Date of Decision: December 16, 2025

RISK ASSESSMENT SUMMARY

Veterinary Master File (VMF) 006-295

Mantel's Canine Freeze-Dried Plasma (cFDP)

(pooled allogeneic canine freeze-dried plasma)

Powder for injectable suspension

Dogs

Mantel's cFDP is indicated for the treatment of hypovolemia and control of hemorrhage in dogs.

Developed by:

Mantel Technologies

Executive Summary
Mantel's cFDP is a pooled allogeneic canine freeze-dried plasma intended for the treatment of hypovolemia and control of hemorrhage in dogs. The product is an animal cell, tissue, and cell- and tissue-based product (ACTP) that is administered intravenously (IV).

Product Characterization
FDA evaluated the product characteristics and determined the coagulation times and clotting factors used for characterization and potency are relevant to the product's function; the manufacturing process includes appropriate controls, and the risk of product contamination is appropriately mitigated; the product has similar properties to other plasma products; and the product components are characterized and do not raise new safety concerns.

Mantel's cFDP donor dogs are required to meet annual screening, be tested for disease agents, and be evaluated before each donation. Plasma from donor dogs is pooled, and the pooled plasma sample is also tested for disease agents. FDA determined these procedures appropriately mitigate the risk of disease transmission from donors to recipients, other animals, and people who are in contact with the product or the animal recipient.

Target Animal Safety
FDA reviewed scientific literature on the use of freeze-dried plasma in human and veterinary medicine. Overall, these publications describe safe historical use of freeze-dried plasma in humans and animals. Adverse events reported with the IV administration of freeze-dried plasma were infrequent and generally classified as non-serious.

The developer conducted three studies using a total of 46 dogs that received 20 mL/kg of Mantel's cFDP IV. All three studies evaluated the safety of administering the product to dogs. These studies also evaluated the safety of administering the product to dogs with different blood groups, the ability of the product to control hemorrhage in dogs with induced coagulopathy, and the ability to treat hypovolemia after blood loss. Adverse events reported included cutaneous hypersensitivity reactions and vomiting.

FDA determined that, based on the historical use of freeze-dried plasma in both people and animals, and the results of the developer's studies conducted in the target animal, there is a low likelihood of harm to animal recipients of Mantel's cFDP.

User Safety
FDA determined that the labeling for Mantel's cFDP adequately mitigates the risks to people who handle, administer, or are exposed to the product.

Environmental Risk
Plasma is found in animals, and the relevant characteristics of the plasma are unchanged in the product. The product is also unlikely to be used in a large number of animals at one time in one geographic location and is for dogs only. Therefore, FDA determined the potential environmental risk of the product is low.

Conclusions
Based on the data and information reviewed, FDA concluded that the developer properly identified and mitigated the potential risks associated with the product. FDA has no additional safety concerns. At this time, the FDA does not intend to object to the marketing of the product.

Table of Contents

I. GENERAL INFORMATION

A. File Number

VMF 006-295

B. Developer

Mantel Technologies
2601 Midpoint Dr
Suite 108
Fort Collins, Colorado, 80525

Drug Labeler Code: 086116

C. Product Definition

Pooled allogeneic canine freeze-dried plasma

D. Product Category

ACTP

E. Donor-Recipient Relationship

Allogeneic

F. Dosage Form

Powder for injectable suspension

G. How Supplied

Each kit contains 20 grams of Mantel's cFDP in a 250 mL single use bag, 250 mL sterile water for injection, and a blood administration set

H. Dispensing Status

Prescription (Rx)

I. Route of Administration

Intravenous (IV)

J. Species

Dogs

K. Indication

For the treatment of hypovolemia and control of hemorrhage in dogs

II. INTRODUCTION

FDA assessed the potential hazards and likelihood of harm associated with the use of Mantel's cFDP. The product is an allogeneic ACTP. As with any allogeneic ACTP, there are potential risks for immunogenic reactions and transmission of relevant disease agents with its use. There is also the potential for contamination or other product quality deviations to occur during manufacturing that could pose a risk to animals. FDA evaluated Mantel's cFDP product characteristics, manufacturing, donor eligibility, the available current scientific literature on freeze-dried plasma, and the studies conducted using Mantel's cFDP to determine if these risks are appropriately mitigated. FDA also evaluated these factors in comparison to other plasma products (e.g., fresh frozen plasma).

III. PRODUCT CHARACTERIZATION

A. Characterization

Mantel's cFDP is a pooled allogeneic canine freeze-dried plasma intended for the treatment of hypovolemia and control of hemorrhage in dogs.

