DateXXX

NameXXX

CompanyXXX or PracticeXXX

Address XXX CityXXX, STXXX ZipXXX

RE: United States Department of Justice vs AniCell Biotech, LLC

Dear XXX

You might have seen or heard that the United States Department of Justice, on behalf of the U.S. Food and Drug Administration ("FDA" or "the Agency"), has recently filed a complaint against AniCell Biotech LLC in federal district court.

In 2015, AniCell Biotech pioneered and created a novel amnion tissue allograft to be used regeneratively for animals. Quite simply, AniCell is in the recycling business. They non-invasively collect what God created all living things from and utilize it as a physical bio-scaffold to address wounds in companion animals, delivered by licensed veterinarians. Tissue-based products like demineralized bone matrix and porcine bladder products in animal health are regulated as medical devices by FDA's Center for Veterinary Medicine ("CVM"). Currently there is no regulatory language to the contrary.

When AniCell founded the company, FDA's CVM published a guidance document "Cell Based Products for Animal Use" to regulate this new category of novel products rather than establishing a formal regulation like it should have. It seeks to categorize all regenerative technologies including tissue-based products as drugs. This was despite the 21st Century Cures Act (signed into law on December 13, 2016) on the human side, established a significantly less onerous and separate pathway for tissue-based regenerative products. FDA furthers its unauthorized regulatory overreach in the complaint by stating that products without stem cells can still be drugs under the law yet fails to point to any such provision of relevant statute or regulations.

After eight years in business, 20,000+ treatments with a 94% efficacy rate and zero severe adverse events recorded, AniCell and its CEO and Founder Brandon Ames have been named in a complaint from the US DOJ seeking a permanent injunction from the marketing and sale of these products based on long-since corrected wording on AniCell's previous website, errant claims by the FDA that AniCell never responded to Agency inquiries, that AniCell never filed an Investigational New Animal Drug application ("INAD") and that AniCell never tried to resolve this issue.

To the contrary, AniCell has had several proactive conversations with the FDA regarding the allegations that our regenerative products are drugs, primarily based on how we initially referred to them on the old website. They corrected the AniCell website in 2017 to address any FDA language concerns and then led the way in science to show how these products mechanically function as a physical bio-scaffold to achieve the primary intended purpose of wound care. AniCell's regulatory attorneys repeatedly requested meetings with the FDA to discuss these issues and have been denied every time. Acknowledging that a difference exists between the regulation of cell-based and acellular tissue products AniCell filed an INAD (INAD file number I-013594) on December 3, 2021, for a cellular therapy, in an attempt to address any lingering concerns. That filing has been overlooked by FDA and is not even mentioned by DOJ in the complaint.

On the other hand, AniCell has successfully worked with the United States Department of Agriculture ("USDA") for several years on various projects. Under the federal Virus-Serum-Toxin Act of 1913, the USDA has oversight over veterinary biologics. It can be argued that there is significant support for AniCell's products being biologics falling under USDA's regulatory jurisdiction and outside FDA's legal reach. Multiple issues have plagued animal health and at the USDA's behest, AniCell has achieved positive impact by being deployed at the request of state agencies to lessen the impact of quarantine periods.

Quite simply, this is an egregious government overreach, and it will impact all aspects of the veterinary regenerative medicine industry and animal health generally going forward. AniCell did not skirt government oversight, as evidenced by the three welcomed FDA inspections of their lab, which are now relied on to prosecute them. It is also interesting to note, no other regenerative products or companies are being subjected to the same level of scrutiny; they have been made a target.

The FDA did not seek either a temporary or permanent restraining order barring the sale of AniCell's products, and there is not immediate cease and desist order in place.

As an advocate for AniCell Biotech and the advances they have helped veterinarians make in caring for animals, I request that you investigate this matter and compare the complaint to what's stated here and decide for yourself. Compare the complaints that have been filed in the past several years to this one to see if this matter rises to this level of scrutiny. I believe this is onerous at best and at worst, vicious targeting used in place of passing quality regulation.

I seek your help in applying pressure to help bring about resolution to this matter that either moves regulatory oversight to its rightful jurisdiction within the USDA Center

for Veterinary Biologics or establishes more meaningful regulation in the CVM that address these new tissue-based technologies.

Sincerely