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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

United States of America,

Plaintiff,

v.

AniCell Biotech LLC, a limited liability company; and

Brandon T. Ames, an individual,

Defendants.

No. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and this Court's inherent equitable authority, to permanently enjoin and restrain Defendants AniCell Biotech LLC,

a limited liability company, and Brandon T. Ames, an individual (collectively, "Defendants"), from violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce, new animal drugs, as defined by 21 U.S.C. § 321(v), that are adulterated within the meaning of 21 U.S.C. § 351(a)(5) because they are unsafe in that they are not the subject of any FDA approval pursuant to 21 U.S.C. § 360b, conditional approval pursuant to 21 U.S.C. § 360ccc, index listing pursuant to 21 U.S.C. § 360ccc-1, or emergency use authorization pursuant to 21 U.S.C. § 360bbb-3, and are not exempt from approval pursuant to 21 U.S.C. § 360b(j).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant AniCell Biotech LLC ("AniCell") is a limited liability company operating from 145 South 79th Avenue, Suite 9, Chandler, Arizona 85226 and 25815 South 154th Street, Gilbert, Arizona 85298 (collectively, "Defendants' Facility"), within the jurisdiction of this Court.

5. Defendant Brandon T. Ames is the founder, President, Chief Executive Officer ("CEO"), and Vice President of Sales of AniCell and is its most responsible individual. He oversees all functions of the business, including manufacturing, distribution, and marketing, along with expenditures, hiring and firing employees, testing of materials, and handling of complaints. Defendant Ames has the ultimate responsibility and authority to prevent, detect, and correct violations of the Act. Defendant Ames performs his duties at Defendants' Facility, within the jurisdiction of this Court.

6. Defendants manufacture, label, and distribute fourteen (14) products of various applications (e.g., grafts, injectable and intravenous liquids, eye drops) under the brand names EquusCell and CanisCell. The EquusCell line of products are derived from

the amniotic tissue of horses, for use in horses. The CanisCell line of products were previously derived from the amniotic tissue of dogs and now are derived from the amniotic tissue of horses, for use in dogs. Some CanisCell products are also for use in cats.

7. Defendants make claims for their products, among other places, on their website www.anicellbiotech.com and in customer-facing pamphlets. Defendants are responsible for the management and content of their website.

8. Defendants distribute their products to customers outside the state of Arizona.

DEFENDANTS UNLAWFULLY DISTRIBUTE ADULTERATED NEW ANIMAL DRUGS IN INTERSTATE COMMERCE

9. It is a violation of the Act to introduce or cause to be introduced, or deliver for introduction or cause to be delivered for introduction, into interstate commerce any drug that is adulterated. 21 U.S.C. § 331(a).

Defendants' Products Are Drugs

10. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man or other animals," 21 U.S.C. § 321(g)(1)(C).

11. The intended use of a product may be determined from the design or composition of the product or any relevant circumstances surrounding the distribution of the product, including, for example, labeling claims, advertising matter, or oral or written statements. *See* 21 C.F.R. § 201.128; *see also* Regulations Regarding "Intended Uses," 86 Fed. Reg. 41383, 41383-402 (Aug. 2, 2021).

12. Defendants' products are drugs within the meaning of the Act because Defendants intend them to (a) cure, mitigate, treat, or prevent disease in animals, such as exercise-induced pulmonary hemorrhage, laminitis (i.e., inflammation and damage of the tissue between the hoof and the underlying bone), osteoarthritis, and renal failure; and/or

(b) affect the structure or function of animals, including by regenerating and/or healing animal tissues.

13. For example, FDA collected evidence during an inspection of Defendants' Facility in 2021 showing that, in their pamphlets for pet and horse owners, Defendants say the following:

A. "AniCell's regenerative amnion products can help repair damaged tissue caused by trauma or chronic ongoing degeneration[:] Bone Fractures[,] Corneal Ulcers[,] [Exercise Induced Pulmonary Hemorrhage,] Joint Issues[,] Laminitis[,] Ligament Damage[,] Osteoarthritis[,] Superficial Wounds[,] Tendon Lesions" and "Renal Failure"

B. "Amnion contains regenerative fetal cells safely collected during live birth versus culturing aged adult cells. It includes the basic building blocks of the [extracellular matrix] such as collagens, carbohydrates, lipids, hyaluronic acid, laminin, fibronectin and other complex growth factors. These materials aid in accelerated repair with enhanced tissue quality."