FDA evaluated data, information, and controls supporting product identity and potency including coagulation times and clotting factors relevant to plasma function. FDA assessed the data and scientific literature in determining the acceptability of these parameters. The selected parameters are 1) general indicators of plasma characteristics and quality and 2) appropriate measures to evaluate the ability of the product to result in coagulation and hemostasis following hemorrhage and/or hypovolemia. The parameters selected are well-established for plasma products, appropriate to characterize the plasma product, and support the product's quality and intended use.

FDA evaluated information pertaining to the manufacture of Mantel's cFDP. FDA assessed batch records and other documents used to perform pooling, filling, and lyophilization. Based on these documents, FDA determined that proper handling and storage of raw materials, filling specifications, and lyophilization parameters are utilized in the manufacture of Mantel's cFDP.

FDA evaluated the methods used for reducing risk of releasing contaminated product, including the methods and acceptance criteria for sterility, mycoplasma, and endotoxin testing. FDA concluded that the manufacturing process includes appropriate controls and supports consistent manufacturing. FDA determined that a quality program is in place to support consistent manufacturing and product evaluation.

In addition to Mantel's cFDP, Mantel's cFDP kit also includes the following components:

- a blood administration set supplied with the product kit; and
- sterile water for injection supplied with the product kit to reconstitute the freeze-dried plasma.

Use of these components is well understood, and these components do not raise new safety concerns with respect to the product.

In addition, manufacture of Mantel's cFDP involves the use of an anticoagulant during blood collection. The use of the anticoagulant during blood collection does not raise new safety concerns with respect to the product. Anticoagulants are routinely used in blood collection and the amount of anticoagulant in Mantel's cFDP is similar to fresh frozen plasma products. Additionally, no adverse events related to residual anticoagulant were observed when the product was administered to dogs (see Section IV.B).

Conclusions: FDA concluded that the relevant product characteristics for Mantel's cFDP are maintained, any identified risks are mitigated, and the components that are in addition to Mantel's cFDP do not raise new safety concerns in regard to the product. In addition, FDA concluded that the manufacture of Mantel's cFDP is consistent with the recommendations in GFI #253: Current Manufacturing Practice for Animal Cells, Tissues, and Cell-, and Tissue-Based Products, including that the process includes appropriate controls, and risk of product contamination is appropriately mitigated.

B. Donor Eligibility

FDA evaluated the donor eligibility procedures for Mantel's cFDP. Allogeneic ACTPs, including freeze-dried plasma, have the potential to transmit diseases from the donor to the animal recipient, to other animals, or humans who are in contact with the product or animal recipient. Plasma from up to ten individual donor dogs are pooled. Pooling has the potential to increase risk associated with relevant disease agent transmission because one contaminated donation can affect multiple recipients. In addition, donors are at risk for exposure to relevant disease agents in their environment and from contact with other animals. FDA considered these risk factors when evaluating the donor eligibility procedures for Mantel's cFDP.

Donor screening and testing for Mantel's cFDP is performed in accordance with FDA CVM Guidance #254, "Donor Eligibility for Animal Cells, Tissues, and Cell- and Tissue-Based Products"'. Each individual donor animal is screened and/or tested for relevant disease agents listed in Table 1. Donor eligibility is determined for each donor and is based on donor screening and disease agent testing. Table 1 shows whether screening and/or testing is used to mitigate the risk of each relevant disease agent.

- Donor screening is based on historical eligibility criteria, health exams, owner questionnaires, complete blood count, serum biochemical profile, and blood typing. Eligibility criteria are related to age, breed, body weight/condition, reproductive history, previous cell-based product administration, travel history, anemia, clinical abnormalities such as vomiting, diarrhea, and respiratory disease, Von Willebrand Factor Deficiency, dog fighting and bites, skin lesions, vaccinations, and flea, tick, and Heartworm preventives. Findings from health exams, owner questionnaires, complete blood count, serum biochemical profile must not be suggestive of an infectious disease.

- Disease agent testing includes 1) donor testing at initial enrollment as a blood donor and annually and 2) testing a sample of the pooled plasma.

Individual donor screening and testing results are reviewed by Mantel personnel to ensure donor screening and testing meets requirements. A Certificate of Analysis with final product testing results will accompany each unit of Mantel's cFDP.

