;

vii. batch or lot number;
viii. assigned beyond use date, based on published data, or appropriate testing;
ix. appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning;
x. device specific instructions; and
xi. beyond use date and time, when applicable.

g) All prescription labels for compounded sterile and nonsterile medications when dispensed to the ultimate user or agent shall bear at a minimum in addition to what is required in UCA 58-17b-602:
   i. the unique lot number assigned to each batch;
   ii. beyond-use-date;
   iii. appropriate ancillary instructions, such as storage instructions or cautionary statements, including cytotoxic warning;
   iv. all active solution and active ingredient names, amounts, strengths, and concentrations unless the product is an intravenous 797 sterile compounded product, which shall bear all solution and ingredient names, amounts, strengths and concentrations, where applicable;
   v. quantity; and
   vi. "This is a compounded preparation" shall be indicated.

g) the beyond use date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in-house or contract service stability testing;
   a. sources of drug stability information shall include the following:
      i. references can be found in Trissel's "Handbook on Injectable Drugs", 17th Edition, October 31, 2012;
      ii. manufacturer recommendations; and
      iii. reliable, published research;
   b. when interpreting published drug stability information, the pharmacist shall consider all aspects of the final sterile product being prepared such as drug reservoir, drug concentration and storage conditions; and
   c. methods for establishing beyond use dates shall be documented; and

h) there shall be a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities that follows the USP-NF Chapters 795 and 797 standards.

USP 31 – NF 26 (2008)
Chapter: <1075> Good Compounding Practices
Section: Labeling

1. The compounder's preparation label should contain information required by state and federal law and accepted standards of practice. [NOTES—(a) The compounder shall use the established name or distinct common name (cannot use the trademarked name of a manufactured product). (b) The compounder cannot indicate that the compounded product is therapeutically equivalent to a manufactured product. (c) The label should state that this is a compounded preparation. (d) The compounder shall not use an NDC number assigned to another product.]
2. The compounder shall label any excess compounded products so as to reference them to the formula used, the assigned control number, and beyond-use date based on the compounder's appropriate testing, published data, or *USP–NF* standards.
3. Preparations compounded in anticipation of a prescription prior to receiving a valid prescription should not be prepared in an inordinate amount. A regularly used amount should be prepared on the basis of a history of prescriptions filled by the pharmacy. These preparations should be labeled or documentation referenced with the following:
   a. A complete list of ingredients or preparation name and reference or established name or distinct common name
   b. Dosage form
   c. Strength
   d. Preparation date
   e. Name and address of compounder
   f. Inactive ingredients
   g. Batch or lot number
   h. Assigned beyond-use date, based on published data, or appropriate testing, or *USP–NF* standards.
   Storage conditions for these preparations should be dictated by their composition and sterility, e.g., stored in a clean, dry place under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer.)
4. The compounder should examine the preparation for correct labeling after completion of the compounding process.

Per Rick Schnatz, PharmD, Manager – USP Healthcare Quality Standards and Compounding

- "Chapter <1075> was omitted from USP starting May 1, 2011. It no longer exists."
  (Telephone conversation on 2/2/15)

Excerpts from USP 38 – NF 33 (to become official on May 1, 2015)

- **Chapter: <797> Section: Introduction**
  - "Sterile compounding differs from nonsterile compounding (see **Good Compounding Practices <1075>**)..."
- **Chapter: <1160> Section: Introduction**
  - "The purpose of this chapter is to provide general information to guide and assist pharmaicsts in performing the necessary calculations when preparing or compounding any pharmaceutical article (see . . . **Good Compounding Practices <1075>**) or when simply dispensing prescriptions."
  - "See USP general chapters . . . **Good Compounding Practices <1075>** for information on specific instruments."