14. By way of further example, FDA collected evidence between 2021 and 2022 showing that, on their website, www.anicellbiotech.com, Defendants describe their products using the following language:

A. "Extending ACTIVE life of animals with all-natural regenerative products for joints, tendons, ligaments, eyes, bones, and superficial wounds."

B. "AniCell Biotech's mission is safely preserving ACTIVE life through the development of safe and quality products that promote tissue regeneration."

C. "Heal Your Pet with AniCell Products".

15. On August 24, 2023, FDA confirmed that this language remains on Defendants' website:

A. "Extending the ACTIVE life of animals with all-natural regenerative products for joints, tendons, ligaments, eyes, bones, and superficial wounds."

B. "AniCell Biotech's mission is safely preserving ACTIVE life through the development of safe and quality products that promote tissue regeneration."

C. "Heal Your Pet with AniCell Products".

Defendants' Drugs Are New Animal Drugs

16. A drug is a "new animal drug" if it is a "drug intended for use for animals other than man . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(v).

17. The Act defines "label" as, *inter alia*, "a display of written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k), and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article," 21 U.S.C. § 321(m).

18. The Supreme Court has held that the term "accompanying" in the second clause of 21 U.S.C. § 321(m) is not restricted to labels that are on or in the article at issue and that physical attachment to the article is not necessary. *See Kordel v. United States*, 335 U.S. 345, 349-50 (1948). Defendants' claims on their website and informational pamphlets, among other sources, constitute labeling because they are part of an integrated distribution program. *See id.* at 350.

19. For a product to be deemed generally recognized as safe and effective ("GRAS/E"), within the meaning of 21 U.S.C. § 321(v), three conditions must be satisfied. First, there must be substantial evidence of its effectiveness. The Act defines "substantial evidence" as "evidence consisting of one or more adequate and well-controlled investigations . . . on the basis of which it could fairly and reasonably be concluded by . . . [qualified] experts that the drug will have the effect it purports or is represented to have . . . ." 21 U.S.C. § 360b(d)(3). Second, the investigations must be published in the scientific literature so that they are made generally available to the community of qualified experts and thereby subject to peer evaluation, criticism, and review. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973). Third, there must be a consensus among the

experts, based on those published investigations, that the product is safe and effective under the conditions prescribed, recommended, or suggested in its labeling.

20. Defendants' drugs lack substantial evidence of safety and effectiveness because there are no published adequate and well-controlled investigations to show that they are GRAS/E for any of the uses on their labeling – or for any use – and, therefore, qualified experts cannot come to a consensus opinion concerning their effectiveness.

21. Because Defendants' drugs are drugs that are not GRAS/E, they are new animal drugs.

Defendants' New Animal Drugs Are Adulterated

22. A new animal drug is adulterated under 21 U.S.C. § 351 if it is unsafe within the meaning of 21 U.S.C. § 360b.

23. A new animal drug is unsafe within the meaning of 21 U.S.C. § 360b unless it is the subject of an approved new animal drug application ("NADA") or an approved abbreviated new animal drug application ("ANADA") pursuant to 21 U.S.C. § 360b(b), a conditional approval pursuant to 21 U.S.C. § 360ccc, an index listing for use in a minor species pursuant to 21 U.S.C. § 360ccc-1, an emergency use authorization pursuant to 21 U.S.C. § 360bbb-3, or it meets the requirements for the investigational new animal drug ("INAD") exemption pursuant to 21 U.S.C. § 360b(j). *See* 21 U.S.C. § 360b(a)(1), 360b(j).

24. Defendants' drugs are not the subject of a NADA, an ANADA, a conditional approval, an index listing, or an emergency use authorization; and they do not meet the requirements for an INAD exemption.

25. Accordingly, Defendants' drugs are new animal drugs that are unsafe within the meaning of 21 U.S.C. § 360b and, therefore, adulterated within the meaning of 21 U.S.C. § 351(a)(5).

Defendants Distribute Adulterated New Animal Drugs In Interstate Commerce

26. "Interstate commerce," under 21 U.S.C. § 321(b)(1), means commerce between any state and any place outside of it. FDA collected evidence during an inspection of Defendants' Facility in 2021 showing that Defendants distribute their adulterated new

animal drugs outside the state of Arizona, such as to California, Florida, Idaho, New Jersey, Texas, Virginia, and Canada, which constitutes distribution in "interstate commerce" within the meaning of 21 U.S.C. § 321(b)(1).

