IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

| | |
|---|---|
| United States of America,<br><br>Plaintiff,<br><br>vs.<br><br>AniCell Biotech LLC, et al.,<br><br>Defendants. | No. CV-23-01803-PHX-SPL<br><br>**ORDER** |

Before the Court is the parties' Joint Motion for Entry of Consent Decree of Permanent Injunction (Doc. 40). Pursuant to the parties' Stipulation,

**IT IS ORDERED t**hat the Joint Motion for Entry of Consent Decree of Permanent Injunction (Doc. 40) is **granted.**

**IT IS FURTHER ORDERED** in accordance with the parties' stipulation:

1. This court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.
2. The complaint for permanent injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("Act").
3. Defendants violated 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 U.S. Food and Drug Administration ("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, or are not exempt from approval pursuant to 21 U.S.C. § 360b(j).

4. For purposes of this decree, the following definitions shall apply:

   A. "Drug" shall have the meaning set forth in 21 U.S.C. § 321(g)(1);

   B. "New animal drug" shall have the meaning set forth in 21 U.S.C. § 321(v);

   C. "Device" shall have the meaning set forth in 21 U.S.C. § 321(h)(1); and

   D. "Current INAD Article" shall mean the article (amnion-derived powdered allograft intended for the treatment of parvovirus in juvenile racoons, referred to as Amnio M), that is the subject of investigational new animal drug file 13594.

5. Subject to paragraph 6, below, upon entry of this decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them (collectively, "Associated Persons"), who have received actual notice of this decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, manufacturing, processing, preparing, packing, repacking, labeling, relabeling, holding, or distributing any product, at or from 145 South 79th Street, Suite 9, Chandler, Arizona; 25815 South 154th Street, Gilbert, Arizona; and at or from any other location(s) at which Defendants now or in the future directly or indirectly receive, manufacture, process, prepare, pack, repack, label, relabel, hold, or distribute any product (collectively, "Defendants' Facility") unless and until:

   A. The product 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, emergency use authorization pursuant to 21 U.S.C. § 360bbb-3, or an investigational new animal drug exemption is in effect for such drug pursuant to 21 U.S.C.§ 360b(j);

B. Defendants report to FDA in writing: (i) the actions they have taken to correct the violations brought to Defendants' attention by FDA and any other source; (ii) the actions they have taken to ensure that any product that they receive, manufacture, process, prepare, pack, repack, label, relabel, hold, or distribute is not a drug unless the product is the subject of an FDA-approved new animal drug application or abbreviated new animal drug application, conditional approval, relevant index listing, emergency use authorization, or is exempt from approval; and (iii) if, subject to an investigational new animal drug exemption, the actions they have taken to ensure that each drug is distributed and used solely for the purposes of, and in compliance with, the investigational new animal drug exemption, this decree, the Act, and its implementing regulations;

C. As and when FDA deems necessary, FDA representatives inspect Defendants' Facility, including buildings, equipment, products, labeling, and all relevant records contained therein; and/or defendants' products; product labels; labeling; promotional material; websites and social media pages owned, created by, controlled by, or related to defendants including, but not limited to, www.anicellbiotech.com; and any other media over which defendants have control, to determine whether the requirements of this decree have been met and whether defendants are operating in conformity with this decree, the Act, and its implementing regulations. FDA will make the determination of whether an inspection is necessary as soon as reasonably practicable after receipt of the written report required by paragraph 5(B). Should FDA deem it necessary, FDA will begin an inspection under this paragraph as soon as reasonably practicable;

D. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate defendants' compliance with paragraph 5, at the rates set forth in paragraph 14; and

E. FDA notifies Defendants as soon as reasonably practicable in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 5(A)–(B) and (D) of this decree, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitute for written notification.

6. The following conduct is not enjoined under paragraph 5:

A. Defendants' receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, or distribution of the Current INAD Article, as long as such receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, or distribution of the Current INAD Article relates only to an investigational study conducted to provide support for a new animal drug application for the Current INAD Article; or the Current INAD Article 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, or emergency use authorization pursuant to 21 U.S.C. § 360bbb-3; and such receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, or distribution is consistent with this decree, the Act, and its implementing regulations;