Per Rick Schnatz, PharmD, Manager – USP Healthcare Quality Standards and Compounding

- "I was not aware of any references to <1075> in the current or soon to be published versions of USP-NF. Any references are likely a mistake."
  (Telephone conversation on 2/2/15)

Per Rick Schnatz, PharmD, Manager – USP Healthcare Quality Standards and Compounding

- SCHNATZ: "In regards to the label for anticipatory compounds, USP offers no guidance on this. However, it doesn't differentiate between "anticipatory label" and "patient label," it just says label."
- NICK: "So the items that <795> indicate should be the 'patient label' should also be on the anticipatory label?"
- SCHNATZ: "That is one interpretation, yes."
  (Telephone conversation on 2/2/15)

Domperidone – How to Obtain

Domperidone is not currently a legally marketed human drug and it is not approved for sale in the U.S. On June 7, 2004, FDA issued a public warning that distributing any domperidone-containing products is illegal. FDA also issued an Import Alert instructing FDA field personnel to detain shipments of finished drug products and bulk ingredients containing domperidone, and refuse admission into the US. FDA took this action because of the concern about the potential serious health risks associated with the use of domperidone by lactating women to enhance breast milk production.
The risks of cardiac arrhythmias, cardiac arrest, and sudden death outweigh any potential benefit of domperidone in healthy lactating women. In addition, the concurrent use of certain commonly used drugs, such as erythromycin, could raise blood levels of domperidone and further increase the risk of serious adverse cardiac outcomes. In several countries where the oral form of domperidone is marketed, the drug's labeling specifically warns that nursing mothers should not use it. Furthermore, domperidone is excreted in breast milk, exposing a breastfeeding infant to unknown risks. However, FDA continues to recognize that there are some patients with severe gastrointestinal motility disorders that are difficult to manage with available therapy, who may benefit from domperidone and in whom domperidone's potential benefits outweigh its risks. While there are currently no pharmacies that are authorized to compound domperidone under the Expanded Access program, domperidone may be obtained under certain circumstances, as described below.

Submit an IND

Patients 12 years of age and older with certain gastrointestinal (GI) conditions may be able to receive treatment with domperidone through an expanded access investigational new drug application (IND). These conditions include gastroesophageal reflux disease with upper GI symptoms, gastroparesis, and chronic constipation. Patients who are eligible to receive domperidone have generally failed standard therapies.. Expanded access INDs facilitate access to investigational drugs (such as domperidone) for patients with serious diseases or conditions for which there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the patient's disease or condition. In addition to other applicable requirements, an IND must be in effect prior to the importation, interstate shipment, and administration of domperidone.

Contact Us

Physicians interested in submitting an expanded access IND for domperidone can obtain more information by contacting DDI (below) to request the **Domperidone Packet** which contains the required forms, instructions, and answers to most questions.
Division of Drug Information (DDI):
toll free at (855) 543-3784 or (301) 796-3400
email: druginfo@fda.hhs.gov

EQUIDONE (domperidone) Gel - Pharmacy Professionals

December 3, 2010

Dear Pharmacy Professional:

The U.S. Food and Drug Administration (FDA) recently approved EQUIDONE (domperidone) Gel for the prevention of fescue toxicosis in pregnant mares. Fescue toxicosis is associated with reproductive problems in both the mare and her foal around the time of birth. A mare at-risk for fescue toxicosis is treated with EQUIDONE Gel once daily starting 10 to 15 days before her expected due date. She may continue to be treated up to 5 days after giving birth. Please see the approval announcement at http://www.fda.gov/AnimalVeterinary/NewsEvents/ CVMUpdates/ucm235719.htm.

EQUIDONE Gel, distributed by Dechra Veterinary Products, is available in the United States as an oral gel. The gel comes in disposable 25 cc syringes that can be used for multiple doses. The strength is 110 mg domperidone per cc of gel. EQUIDONE Gel is the only FDA-approved animal drug that contains domperidone as the active ingredient. Now that EQUIDONE Gel is approved and available for veterinary use in the United States, domperidone should not be imported from other countries or compounded from bulk.