27. Therefore, Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce, a new animal drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(5) because it is unsafe in that it is not the subject of any FDA approval pursuant to 21 U.S.C. § 360b, a conditional approval pursuant to 21 U.S.C. § 360ccc, index listing pursuant to 21 U.S.C. § 360ccc-1, or emergency use authorization pursuant to 21 U.S.C. § 360bbb-3, and it is not exempt from approval pursuant to 21 U.S.C. § 360b(j).

DEFENDANTS' HISTORY OF VIOLATING THE ACT AND IGNORING FDA'S PRIOR WARNINGS

28. FDA issued a Warning Letter to Defendants, dated July 3, 2018, informing them that they were violating the Act by distributing adulterated new animal drugs in interstate commerce. The Warning Letter cited examples of claims in Defendants' product labeling (webpages on www.anicellbiotech.com) that establish that the intended use of their products is to mitigate, treat, or prevent diseases in animals, making the products drugs under the Act. The Warning Letter also stated that Defendants' drugs were new animal drugs in that they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. The Warning Letter went on to explain that Defendants' drugs were unsafe within the meaning of the Act because they were not the subject of an approved NADA, a conditional approval, or an index listing for use in a minor species. Accordingly, the Warning Letter concluded, Defendants' products were adulterated under the Act. The Warning Letter also instructed Defendants to notify FDA of the steps that Defendants have taken to bring themselves into compliance with the law; reminded Defendants that it was their responsibility to ensure that their products were in compliance with the Act and stated

that the letter was not intended to be an all-inclusive review of Defendants' products; and informed Defendants that "[f]ailure to promptly correct the violations . . . may result in enforcement action without further notice . . . [to include] seizure . . . and/or injunction."

29. By letter dated August 22, 2018, Defendants responded to the Warning Letter, stating that their products are devices and not new animal drugs. Specifically, they stated that they "do not seek to make claims on [the] products that would qualify them as new animal drugs." Defendants also informed FDA that they had made modifications to the language on their website and drafted a standard operating procedure ("SOP") for the purpose of "reviewing Marketing and Promotion content for compliance with FDA regulations."

30. FDA reviewed Defendants' response to the Warning Letter and responded by letter dated December 20, 2018. In that letter, FDA pointed to material still available on Defendants' website and social media sites that demonstrated that Defendants' products are intended to treat disease in animals. FDA thus told Defendants that their "response does not fully address [FDA's] concerns and, accordingly, your products are still considered drugs . . . [and] are also unsafe under [the Act] and adulterated." FDA also explained that Defendants' products "do not meet the definition of 'device'" under the Act because devices do "not achieve [their] primary intended purposes through chemical action within or on the body," pursuant to 21 U.S.C. § 321(h). Rather, FDA explained, the concentrated growth factors and extracellular matrix ("ECM") that Defendants claimed their products contained interact chemically to cause their effects, excluding the products from the device definition. FDA reminded Defendants that the agency had informed them that their products were regulated as new animal drugs during FDA's first meeting with Defendants in 2016 and had at that time referred Defendants to FDA's Guidance For Industry ("GFI") 218 – Cell-Based Products for Animal Use – for further information. FDA concluded its December 2018 letter by stating that "[f]ailure to promptly correct these violations may result in legal action without further notice, including without limitation, seizure and injunction."

31. Prior to the 2018 Warning Letter, FDA had informed Defendants twice that Defendants' products were new animal drugs that needed approval to be legally marketed – first at a February 2016 meeting with FDA that Defendants requested on the topic of "a development plan and advice for obtaining approval for development" of their EquusCell and CanisCell products at the time and, second, during a subsequent inspection of Defendants by FDA in September 2017. During the February 2016 meeting, FDA explained that Defendants' products are new animal drugs that require FDA approval. FDA also explained the new animal drug approval process in detail and recommended to Defendants that they begin the approval process by opening an INAD file with FDA for an initial product followed by a meeting with FDA to discuss the development plan for that product. FDA followed up by email in March 2016 to provide information to Defendants about how to open an INAD file, request a fee waiver, and learn more about the new animal drug approval process. Then, in September 2017, FDA inspected Defendants' Facility and found that Defendants were still unlawfully distributing their unapproved new animal drugs in interstate commerce. At the time, Defendants asserted that their products were devices despite FDA's prior statement that Defendants' products were new animal drugs. To date, Defendants have not opened an INAD file for any of their currently marketed EquusCell or CanisCell products.