B. Defendants' receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, or distribution of devices intended solely for animals that Defendants receive, manufacture, process, prepare, pack, repack, label, relabel, hold, or distribute at the date of entry of this

decree, provided Defendants comply with the following provisions:

i. Defendants ensure that within ten business days after entry of this decree, they retain, at Defendants' expense, an independent person ("Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to review Defendants' products, product labels, labeling, promotional material, and websites and social media pages owned, created by, controlled by, or related to defendants to determine whether any product is a device. Defendants shall notify FDA in writing of the identity and qualifications of the Expert within three business days of retaining such Expert;

ii. Defendants ensure that within 30 business days after entry of this decree, the Expert conducts a comprehensive review of the products, product labels, labeling, promotional material, and websites and social media pages owned, created by, controlled by, or related to Defendants to determine whether any product Defendants receive, manufacture, process, prepare, pack, repack, label, relabel, hold, or distribute is a device;

iii. Defendants ensure that within 60 business days after entry of this decree, the Expert certifies in writing to FDA that: (a) the Expert has reviewed Defendants' products, product labels, labeling, promotional material, and websites and social media pages owned, created by, controlled by, or related to Defendants to determine whether any product Defendants receive, manufacture, process, prepare, pack, repack, label, relabel, hold, or distribute is a device; and (b) Defendants are, in the Expert's opinion, in compliance with this decree, the Act, and its implementing regulations. Defendants shall

ensure that the Expert's certification is accompanied by a detailed report of this review, which shall be submitted to FDA at the same time it is presented to Defendants, that shall include, but not be limited to (a) specific results of the Expert's review, including references to product names and copies of all materials reviewed; and (b) the Expert's determination of whether Defendants have taken steps to ensure that any device Defendants receive, manufacture, process, prepare, pack, repack, label, relabel, hold, or distribute continues to meet the Act's definition of device throughout its distribution;

iv. As and when FDA deems necessary, FDA representatives may inspect Defendants' Facility, including buildings, equipment, products, labeling, and all relevant records contained therein; and/or Defendants' products; product labels; labeling; promotional material; websites and social media pages owned, created by, controlled by, or related to Defendants including, but not limited to, www.anicellbiotech.com; and any other media over which Defendants have control, to determine whether the requirements of this decree have been met and whether Defendants are operating in conformity with this decree, the Act, and its implementing regulations;

v. Within 30 calendar days after receiving an invoice for payment, which shall be sent to brandon@anicellbiotech.com, Defendants reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with paragraph 6(B), at the rates set forth in paragraph 14; and

vi. Following receipt of the Expert's certification pursuant to paragraph 6(B)(iii), FDA will notify Defendants in writing if Defendants appear

to not be in compliance with the requirements set forth in paragraph 6(B) of this decree, including the requirement that the products are devices under the Act ("Non-compliance Notice"). Such Non-compliance Notice will provide Defendants with a written explanation of the basis for that conclusion. If FDA determines that Defendants have not satisfied the criteria under paragraph 6(B) with respect to some or all products, FDA's Non-compliance Notice will identify the specific products it determines are not in compliance, and Defendants are thereby subject to paragraph 5 with respect to those products that are not in compliance;

C. Defendants' receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, or distribution of any device intended solely for animals that Defendants did not receive, manufacture, process, prepare, pack, repack, label, relabel, hold, or distribute as of the date of entry of this decree, provided that: (i) it was not received, manufactured, processed, prepared, packed, repacked, labeled, relabeled, held, or distributed prior to the Expert's certification pursuant to paragraph 6(B)(iii), (ii) it was not the subject of a Non-compliance Notice issued pursuant to paragraph 6(B)(vi), and (iii) Defendants notify FDA 20 business days before introducing the device in interstate commerce for the first time; and

D. Defendants' receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, or distribution of any product in accordance with a written request by Defendants to FDA, provided that: (i) Defendants have submitted to FDA all documentation and justification for such request that FDA deems necessary; and (ii) FDA has authorized Defendants in writing to perform such activity with respect to such product.

7. Within ten business days after entry of this decree, Defendants shall provide FDA written notice specifically identifying (a) each of Defendants' products by name and

(b) which products Defendants are receiving, manufacturing, processing, preparing, packing, repacking, labeling, relabeling, holding, or distributing pursuant to the requirements of paragraph 6(B). Defendants' written notice shall also state that, under FDA's supervision (which supervision may be done by email or other means as FDA determines to be appropriate), Defendants are prepared to destroy all of their products in their possession, custody, or control, with the exception of those products Defendants identify as subject to the requirements of paragraph 6(B). Defendants' written notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall not commence or permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction. Within 15 business days after receiving written authorization from FDA to commence destruction, Defendants shall, under FDA's supervision (which supervision may be done by email or other means as FDA determines to be appropriate), complete the destruction in compliance with the FDA-authorized Destruction Plan. Defendants shall not dispose of any of their products (including components and raw and in-process materials and finished product) in a manner contrary to the provisions of the Act, any other federal law, or the laws of any state or territory, as defined in the Act, in which the products are disposed. Defendants shall bear the costs of destruction and FDA's supervision thereof at the rates set forth in paragraph 14. If FDA notifies Defendants under paragraph 6(B)(vi) that specific products are not in compliance with paragraph 6(B) of this decree, Defendants shall re-implement this paragraph with respect to such products within 15 business days after receipt of the Non-compliance Notice. Notwithstanding the above, Defendants may request FDA's authorization to exempt a product from the destruction requirements of this paragraph; Defendants must make this request in writing and must submit to FDA all documentation and justification for the request that FDA deems necessary. If FDA authorizes the request to exempt a product from destruction, the authorization will be in writing.