Table 1: Screening and testing for relevant disease agents[1]

Relevant Disease Agent	Donor Screening	Donor Testing	Pooled Plasma Testing
Anaplasma spp.	x	x	x
Babesia spp.	x	x	x
Bartonella spp.	x	x	x
Bluetongue Virus	x		
Borrelia burgdorferi	x		
Brucella canis	x	x (high risk dogs)	x
Canine Adenoviruses 1, 2	x		
Canine Coronavirus	x		
Canine Distemper Virus	x		
Canine Herpesvirus	x		
Canine Influenza Virus	x		
Canine Oral Papilloma Virus	x		
Canine Parainfluenza Virus	x		
Canine Parvovirus	x		
Dirofilaria immitis	x	x	
Ehrlichia spp.	x	x	x
Hemotropic Mycoplasma	x	x	x
Hepatozoon spp.	x		x
Leishmania spp.	x	x (high risk dogs)	x
Leptospira spp.	x		
Neorickettsia spp.	x	x	x
Neospora caninum	x		
Rabies Virus	x		
Rickettsia spp.	x		x
Swine Herpesvirus	x		
Trypanosoma cruzi	x	x (high risk dogs)	x
West Nile Virus	x		

Conclusions: Based on the donor eligibility procedures and product testing, FDA determined the risk associated with the potential for relevant disease agent transmission is appropriately mitigated.

[1] The developer performs ongoing surveillance for relevant disease agents, and updates to the list of disease agents and screening and testing procedures are made to address any newly identified risk factors.

IV. TARGET ANIMAL SAFETY

A. Scientific Literature

FDA considered the history of IV use of freeze-dried plasma in human and veterinary medicine to inform the risk profile of Mantel's cFDP. The IV administration of human freeze-dried plasma is well reported in the literature, including systematic reviews, clinical studies, and retrospective data analyses. Reported adverse events include erythema, chills, urticaria, fever, severe hypotonia including anaphylactic shock, and bronchospasm. The use of IV freeze-dried plasma is also reported in multiple veterinary species. Reported adverse events in veterinary species are similar to those known to occur after administration of fresh frozen plasma. Refer to section IX References for a list of publications reviewed.

Conclusions: Adverse events were reported with the IV administration of freeze-dried plasma. The adverse events that occurred were generally non-serious and similar to those observed with IV administration of fresh frozen plasma. FDA concluded that the scientific literature on historical use of freeze-dried plasma in human and veterinary medicine supports a low likelihood of harm to animal recipients of Mantel's cFDP.

B. Laboratory studies using Mantel's cFDP

The following three laboratory studies were conducted under one protocol, entitled "Canine Freeze Dried Plasma Safety and Efficacy Studies". All three studies utilized a non-randomized, uncontrolled, single-arm, cross-over study design.

1. Study 1: Cross-match safety study

Study Dates: August 8, 2022 through August 12, 2022

Study Design:

Objective: The goal of the study was to determine the safety of Mantel's cFDP regardless of Dog Erythrocyte Antigen (DEA) 1.1 blood type of the donors and recipients.

Study Animals: Six intact male laboratory Beagles, five to seven years of age

Experimental Design: Mantel's cFDP produced from DEA 1 positive dogs was administered IV to five DEA 1 negative dogs. Mantel's cFDP produced from DEA 1 negative dogs was administered IV to one DEA 1 positive dog. No control dogs were used in this study.

Administration: All six dogs each received Mantel's cFDP IV continuously until achieving a total dose of 20 mL/kg. The product was administered at a target rate of 4 mL/minute to 6 mL/minute, determined by visually monitoring the IV drip chamber. The average administration rates ranged from 5.7 mL/minute to 8.4 mL/minute.

Measurements and Observations: After product administration, dogs were evaluated for clinical signs of hypersensitivity reactions and C-reactive protein (CRP).

Results:

- Vomiting and cutaneous hypersensitivity reactions (including facial swelling, hives, and facial erythema) occurred in three of the six dogs. These three dogs received diphenhydramine (2 mg/kg intramuscularly or subcutaneously). These three dogs did not receive any additional medications for cutaneous hypersensitivity reactions or vomiting. Vomiting occurred in an additional fourth dog who did not have cutaneous hypersensitivity reactions and who was not treated with any medications. Signs of nausea (lip smacking) and an increased respiratory rate occurred in a fifth dog who was not treated with any medications. No other abnormal clinical signs were reported. No abnormal changes in body temperature, mucous membrane color, or heart rate occurred. Lung sounds were clear, without increased bronchovesicular sounds, during and after Mantel's cFDP administration. Pain was not evident with administration, and all dogs were calm during administration

- Twenty-four hours post-administration of Mantel's cFDP, all dogs had elevated CRP (3.104 mg/L to 25.447 mg/L), compared to the baseline for each individual (<0.003 mg/L to 3.969 mg/L). The higher CRP values (14.011 mg/L to 25.447 mg/L) occurred in the dogs that exhibited cutaneous hypersensitivity reactions, vomiting, and signs of nausea. This elevation was consistent with reported CRP levels in humans after blood transfusions, but markedly lower than CRP levels in humans with severe transfusion reactions such as Transfusion-Related Acute Lung Injury (TRALI).

