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INDUSTRY EDUCATION

Guidance for Industry #256

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Rod Haselhorst, RPh
Vice President, Compounding Support Services

Industry Update Regarding the Below Previous Blog Post (9/12/2022)

Many compounders and compounding advocacy groups have expressed concern regarding the upcoming FDA guidance on veterinary compounding. On Friday, September 9th the FDA granted a six-month extension (until April 2023) on enforcement of Veterinary Guidance for Industry ("GFI") 256. Check out our below blog post reviewing key points from GFI 256 as well as how you can nominate substances to the FDA's List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals.

Thank you to our industry partners, the Alliance for Pharmacy Compounding, the American College of Veterinary Pharmacists, the American Pharmacists Association, the National Community Pharmacists Association, and the Society of Veterinary Hospital Pharmacists for the hard work to influence the extension to the enforcement date.

GFI #256 – What You Need to Know About Animal Drug Compounding for Non-Food Producing Animals

For the past ten years, the FDA has attempted to develop enforcement policies related to animal drug compounding from bulk drug substances through the issuance of Guidance for Industry (GFI). In 2015, the FDA released GFI #230, but subsequently withdrew the guidance in 2017 due to significant push-back from the veterinary and pharmacy communities, as well as Members of Congress.

In 2019, the FDA released a new Draft GFI #256 along with an extended comment period. The FDA received thousands of comments from stakeholders expressing concerns. On April 13, 2022, the FDA released the Final GFI #256, titled “Compounding Animal Drugs from Bulk Drug Substances” (https://www.fda.gov/media/132567/download). Unfortunately, it appears that the FDA did not address many of the concerns raised by industry experts during the 2019 Draft GFI comment period. While the magnitude of the impact of GFI #256 will not be known until FDA begins to make enforcement decisions based on the guidance, GFI #256 will undoubtedly affect therapeutic options and treatment decisions made by veterinarians for their patients.

As noted in multiple stakeholder comments to the Draft GFI, the parameters by which FDA considers a patient-specific compounded drug a copy of an FDA-approved or indexed drug when compounded for non-food producing animals will potentially increase barriers and limit access to patient treatment options. Indeed, unless there is a documented difference from the prescriber that the compounded drug will produce a clinical difference relative to the FDA-approved or indexed drug, a drug compounded from bulk drug substance is a considered a copy of an FDA-approved or indexed drug when the compounded drug product (1) shares an active ingredient or active moiety as the marketed FDA-approved or indexed drug, and (2) can share the same route of administration as the marketed FDA-approved or indexed drug.

Similar to the FDA’s essentially a copy policies in the human drug realm, the FDA does not intend to question the prescriber’s clinical judgment in prescribing a compounded drug from bulk drug substances. That said, the FDA does intend to scrutinize the thoroughness of the clinical difference documentation, which must be maintained by the compounder. Pages 12-14 of the GFI provide detailed examples of the FDA’s expectations regarding this documentation. A few examples provided by the FDA of acceptable documentation include:

- Patient is allergic to any of the listed ingredient(s) in an FDA-approved or indexed drug;
- Certain ingredients within an FDA-approved or indexed drug are toxic to the patient;
- Patient requires significant or fractional dosing of the FDA-approved or indexed drug to see benefits that cannot be reasonably accomplished with the FDA-approved or indexed drug; and
- Patient cannot be safely pilled with the approved capsule.

More significantly, GFI #256 substantially restricts compounding of non-patient specific drugs for veterinarian office stock. Unlike patient-specific compounded drugs, which may be compounded from any active pharmaceutical ingredient with an USP-NF monograph, compounded drugs for office stock may not be compounded from bulk drug substances unless the bulk drug substance is specifically listed on a list maintained by FDA at https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals. This represents a substantial change in FDA enforcement policy which will limit access to necessary treatment options for veterinarians and their patients.

If a compounder or veterinarian believes that a bulk drug substance should be listed by the FDA for use in compounding for veterinarian office stock, the compounder or veterinarian should consider nominating that bulk drug substance. Pages 19-22 of GFI #256 describe the nomination process and criteria that FDA will consider when determining the clinical need for a bulk drug substance for office stock compounding. On a similar note, compounders should consider joining and interacting with the Alliance for Pharmacy Compounding, which is active in supporting bulk drug substance nominations and policy issues affecting human and animal drug compounding.

For further information or questions, please feel free to reach out to us by heading to www.fagronacademy.us!