This paragraph does not apply to the Current INAD Article.

8. Within 15 business days after receiving FDA's written notification pursuant to paragraph 5(E) or 75 business days after entry of this decree, whichever is earlier, Defendants shall retain an independent person ("Auditor") who may be the same person as the Expert described in paragraph 6(B)(i) and is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to review Defendants' products, product labels, labeling, promotional material, and websites and social media pages owned, created by, controlled by, or related to Defendants to determine whether any product is a drug and/or device. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor within three business days of retaining such Auditor. Defendants shall ensure that the Auditor conducts audit inspections of Defendants' Facility every six months for a period of one year and then every 12 months for a period of four years. The first audit inspection shall occur no later than six months after Defendants' retention of the Auditor.

   A. At the conclusion of each audit inspection, Defendants shall ensure that the Auditor prepares a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this decree, the Act, and its implementing regulations, and identifying any deviations from such requirements ("Audit Report Observations") and recommended corrective actions, and shall provide a list of all materials reviewed, including but not limited to the products, product labels, labeling, promotional material, and websites and social media pages;

   B. Defendants shall ensure that each Audit Report contains a written certification stating that (1) the Auditor has personally reviewed all of Defendants' products, product labels, labeling, promotional material, and websites and social media pages owned, created by, controlled by, or related

to Defendants; and (2) Defendants are in compliance with the requirements of this decree, the Act, and its implementing regulations;

C. Defendants shall further ensure that, as part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations;

D. Defendants shall ensure that the Audit Reports are delivered contemporaneously to Defendants and FDA no later than 20 business days after the date the Audit Inspection is completed. Defendants shall maintain the Audit Reports in separate files at Defendants' Facility and shall promptly make the Audit Reports available to FDA upon request; and

E. If an Audit Report contains any Audit Report Observations indicating that Defendants are not in compliance with this decree, the Act, or its implementing regulations, Defendants shall, within 20 business days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. Within 40 business days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, the Auditor shall complete its review of the actions taken by Defendants to correct the Audit Report Observations. Within ten business days after completing that review, the Auditor shall report in writing contemporaneously to Defendants and FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

9. Upon entry of this decree, Defendants and all Associated Persons (as described in paragraph 5) are permanently restrained and enjoined under 21 U.S.C. § 332(a) 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, a new animal drug, as defined by 21 U.S.C. § 321(v), 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, conditional approval pursuant to 21 U.S.C. § 360ccc, relevant index listing pursuant to 21 U.S.C. § 360ccc-1, emergency use authorization pursuant to 21 U.S.C. § 360bbb-3, and is not exempt from approval pursuant to 21 U.S.C. § 360b(j); and

B. Failing to implement and continuously maintain the requirements of this decree, the Act, and its implementing regulations.

10. If, at any time after this decree has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, promotional materials, websites, or social media pages owned or controlled by Defendants, an Expert report, an Audit Report, or any other information, that Defendants have failed to comply with any provision of this decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, manufacturing, processing, preparing, packing, repacking, labeling, relabeling, holding, or distributing any products;

B. Recall, at Defendants' expense, any product that is in violation of this decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit reports or plans prepared pursuant to this decree;

D. Submit additional reports or information to FDA as requested;

E. Institute or reimplement any of the requirements set forth in this decree;

F. Issue a safety alert; and/or

G. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this decree, the Act, or its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 14.

11. The following process and procedures shall apply when FDA issues an order under paragraph 10:

A. Unless a different timeframe is specified by FDA in its order, within ten business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants also shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives;

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action;

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this court on an expedited

basis. While seeking court review, Defendants shall continue to diligently implement and comply with FDA's order unless and until the court stays, reverses, vacates, or modifies FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 23 of this decree;

D. The process and procedures set forth in paragraphs 11(A)–(C) shall not apply to any order issued pursuant to paragraph 10 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this court for relief while they implement FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 23;

E. Any cessation of operations or other action described in paragraph 10 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this decree, the Act, and its implementing regulations, and that Defendants may resume operations.

12. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' Facility and, without prior notice, take other measures necessary to monitor and ensure continuing compliance with the terms of this decree, the Act, and its implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' Facility including, but not limited to, all buildings, equipment, raw ingredients, in-process or unfinished and finished materials and products, containers, packaging material, labeling (including non-public and password-protected websites and social media pages), and other promotional material; to take photographs and make video recordings; to take samples, without charge to FDA, of raw ingredients, in-process or unfinished and finished materials and products,

containers and packaging material, labeling (including non-public and password-protected websites and social media pages), and other promotional material; and to examine and copy all records related to the receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, and distribution of Defendants' products, including components. The inspection shall be permitted upon presentation of a copy of this decree and appropriate credentials. The inspection authority granted by this decree is separate and apart from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

13. Defendants shall promptly, and no later than ten business days after any FDA request, provide any information or records to FDA regarding Defendants' labels, labeling, promotional materials, websites or social media pages, and any other media over which Defendants have control, containing claims about the intended use(s) and mechanism(s) of action of Defendants' products; as well as the receipt, manufacture, processing, preparation, packing, repacking, labeling, relabeling, holding, and distribution of Defendants' products, including components.

14. Defendants shall reimburse FDA for the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this decree, including the travel incurred by investigatory and expert personnel, at the standard rates prevailing at the time the activities are accomplished. Defendants shall make payment to FDA within 30 calendar days after receiving an electronic invoice for payment, which shall be sent to brandon@anicellbiotech.com. Defendants shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date this decree is signed by the parties, these rates are: $119.53 per hour or fraction thereof per representative for inspection, supervision, and investigative work; $142.71 per hour or fraction thereof per representative for analytical or review work; $0.70 per mile, plus tolls, for travel

expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that these standard rates are modified, these rates shall be increased or decreased without further order of the court. Defendants shall notify FDA within 15 business days if the email address at which Defendants receive electronic invoices changes.

15. Within five business days after entry of this decree, Defendants shall post a copy of this decree in a conspicuous location in a common area at Defendants' Facility and on all websites and social media pages owned, operated, or controlled by Defendants and shall ensure that this decree remains posted for as long as this decree remains in effect. Within ten business days after entry of this decree, Defendants shall provide to FDA an affidavit, signed by a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, including but not limited to the identification of the websites and social media pages on which this decree was posted.

16. Within ten business days after entry of this decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this decree. Within 15 business days after entry of this decree, Defendants shall provide to FDA an affidavit, signed by a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

17. Within ten business days after entry of this decree, Defendants shall provide a copy of this decree by personal service or certified mail (return receipt requested), or email (delivery and read receipt requested) to each and all Associated Persons. Within 20 business days after entry of this decree, Defendants shall provide to FDA an affidavit, signed by a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the

names, addresses, and positions of all Associated Persons who have received a copy of this decree, and attaching a copy of the executed certified mail return receipts and email delivery and read receipts, as applicable. Within ten business days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

18. If any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this decree, Defendants shall immediately provide a copy of this decree, by personal service or certified mail (return receipt requested), or email (delivery and read receipt requested), to such Associated Person(s). Within ten business days after the commencement of each such association, Defendants shall provide to FDA an affidavit, signed by a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and position(s) of all Associated Persons who received a copy of this decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts and email delivery and read receipts, as applicable.

19. Defendants shall notify FDA in writing at least ten business days before any change in ownership, name, or character of their business that occurs after entry of this decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure, responsibility of any individual Defendant, or identity of AniCell Biotech LLC, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this decree. Defendants shall provide a copy of this decree to any prospective successor or assign at least 20 business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten business days prior to such assignment, change in responsibility of any individual Defendant, or change

in ownership.

20. All notifications, certificates, reports, correspondence, and other communications to FDA required by the terms of this decree shall be prominently marked "Consent Decree Correspondence," shall reference this civil action by case name and civil action number, and shall be electronically sent to CVMAnimalDrugCompliance@fda.hhs.gov. FDA will notify Defendants if the email address at which FDA receives these communications changes.

21. All deadlines in this decree may be extended or shortened by mutual consent of FDA and Defendants in writing, without leave of court.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the court of any FDA decision rendered pursuant to this decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

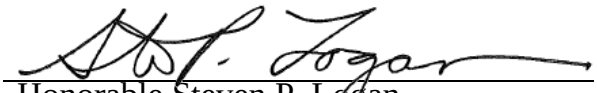
24. No sooner than 60 months after issuance of this decree, Defendants may make a written request to FDA for leave to ask this court for relief from this decree. Such written request shall be made pursuant to paragraph 20 of this decree. If, upon consideration of the written request, in FDA's judgment, Defendants have maintained a state of continuous compliance with this decree, the Act, and its implementing regulations for at least 60 months, FDA will advise Defendants that

they may request the court to grant such relief and that the United States will not oppose that request.

**IT IS FURTHER ORDERED** that any pending motions are **denied as moot** and the Clerk of the Court shall terminate this action.

**IT IS FURTHER ORDERED** that this Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this decree and for the purpose of granting such additional relief as may be necessary or appropriate.

Dated this 17th day of April, 2025.



Honorable Steven P. Logan
United States District Judge