2. Study 2: Coagulopathy study

Study Dates: August 25, 2022 through November 17, 2023

Study Design:

Objective: The goal of this study was to determine the safety of Mantel's cFDP and its effect on coagulation times (e.g., prothrombin time (PT) and activated partial thromboplastin time (aPTT)) after administration of warfarin.

Study Animals: Twenty-four laboratory Beagle dogs (four intact males, 19 spayed females, and one intact female), two to five years of age

Experimental Design: Prothrombin time (PT), activated partial thromboplastin time (aPTT), fibrinogen, anti-thrombin and D-dimer were measured for each dog at the start of the study. Each dog then received 6 mg warfarin by mouth daily for two days. Once a dog showed more than a 25 percent increase in PT, the dog received a total of 20 mL/kg of Mantel's cFDP IV. PT, aPTT, fibrinogen, anti-thrombin, and D-dimer measurements were repeated after half (10 mL/kg) of Mantel's cFDP was administered, after a total of 20 mL/kg of Mantel's cFDP was administered, 30 minutes after Mantel's cFDP administration was completed, and 120 minutes after Mantel's cFDP administration was completed. No control dogs were used in this study.

Administration: All 24 dogs received Mantel's cFDP IV continuously until achieving a total dose of 20 mL/kg. For the first four dogs treated in the study, the

product was administered at a target rate of 4 mL/minute to 6 mL/minute, determined by visually monitoring the IV drip chamber. The average administration rate for these four dogs ranged from 3 mL/minute to 4.6 mL/minute. For the other 20 dogs treated later in the study, the transfusion rate was set at 1 to 2 mL/minute for the first 15 to 30 minutes, then increased to a rate of 3 to 4 mL/minute. The rate of these transfusions was controlled via peristaltic IV infusion pumps.

Measurements and Observations: PT, aPTT, fibrinogen, anti-thrombin, and D-dimer were measured as described above in the “Experimental Design” section. Dogs were also monitored for CRP and hypersensitivity reactions.

Results:

- Prior to warfarin treatment, PT was within a physiological normal range (7.3 to 8.8 seconds with an average of 7.8 seconds). After warfarin and prior to product administration, PT was indicative of a coagulopathic state (19.7 to 24.7 seconds with an average of 20.3 seconds). PT values returned to normal after product administration and continued to be within a normal physiological range 120 minutes post-product administration (9.8 to 10.8 seconds with an average of 9.8 seconds).

- Prior to warfarin treatment, aPTT was within a physiological normal range (11.2 to 13.5 seconds with an average of 12.5 seconds). After warfarin and prior to product administration, aPTT was prolonged (14.8 to 18.9 seconds with an average of 16.5 seconds). aPTT values were normal after product administration and continued to be within a normal physiological range 120 minutes post-product administration (12.6 to 16.9 seconds with an average of 15 seconds).

- Fibrinogen did not have clinically significant changes in response to administration of Mantel’s cFDP

- Anti-thrombin and D-dimer did not have clinically significant changes in response to administration of Mantel’s cFDP.

- Vomiting occurred in 11 dogs (45.8%), and cutaneous hypersensitivity reactions occurred in 11 dogs (45.8%). Two dogs had both vomiting and cutaneous hypersensitivity reactions (8.3%). All dogs with cutaneous hypersensitivity reactions received diphenhydramine (2 mg/kg intramuscularly or subcutaneously). Of the dogs that vomited, one dog did not receive any medication and ten dogs only received 2 mg/kg diphenhydramine. No other adverse events were reported.

- Prior to warfarin administration, CRP values were less than 5 mg/L, except for one dog who had a CRP value of 6.3 mg/L. 24 hours post-administration of Mantel’s cFDP, CRP values ranged from less than 5 mg/L to 45.1 mg/L. The same dog that had the baseline CRP of 6.3 mg/L had the post-

administration CRP value of 45.1 mg/L. All other dogs had post-administration CRP levels below 25.7 mg/L.