Each FDA-approved animal drug goes through a rigorous evaluation process. Before the drug is approved, it is clinically tested for safety and effectiveness in the target animal species. FDA also thoroughly inspects and evaluates the adequacy of the manufacturing process to make sure the drug's identity, strength, quality, and purity are preserved. FDA continues to monitor the drug's quality and safety after it is approved. An animal drug that is compounded from bulk drug ingredients is not FDA-approved. The safety and effectiveness of the compounded drug, as well as the adequacy of the manufacturing process, have not been evaluated.

There may be instances where you may be asked to compound domperidone for specific patients that require the drug in strengths or forms that are not offered by EQUIDONE Gel. In these limited cases, domperidone can only be legally compounded if it is done by or on the order of a licensed veterinarian within the practice of veterinary medicine, and if FDA-approved EQUIDONE Gel is used as the starting material. Additional requirements and information on legal animal drug compounding are available in Title 21, Code of Federal Regulations, Section 530.13.

August 12, 2014

From March 18, 2013, to March 22, 2013, and August 23, 2013 to September 3, 2013, U.S. Food and Drug Administration (FDA) investigators conducted inspections of your facility, The Compounding Shop, Inc., located at 4000 Park St. N, St. Petersburg, FL 33709-4034. **. Investigators also noted that your firm continues to make domperidone drug products, despite having received prior warnings regarding this practice in an Untitled Letter issued on March 17, 2005, and a second letter dated May 3, 2005. Domperidone is not the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, nor is it a component of an FDA-approved human drug product, nor does it appear on a list developed by the Secretary under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a].**

A. Compounded Drugs Under the FDCA

In addition, under the CPG, when determining whether to initiate enforcement action, FDA considered whether a firm compounded finished drugs from bulk active ingredients that were not components of FDA-approved drugs without an FDA sanctioned investigational new drug application. Because domperidone was not a component of an FDA-approved human drug, your compounded drugs containing domperidone would not qualify for the exercise of enforcement discretion set forth in the CPG. **Further, the exemptions provided by section 503A(a) did not apply to compounded drug products containing domperidone because domperidone was not the subject of an applicable USP or NF monograph, was not a component of an FDA-approved human drug under section 503A(b)(1)(A)(i) of the FDCA, and it did not appear on a list of bulk drug substances developed by the Secretary under section 503(b)(1)(A)(i)(III).**

Since FDA inspected your facility, Congress enacted and the President signed into law the Compounding Quality Act (CQA)[4], which amended FDCA section 503A by eliminating the advertising restrictions that had been the basis for conflicting judicial decisions. The CQA otherwise left section 503A intact, and so clarified that the remainder of section 503A is applicable in every federal judicial circuit, including the requirement of valid prescriptions for individually identified patients and the requirement to only compound drug products using bulk drug substances if each bulk drug substance is the subject of an applicable USP or NF monograph, is a component of an FDA-approved human drug, or appears on a list developed by the Secretary under section 503A(b)(1)(A)(i)(III). Accordingly, the drugs you compound without valid prescriptions for individually identified patients and any drug products you compound using domperidone, which is not the subject of an applicable USP or NF monograph, not a component of an FDA-approved human drug, and did not appear on a list developed by the Secretary under section 503A(b)(1)(A)(i)(III), are not entitled to the exemptions in section 503A.[5]

In addition, we remind you that there are a number of other conditions that must be satisfied to qualify for the exemptions in section 503A of the FDCA.[6]

Section 503A of the Federal Food, Drug, and Cosmetic Act

Please note: Section 503A has been amended by the Compounding Quality Act, as described in Section 106(a) of the Act, and these amendments are not reflected in the text below.

<<NOTE: 21 USC 353a.>> ``SEC. 503A. PHARMACY COMPOUNDING.

``(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding--

``(1) is by--

``(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

``(B) a licensed physician, on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

``(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

``(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--

``(i) the licensed pharmacist or licensed physician; and

``(ii)(I) such individual patient for whom the prescription order will be provided; or

``(II) the physician or other licensed practitioner who will write such prescription order.

