Committee on Pharmacopeia
Monday, January 27, 2014, 12:00 noon

Call In: 1-800-487-5636
Code: 184625

Agenda


1. Welcome and Introductions (Sally Schwarz)

2. Pharmacy Compounding vs. manufacturing issues: overview of ongoing regulatory issues. Discuss the involvement of SNMMI regarding the nuclear pharmacies issues and the technologist issues (e.g. Direct Supervision). (Steve Dragotakes/Sue Bunning)

   • President recently signed Pharmacy Compounding legislation into law. The law puts us in a no-man’s land. FDA has signaled that they are willing to work with us on guidance document, but they need to guide us. We have been asked to give input with CORAR, whose document we will be using as a base, and CORAR will present to FDA. We will submit our own document if the relationship is not mutual and changes.

   • Potential changes to the document: “Direct” supervision should be struck from the document. Compounded “by” or “under the supervision of” is better. It is not compounding, so it should NOT be listed. A new item #10 should be added: The compounding pharmaceutical is not on the FDA’s list for drug compounding, which is parallel to what is in 5.3A.

      o Sue Bunning: We have a task force working on the comments for these changes. In #7, the FDA put an arbitrary number of 20%. Pharmacies in New York and New Jersey are concerned that they are not going to be able to conduct business.

      o Dennis Swanson agrees. We need to define it more specifically as to what are minor deviations. Page 4, #2 the statements contradict each other. You can’t send compounded products and just have them sit there.

      o Sue Bunning: We are trying to think of a way to have emergency patients on the weekends to continue.

        ▪ Dennis Swanson: That is not the issue. He has no problem with that, but rather is talking about a truly compounded drug for a specific patient for a specific need. Example: compound MAA Kit. Under #6B, how current is the drug shortage list? Shortages come and go.
Rich Nickel: I have a potential list; however, sometimes it is not prompt enough. This list might affect non-PET drugs. PET drugs are regulated under 212.

Sally Schwarz: It might be well stated to exempt PET drugs under this compound.

Tim Quinton: With regards to state law requiring a name that is not exactly true—or at least in Kentucky. “But the patent’s name is,” the “is” should be changed to “maybe.”

Sue Bunning: This section took up a lot of time when Congress was debating this. There have been multiple attempts to do this. FDA really wants this name. Our attempt at being the best scenario.

Jim Ponto: If it is truly compounding, then there does need to be a patient’s name. FDA definition of compounding differs from the USP definition. As long as the definition is built into (which it is under #3) and that’s where it’s really important, then it’s a non-issue. A way to fix the state law issue is to add “And if required by state law.”

- Sue Bunning: I have a call with CORAR tomorrow. Some Task Force members will be on it as well.
- Technologist issues: proposed regulations are days away. We need to be careful in what we are saying to not put Technologists in danger. Perhaps there should be a disclaimer.

3. USP 797 Update: Discuss any updates regarding forward progress. (Jim Ponto)
   i. UltraTag RBC Kit

4. USP 823 Update: Petitioned FDA to replace Part 212 reference to USP 32 for the revised Chapter <823> or the USP 36. (Sally Schwarz)

   - Currently trying to move it forward and get it on the FDA’s radar.

Discuss the USP <1823> Informational chapter for <823>. Ad Hoc Committee headed by Sally Schwarz (Sally Schwarz)

   - Currently in the process of writing USP <1823>. Plans to move this forward within a year.

5. USP <821> Identification and Assay of Radionuclides Update: Discuss development of <1821> informational chapter—Ad Hoc Committee headed by Jim Ponto. (Jim Ponto)

   - Currently being slowly revised. If everything goes well, a draft will possibly go out at the end of the year.
6. Possible committee for housing future standards for IND? 
IND/RDRC PET drug production. (Sally Schwarz)

- This is something we talked about in June. The idea was presented to RDRC and they seemed welcome to it. The non-approved PET monograph drugs will be removed.
  - Steve Zigler: This committee published a paper in SNM, to me personally, the next step would be for someone to step in and disseminate practice standards.
    - Ron Weiner: He is open to this. He’s doing the same thing in Australia with Gallium standards.
    - Dennis Swanson: Would the community participate? Are there competitions or grant issues here that would preclude people from participating? He did not find resistance to sharing information, but he is disappointed with the quality control standards.
    - Sally Schwarz: There is more than one right way to sort this out. Nothing is written in stone about the kind of data we are providing. I certainly think we have to write a disclaimer, that it is not the only route that is available, but that it is acceptable. The available information was outdated.
- ACTION: Sally Schwarz will send out a list of compounds that we would be interested in pursuing or would be available to us. There are INDs available.

7. Adjournment

- The Committee is invited to the Government Relations Committee meeting at Palm Springs on Saturday February 8, from 12:00-1:00pm. Compounding will be discussed the last thirty minutes of the meeting.
- The Committee on Pharmacopeia adjourned at 1:14pm.