3. **Study 3: Hypovolemia study**

Study Dates: August 15, 2022 through February 23, 2024

Study Design:

Objective: The goal of this study was to determine the safety of Mantel's cFDP and its effect on perfusion parameters after induction of hemorrhagic shock by controlled blood loss.

Study Animals: Sixteen laboratory Beagle dogs (four intact males, 11 spayed females, and one intact female), two to seven years of age

Experimental Design: Hypovolemic shock was induced by collecting blood from the jugular veins of all study dogs. Blood was collected from the jugular vein until the mean arterial pressure reached 60 mmHg. After dogs had a mean arterial pressure of 60 mmHg (+/- 10%) for 15 minutes, 20 mL/kg Mantel's cFDP was administered IV. Perfusion parameters were measured as described in "Measurements and Observations" section below. No control dogs were in this study.

Administration: All 16 dogs received Mantel's cFDP IV continuously until achieving a total dose of 20 mL/kg. For the first four dogs treated in the study, the product was administered at a target rate of 4 mL/minute to 6 mL/minute, determined by visually monitoring the IV drip chamber. The average administration rates for these four dogs ranged from 7 mL/minute to 9 mL/minute. For the other 20 dogs treated later in the study, the transfusion rate was set at 1 to 2 mL/minute for the first 15 to 30 minutes, then increased to a rate of 3 to 4 mL/minute. The rate of these transfusions was controlled via peristaltic IV infusion pumps.

Measurements and Observations: Perfusion parameters were measured 1) at baseline, 2) after blood collection to a hypovolemic state, 3) after administration of half (10 mL/kg) of Mantel's cFDP, and 4) after a total of 20 mL/kg of Mantel's cFDP was administered. Perfusion parameters included:

- Mean arterial pressure
- Systolic blood pressure
- Central venous pressure
- Caudal vena cava to Aorta ratio
- Left ventricular diameter
- Central venous oxygen saturation
- Venous to arterial CO_2 gap
- Base deficit (decrease in actual base excess)
- Lactate

Dogs were also monitored for increases in CRP and hypersensitivity reactions.

Results:

- Ten dogs (62.5%) had cutaneous hypersensitivity reactions. No vomiting or other reactions were reported. The cutaneous hypersensitivity reactions resolved after diphenhydramine treatment in all but one dog. That dog had persistent facial swelling 60 minutes after diphenhydramine was administered. The dog's facial swelling resolved after administration of dexamethasone.

- Prior to hypovolemia, CRP values were less than 5.1 mg/L. Twenty-four hours post-administration of Mantel's cFDP, CRP values ranged from less than 5 mg/L to 37.6 mg/L.

- After inducing shock and prior to administration of Mantel's cFDP, the average mean arterial pressure for the 16 study dogs was 60 mmHg (+/- 10%). After administration of 20 mL/kg Mantel's cFDP, the average mean arterial pressure for the 16 study dogs was 75.8 mmHg. After administration of 10 mL/kg, the average dynamic individual mean arterial pressure and systolic blood pressure values increased 53.5% (standard deviation (SD) +/- 31.8) and 67.2% (SD +/- 36.2), respectively. With Mantel's cFDP administered at 20 mL/kg, average dynamic individual mean arterial pressure and systolic blood pressure values increased further to 68.8% (SD +/- 31.8) and 67.2% (SD +/- 36.2), respectively.

- The central venous pressure started within the normal canine reference range for all dogs (up to 3 cm H2O). It decreased below zero after blood collection, indicating a hypovolemic state. It returned to the normal reference range after the administration of 10 mL/kg Mantel's cFDP. After the administration of the total dose (20 mL/kg) of Mantel's cFDP, the average central venous pressure increased above baseline to an average of 3.5 cmH2O. An above normal central venous pressure of 3 to 5 cm H_2O has been cited as an endpoint for fluid resuscitation in canines, and no clinical signs related to overperfusion were observed, suggesting that this is an appropriate initial dose.

- Administration of Mantel's cFDP returned the caudal vena cava to aorta ratio, as well the left ventricle diameter, back to the baseline values after induction of the hypovolemic state.

- A dose of 10 mL/kg Mantel's cFDP improved decreased central venous oxygen saturation, a marker of micro-perfusion through oxygen delivery and oxygen extraction in shock. However, the 20 mL/kg dose was needed to correct the venous to arterial CO2 gap. This CO2 gap is another predictor of oxygen extraction.

