Facing Drug Shortages Due To COVID-19? 503B Outsourcing Facilities Are Here to Help!

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Is your facility having trouble sourcing much needed commercially available drug products? You aren't alone. Many medications used in veterinary medicine have uses in humans as well, especially pain medicines such as hydromorphone and fentanyl and sedatives/anxiolytics such as midazolam. These drugs are now in short supply due to an influx of critical care COVID-19 patients at hospitals nationwide. Demand on the human side will continue to challenge the availability to the veterinary community. Even as the supply chain begins to catch up with demand, it is anticipated that wholesalers will allocate stock to human hospitals and clinics before veterinarians and veterinary clinics.

But there is hope! The FDA acknowledged the impending drug shortages and, on April 16, 2020, issued a guidance for industry addressing the problem. The guidance is entitled "Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During The COVID-19 Public Health Emergency" and it encourages 503B Outsourcing Facilities to step up and help close the gap in the supply chain.

So, why a 503B Outsourcing Facility? Well, commercially available products from traditional manufacturers are often marketed to human patients and aren't available in doses and routes of administration needed for veterinary clients. As a result, veterinarians must turn to traditional compounding facilities, also known as 503A compounding pharmacies, to fill that gap. Unfortunately, regulations are lacking to ensure the products produced by 503A pharmacies maintain the quality needed to be safe and therapeutic. Also, depending on state regulation, many 503A pharmacies may not provide compounded drug products for office use. This is where 503B Outsourcing Facilities can fill a critical need for veterinarians. These facilities must register with the FDA and operate in accordance with 21 CFR Part 210 and 211 to maintain compliance with current Good Manufacturing Practices (cGMP) just like a pharmaceutical manufacturer does. All products manufactured by a 503B Outsourcing Facility have quality built into every step of the process (such as raw material testing, equipment validation, and environmental monitoring) and are tested to ensure potency, sterility (if needed), and stability. cGMP effectively reduces variability between lots and ensures that your clients receive consistent drug therapy over time thus ensuring better clinical outcomes. 503B Outsourcing Facilities can also dispense to veterinary offices and clinics, so the medications can be maintained in stock at your facility and ready when needed.

Since the FDA guidance was released, 503B Outsourcing Facilities are ramping up production of the drugs currently in shortage. This includes hydromorphone, ketamine, fentanyl, midazolam, and others. Currently there are 76 registered outsourcing facilities in the United States, some of which specialize in veterinary medicine. To find an FDA registered 503B Outsourcing Facility visit https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities.

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