32. In November 2019, following FDA and Defendants' 2018 letter exchanges stemming from the Warning Letter, FDA again inspected Defendants' Facility. During that inspection, FDA discovered that Defendants were continuing to distribute their new animal drugs in interstate commerce without FDA approval. During discussion of the issue with FDA investigators, Defendant Ames stated that at least some of Defendants' products did not contain stem cells but acknowledged that Defendants were readying a new animal drug application for a product to treat Exercise Induced Pulmonary Hemorrhage (EIPH). The FDA investigators explained to Defendant Ames that products without stem cells can still be drugs within the meaning of the Act. At the close of the inspection, FDA issued a List of Inspectional Observations ("Form FDA-483") to Defendants, which documented,

among other things, the FDA investigators' observation that Defendants were "[m]arketing and s[elling] [] unapproved new animal drugs, which are not the subject of an approved new animal drug application, conditionally approved new animal drug application, or index listing" through "all dosage forms of EquusCell and CanisCell brand products." The FDA investigators also orally explained to Defendants that, upon further review by the agency, FDA may pursue legal sanctions to include seizure or injunction. To date, Defendants have not submitted a new animal drug application for the treatment of EIPH or any disease.

33. In March 2021, AniCell, by its attorney, informed FDA by telephone that, among other things, Defendants had stopped selling products containing cells, were continuing to sell products that did not contain cells, believed that the products in the latter category were devices, and planned to open an INAD file with FDA for one of their products for the treatment of sesamoiditis in horses and another INAD file for a product for the treatment of parvovirus in racoons. During the call, FDA explained that the presence or absence of cells is not determinative of whether a product is regulated as a drug and referred AniCell's counsel to FDA's 2018 Warning Letter, which applied to all of Defendants' marketed products.

34. In July 2021, FDA emailed AniCell's attorney to follow up on the March 2021 telephone call. In that email, FDA reiterated that Defendants' EquusCell and CanisCell product lines are new animal drugs that require approval, conditional approval, or index listing to be legally marketed. FDA also provided instructions regarding how to open an INAD.

35. In October 2021, having yet to receive an INAD submission from Defendants for their EquusCell and CanisCell products, FDA inspected Defendants' Facility for the third time, noting again that Defendants continue to distribute in interstate commerce unapproved new animal drugs via their EquusCell and CanisCell product lines. The FDA investigators again warned Defendants that FDA could pursue legal sanctions for failure to comply with the Act, to include seizure or injunction. During discussion with FDA investigators, Defendant Ames stated that he had no plans to submit applications to FDA

for his currently marketed products as he believed that they were not new animal drugs and were devices under the Act.

36. Finally, in November 2021, Defendants submitted a written response to the items flagged by FDA investigators during the October 2021 inspection. Defendants acknowledged that their products "facilitate[e] the healing and repair of structural damage to the body" through "a chemical action" but continued to assert that their products were devices and not new animal drugs.

37. Thus, despite over five (5) years of the FDA consistently explaining to Defendants that their products were new animal drugs, and not devices, and that new animal drugs require approval to be legally distributed in interstate commerce, Defendants have failed to correct their violations. Defendants have demonstrated that they are unwilling or unable to take adequate steps to come into compliance with the Act.

38. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce, new animal drugs, as defined by 21 U.S.C. § 321(v), that are adulterated within the meaning of 21 U.S.C. § 351(a)(5) because they are unsafe in that they are not the subject of any FDA approval pursuant to 21 U.S.C. § 360b, conditional approval pursuant to 21 U.S.C. § 360ccc, index listing pursuant to 21 U.S.C. § 360ccc-1, or emergency use authorization pursuant to 21 U.S.C. § 360bbb-3, and are not exempt from approval pursuant to 21 U.S.C. § 360b(j).

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce any drug intended for use in animals, unless and until: the drug is the subject of an approved new animal drug application or abbreviated new animal drug application pursuant to 21 U.S.C. § 360b(b); a conditional approval pursuant to 21 U.S.C. § 360ccc; an index listing pursuant to 21 U.S.C. § 360ccc-1; an emergency use authorization pursuant to 21 U.S.C. § 360bbb-3; or, an investigational new animal drug application is in effect for such drug pursuant to 21 U.S.C. § 360b(j).

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Respectfully submitted this 29th day of August, 2023,

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