- Mantel's cFDP administration resulted in a resolution of increased blood lactate, indicating Mantel's cFDP supported adequate tissue oxygenation.

- Base deficits associated with induced hemorrhagic shock were corrected by administering Mantel's cFDP.

- All dogs had a decrease in calcium on blood gas analysis after Mantel's cFDP administration. Decreases in calcium (average decrease of 0.3 mmol/L) were not clinically significant, and bradycardia or arrhythmias were not identified on electrocardiogram. Tetany, seizures, or hyperactive reflexes were not observed. Hyperglycemia was not noted during Mantel's cFDP administration. These findings suggest the anti-coagulants used in the manufacture of Mantel's cFDP are low risk for causing hyperglycemia or clinically significant changes in calcium.

4. Safety conclusions across all three studies

Cutaneous hypersensitivity reactions were observed in 24 of the 46 dogs (52.2%) treated with Mantel's cFDP. The cutaneous reactions were delayed significantly after administration began, typically noted after transfusion of more than 10 mL/kg or after transfusion was completed (20 mL/kg). All cutaneous hypersensitivity reactions resolved with the administration of diphenhydramine (2 mg/kg intramuscularly or subcutaneously), except for one dog. This dog's reaction resolved after administration of diphenhydramine and dexamethasone. Vomiting occurred in 15 of the 46 treated dogs (32.6%). Of these dogs, two were not treated with any medications and 13 of these dogs were treated only with diphenhydramine. No other reactions were reported in the 46 study dogs. Cutaneous hypersensitivity reactions and vomiting have been reported in dogs receiving fresh frozen plasma and other blood transfusion products.

CRP was measured across all three studies. Normal CRP values for dogs are typically 10 to 20 mg/L, and CRP can reach up to 720 mg/L in some infectious and inflammatory conditions. At baseline in the three studies, two dogs had a CRP value greater than 5 mg/L (6.3 mg/L and 5.1 mg/L). All other dogs had a baseline CRP less than 5 mg/L. The average CRP elevation 24 hours post Mantel's cFDP transfusions was 16.6 mg/L. Five of the 46 treated dogs had CRP greater than 25 mg/L 24 hours after transfusion; four of these dogs had cutaneous hypersensitivity reactions that resolved with diphenhydramine and one dog had vomiting. The highest CRP elevation 24 hours after transfusion was 45.1 mg/L in a dog that had a cutaneous hypersensitivity reaction that resolved within 60 minutes of diphenhydramine administration.

Overall, the three studies support a low likelihood of harm to animal recipients of Mantel's cFDP. The three studies also support that Mantel's cFDP has similar risks compared to other forms of canine plasma.

V. HUMAN FOOD SAFETY

Mantel's cFDP is intended for use in dogs. Because it is not intended for use in food-producing animals, FDA did not evaluate data pertaining to residues in food (i.e., human food safety) in this risk evaluation.

Conclusions: FDA concluded there is no human food safety risk associated with Mantel's cFDP as the product is intended for use in dogs only.

VI. USER SAFETY

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Mantel's cFDP:

"For intravenous use in dogs only. Not for use in humans. Keep out of reach of children."

"Federal law restricts this drug to use by or on the order of a licensed veterinarian".

Conclusions: FDA concluded that product labeling adequately mitigates risks to Mantel's cFDP user safety.

VII. ENVIRONMENTAL RISK

FDA evaluated the potential risk to the environment from marketing Mantel's cFDP. Hazards to the environment were not identified. The product is derived from tissues endogenous to animals. The relevant characteristics of the plasma are unaltered. The product is not expected to be used in a large number of animals at one time in one geographic location, and the product is intended for use in non-food producing animals only.

Conclusions: FDA concluded the potential risk to the environment is low from the marketing of Mantel's cFDP.

VIII. AGENCY CONCLUSIONS

FDA concluded that the developer of Mantel's cFDP properly identified and appropriately mitigated the potential risks associated with the product, the product has similar properties to other plasma products, and FDA has no additional safety concerns. Although Mantel's cFDP is not approved, conditionally approved, or index listed[2], because FDA has determined the risks associated with Mantel's cFDP are appropriately mitigated, at this time the Agency does not intend to object to marketing of the product.

Marketing Status

This product may be dispensed only by or on the lawful order of a licensed veterinarian (Rx marketing status) under section 503(f)(1)(A)(i) of the FD&C Act due to the method of its use.

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[2] See sections 512, 571, and 572 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 360b, 360ccc, and 360ccc-1]

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