``(b) Compounded Drug.--

``(1) Licensed pharmacist and licensed physician.--A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations that--

``(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

``(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or [[Page 111 STAT. 2329]]

``**(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);** that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and that are accompanied by valid certificates of analysis for each bulk drug substance;

7/2/2014 – Final Guidance

In the Federal Register of April 7, 1998 (63 FR 17,011), FDA invited all interested persons to nominate bulk drug substances for inclusion on the list. In the Federal Register of January 7, 1999 (64 FR 996), FDA published a proposed rule listing bulk drug substances that can be used in pharmacy compounding. In the Federal Register of December 4, 2013 (78 FR 72,841), FDA published a notice withdrawing the 1999 proposed rule and inviting all interested persons to nominate bulk drug substances for inclusion on a list of bulk drug substances that can be used for compounding under section 503A of the FD&C Act. Until a bulk drug substances list is published in the Federal Register as a final rule, human drug products should be compounded using only bulk drug substances that are components of drug

http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm183088.htm (last updated: 2/5/2010)

What is estriol and why is FDA concerned about "BHRT" drugs that contain it?

> Some compounded "BHRT" drugs contain an estrogen component called estriol. No drug containing estriol has been approved by FDA and the safety and effectiveness of estriol is unknown. Pharmacies may not compound drugs containing estriol unless they have an FDA-sanctioned investigational new drug application.

FDA announces meeting of Pharmacy Compounding Advisory Committee

[01/23/15] The U.S. Food and Drug Administration issued a notice in the Federal Register today, announcing that a meeting of the Pharmacy Compounding Advisory Committee will take place on February 23-24, 2015.

The committee provides advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). During the meeting, the committee will discuss:

- The list of bulk drug substances that may not be compounded under the exemptions provided by sections503A and 503B of the FD&C Act because the drug products or their components have been withdrawn or removed from the market because they were found to be unsafe or not effective. On July 2, 2014, FDApublished a proposed rule that would add 25 drug products to this list and modify the description of one drug product on this list to add an exception. This discussion will include the comments FDA received on the proposed rule.
- The list of bulk drug substances that may be used for compounding under the exemptions provided by section 503A of the FD&C Act. On December 4, 2013 and July 2, 2014, FDA published notices in the Federal Register soliciting nominations for this list. The committee will discuss six of the nominated substances, inviting nominators to make a short presentation supporting each drug substance nomination.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

- Written submissions may be made to the contact person on or before February 9, 2015.
- Presentations from the public will be scheduled at the following approximate times:

February 23, 2015:

- 10:15 to 10:45 a.m.
- 3:35 to 3:50 p.m.

February 24, 2015:

- 9:30 to 9:45 a.m.
- 11:45 a.m. to 12 p.m.

Those individuals interested in making formal oral presentations should notify the contact person to register to speak and to submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 12, 2015.

FDA recently announced the membership of the Pharmacy Compounding Advisory Committee, which is comprised of 14 members – 12 voting and two non-voting.

Open-Microphone Web Meeting for General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

Type of Posting	General Announcement
Posting Date	16–Jan–2015
Expert Committee	Compounding

In December 2014, the Compounding Expert Committee republished General Chapter <800> due to the nature and significance of the comments received on the original Pharmacopeial Forum (PF) proposal. The General Chapter, which was originally published in PF 40(3) [May–Jun. 2014], provides standards to protect personnel and the environment when handling hazardous drugs. The revised general chapter clarifies wording and reflects new and revised guidance documents and stakeholder input.

In an effort to answer stakeholder questions, USP will hold an open microphone web meeting on **February 20, 2015 (2:00 pm – 4:00 pm EST)** to discuss the revised General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings.

The agenda of the session will include:

- An overview of USP
- Background on the proposed General Chapter <800>
- An overview of the revised content in General Chapter <800>
- Information about how to submit public comments on the proposed general chapter.
- An opportunity for participants to ask questions about the proposed general chapter.

The proposed General Chapter <800> is **available for download**. The comment period for General Chapter <800> will end on **May 31st, 2015**.

