FDA CVM Meeting Talking Points: GFI #256 – 21 Jan 2020

Introduction. (SCOTT and DAVID)

- A proposal that does significantly more harm than good.
- This is similar to and no improvement on the previous draft GFI that was withdrawn in 2017.
- We believe it demonstrates a misunderstanding of clinical need and practice in veterinary medicine and compounding, as well as the realities of the marketplace.
- Grave concerns that it will result in reduced ability to care adequately for animal patients – which will lead to animal deaths – and increased cost to animal owners
- 99.3% of veterinarians report that compounding is important or very important in their practice.
- May we start by asking: What is the impetus for this draft? What problem are you trying to solve?

1. **Compounding from approved drugs results in lower quality and danger to patients** (ANTHONY)
   A. Uncertain potency (data +/- 15%)
   B. Dangerous excipients (toxic xylitol)
   C. No science that starting with approved drugs is higher quality (USP study on potency failure on methimazole suspension starting with finished tablets)
   D. FDA has other Guidance that speaks against splitting tablets without scores, in contrast to #256 (lomustine capsule and chlorambucil tablets are both hazardous drugs with narrow therapeutic margins—unsafe and imprecise to split)
   E. **96% of veterinarians report that limiting bulk APIs will have a negative impact on their practice and patients.

2. **Potential harm to animal patients, harm to people** (ANTHONY and MARCY)
   A. Unnecessary suffering and death (many veterinarians commented on this—over 130 pages of comments)
   B. Office use is important for immediate treatment (Voriconazole anti-fungal treatment needs to begin immediately—sight-threatening infection of the cornea) 95.3% of veterinarians reported that their ability to maintain office stock was important to their patients' health and medical outcomes.
   C. Importance to compliance
   D. Transfer of zoonotic disease (ringworm)
   E. Restrictions on 11 active ingredients (negative list) reported as having a negative impact by 94% of veterinarians
   F. Manufacturer backorders (no mention of compounding during shortages)
   G. Manufacturer restrictions (Zoetis)
   H. 80% of veterinarians reported that they DISAGREE that patient compliance would increase with increased FDA authority over compounding.

3. **Significantly increased costs (estimated 300%)** (MARCY)
   A. Cost of starting ingredients, especially with HH drugs
   B. Cost of extra processing
   C. Burden and cost of medical justification and pharmacy documentation
   D. Lack of insurance to cover increased costs (1% - 2%)
   E. Affordability is a life or death matter
   F. **98% of veterinarians report higher costs will have a negative impact on their practice and patients

4. **This is FDA inserting themselves into the state-licensed practices of pharmacy and veterinary medicine** (SHAWN)
   A. FDA isn't permitted access to prescription data
   B. FDA doesn't have authority to ask a prescriber to justify their medical decisions. >90% of veterinarians report this will have a negative impact.
   C. Existing state regulatory and USP quality scheme works (Many changes since 2012)
   D. Frequent Board of Pharmacy inspections, DEA inspections and voluntary NABP inspections and PCAB quality accreditation.
   E. USP-qualified inspectors
   F. Out of state registration and inspection requirements
   G. High quality bulk APIs already regulated by FDA and required by USP standards
   H. State reporting requirements (uncertain—check with RPh)

5. **FDA doesn't have authority to regulate veterinary compounding.** (JENN)
   In support of that position, the 2015 Congressional letter and appropriations asked FDA for a withdraw. FDA did withdraw in 2017, but then brought back a new draft that is remarkably similar to the earlier draft. Why?

6. **What can we learn from FDA that they are willing to share?** (DAVID LEAD QUESTIONS)
   A. Timing?
   B. How far they are willing to deviate?
   C. Not that dissimilar from 2015.
   D. Why so restrictive/different in human and animal?
      - Statement of medical need
      - Starting with finished goods 96% feel this will have a negative impact

7. **Conclusion.** (SCOTT)
   A. We cannot support this draft and will submit comments demonstrating our concerns.
   B. We hope this conversation today has been helpful to FDA in understanding our concerns and clarifying some of the reasons the draft is so problematic.
   C. We're sincerely grateful for the invitation to meet, and we look forward to welcoming FDA staffers to our EduCon event in Denver in April, where they will present and discuss further the draft GFI.