If you would like to participate in the open microphone web meeting, please register by **5 pm on February 19, 2015**. Space may be limited, so please register as soon as possible. If you are unable to participate, the web meeting will be recorded and posted on the USP Web site.

Feb 17, 2015 Task Force Meeting Sign-In

Print Name	Affliation
Jennifer Jeppsen	Walgreens
Donelle Perez	
JACOB CORSI	ISOMERIC
Rob Smith	Rock Canyon
JASON MORRIS	SOUTH VALLEY
Ryan Johansen	Jolleys
Koby Taylor	Fusion Specialty Pharmacy
Chris Cox	Smith Rexall Drug
Jeff Russell	Rite Aid
Christine Jacobson	Wasatch Pharmacy Care
Chris Debring	DOPL
Jennifer Healey	DOPL
Sharla McIntyre	DOPL
Camille Farley	DOPL
Nick Cox	U of U COP
Kavish Chowdary	UOU clinics

BRIEFING

〈800〉 Hazardous Drugs—Handling in Healthcare Settings, *PF* 40(3) [May–Jun. 2013]. Based on the public comments received for the proposed 〈800〉 in *PF* 40(3), the USP Compounding Expert Committee has developed a revised chapter. This chapter has been created to identify the requirements for receipt, storage, compounding, dispensing, and administration of hazardous drugs (HDs) to protect the patient, healthcare personnel, and environment. Facility requirements that differ from *Pharmaceutical Compounding—Sterile Preparations* 〈797〉 and this chapter will be harmonized through an upcoming revision of 〈797〉, which will include the following:

- Elimination of the current allowance in 〈797〉 for facilities that prepare a low volume of HDs that permits placement of a Biological Safety Cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI) in a non-negative pressure room. All HD compounding must be done in a separate area designated for HD compounding.
- Addition of an allowance in 〈800〉 for a Containment Segregated Compounding Area (C-SCA), a separate, negative pressure room with at least 12 air changes per hour (ACPH) for use when compounding HDs. Low- and medium-risk HD compounded sterile preparation (CSP) may be prepared in a BSC or compounding aseptic containment isolator (CACI) located in a C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours.

Major changes from the proposal of 〈800〉 in *PF* 40(3) include:

- Clarified wording in many sections.
- Removed statement concerning no acceptable level of HDs.
- Revised section on list of HDs, to allow entities to perform an assessment of risk for non-antineoplastic drugs and final dosage forms to determine alternative containment strategies and/or work practices.
- Clarified that HDs may be unpacked in either a neutral/normal or negative pressure area.
- Allowance for either external venting or redundant high-efficiency particulate air (HEPA) filtration of containment primary engineering controls (C-PECs) used for nonsterile compounding.

The proposed chapter is posted online at www.usp.org/usp-nf/notices/general-chapter-hazardous-drugs-handling-healthcare-settings with line numbers. Please provide the line numbers corresponding to your comments when submitting comments to *CompoundingSL@usp.org*.

(CMP: J. Sun.) Correspondence Number—C151881

Add the following:

‹800› HAZARDOUS DRUGS—HANDLING IN HEALTHCARE SETTINGS

1. INTRODUCTION AND SCOPE

This chapter describes practice and quality standards for handling hazardous drugs (HDs) to promote patient safety, worker safety, and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.

This chapter applies to all healthcare personnel who handle HD preparations and all entities which store, prepare, transport, or administer HDs (e.g., pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices). Personnel who may potentially be exposed to HDs include, but are not limited to: pharmacists, pharmacy technicians, nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians.

Entities that handle HDs must incorporate the standards in this chapter into their occupational safety plan. The entity's health and safety management system must, at a minimum, include:

- Engineering controls
- Competent personnel
- Safe work practices
- Proper use of appropriate Personal Protective Equipment (PPE)
- Policies for HD waste segregation and disposal

The chapter is organized into the following main sections:

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling Hazardous Drugs
5. Facilities
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, and Transport
12. Dispensing Final Dosage Forms
13. Compounding