

**COVID-19 EMERGENCY**  
**INVESTIGATIONAL VACCINE SUPPLY AGREEMENT**

This COVID-19 Emergency Investigational Vaccine Supply Agreement (“**Agreement**”) is made effective this \_\_\_\_\_, 2022, by and among Zoetis LLC, having the address 333 Portage Street, Kalamazoo, MI 49007 (“**Zoetis**”) and **THE CITY OF SAINT PAUL, THROUGH ITS DEPARTMENT OF PARKS AND RECREATION COMO PARK ZOO**, located at 1225 Estabrook Drive, Saint Paul, MN 55103 (“**Zoo**”).

To assist in the ongoing effort to combat the COVID-19 pandemic, Zoo has requested that Zoetis supplies 6 x 10-dose vials of SARS-CoV-2 vaccine (“**Investigational Vaccine**”) to Zoo for use solely in the animals as set forth in Attachment 1 (“Animal(s)”) at the Zoo premises for emergency purposes. Subject to the terms and conditions below, Zoetis will endeavor to supply the Investigational Vaccine to Zoo for the sole purpose of facilitating Zoo’s pandemic crisis response to a COVID-19 outbreak.

Zoo acknowledges that the Investigational Vaccine is an investigational vaccine which was developed for the use in certain companion animals. Zoo further acknowledges that the use of the Investigational Vaccine in animals has not received marketing authorization. Nevertheless, Zoo has requested that Zoetis supply it with the Investigational Vaccine for use in Animal(s), to assist Zoo’s emergency medical response. Zoetis agrees to supply the Investigational Vaccine to Zoo, subject to the terms and conditions set out in this Agreement.

**I. SCOPE**

Zoetis and Zoo agree that any Investigational Vaccine supplied by Zoetis to Zoo under this Agreement will be used in compliance with instructions set forth in Attachment 2 (Instruction Sheet) by Zoo solely in Animal(s) in efforts to immunize against the COVID-19 outbreak. The Investigational Vaccine shall not be used in humans. Zoo agrees not to provide the Investigational Vaccine to any third party or allow the use of the Investigational Vaccine by any third party. Zoo agrees to submit reports to Zoetis with information pertaining to Zoo’s use of the Investigational Vaccine.

**II. WAIVER OF LIABILITY AND DISCLAIMER OF WARRANTIES**

Zoo acknowledges that the Investigational Vaccine is a veterinary investigational vaccine, without marketing authorization in any species, and that it has not been approved for use in Animal(s).

Neither Zoetis nor its affiliates have sufficient scientific information about the use and the risks of the Investigational Vaccine in Animal(s), and the Zoo acknowledges that the use of the Investigational Vaccine in Animal(s) is untested and may result in serious and life-threatening risks and injury to the patients. The Zoo further acknowledges that the use of the Investigational Vaccine in Animal(s) may result in currently unknown and unforeseeable risks and damages to the patients and that Zoetis and its affiliates can only provide suggested guidance for the use of the Investigational Vaccine in Animal(s) based on our knowledge of the Investigational Vaccine at this time. Zoo further acknowledges that 1) neither the final product nor the starting materials used to make the product have been evaluated by the USDA for purity, safety, or identity, and 2) the Center for Veterinary Biologics (CVB) is allowing use of this vaccine due to an emergency and that use is at the Zoo’s own risk.

Zoo expressly acknowledges that any warnings herein may be limited in scope and do not describe the risk arising from accidental exposures of humans (veterinarian or animal owner) to the Investigational Vaccine. Zoo expressly agrees that Zoetis is not providing and cannot provide warnings intended to describe the safety profile of the Investigational Vaccine after inadvertent administration to humans or erroneous application, whether intentional or unintentional to Animal(s), or animals not listed in Attachment 1, or humans.

Zoetis and Zoo agree that Zoetis will have no responsibility or liability whatsoever for any claim or cost (whether by Zoo or any third party) arising from, or in any way related to, the Investigational Vaccine use or misuse by the Zoo and supplied pursuant to this Agreement, including, without limitation, any claim or cost arising from, or in any way related to, any actual or alleged adverse reaction, drug interactions, defect or other failure (including failure to warn), whether known or unknown, of the Investigational Vaccine supplied under this Agreement.

**ZOO AND ZOETIS FURTHER AGREE THAT ZOETIS WILL PROVIDE INVESTIGATIONAL VACCINE SUPPLIED PURSUANT TO THIS AGREEMENT AS-IS. ZOETIS SPECIFICALLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING (WITHOUT LIMITATION) IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.**

### **III. INDEMNIFICATION**

Zoo agrees to indemnify and hold harmless Zoetis, its affiliates, and/or any of their respective employees and legal successors against any claims or losses — including (without limitation) damages, fines, penalties, and costs of defense, such as attorneys' fees and costs, direct, indirect or consequential losses, loss of profit, loss of reputation — that arise from, or in any way relate to, any Investigational Vaccine supplied pursuant to this Agreement.

Notwithstanding anything in this Agreement, in accordance with the laws of New York, United States, Zoetis and any of its affiliates involved in the supply of Investigational Vaccine, and their officers, servants, employees or agents shall benefit from immunity from civil liability for any loss or damage resulting from the use of the Investigational Vaccine supplied under this Agreement.

### **IV. LIMITATIONS OF USE. INTELLECTUAL PROPERTY**

- a. Limitation of Use. Investigational Vaccine may not be used, reverse engineered, or otherwise used, except in the administration to Animal(s) in an attempt to prevent the spread of COVID19. Investigational Vaccine may not be used in humans or animal species outside of Animal(s) without prior written authorization from Zoetis. Zoo will not transmit the Investigational Vaccine, or allow it to be transmitted, to any location other than Zoo's own facilities without obtaining Zoetis' prior written consent.
- b. Except for the administration of the vaccine permitted hereunder, it is understood that no patent right, license or option is hereby granted by Zoetis to the Zoo by this Agreement. Zoo shall use the results of its use of Investigational Vaccine hereunder for internal research purposes only and such results shall not be disclosed to any third party without Zoetis approval. Zoetis will be the owner of any improvements or modifications, even if made without consent under this Agreement, including intellectual property rights, generated by the Zoo specifically related to Investigational Vaccine and the Zoo's use under this Agreement.
- c. Zoo shall not make any presentation or publication relating to this Agreement or the Results of the Services without Zoetis's prior written consent. Notwithstanding the foregoing sentence, Zoo and Zoetis recognize the traditional freedom of all scientists to publish and present promptly the results of their research. Zoo and Zoetis also recognize that patent rights can be jeopardized by public disclosure prior to filing of suitable patent applications and that confidential information can be inadvertently disclosed. Therefore, Zoo will assure that all proposed presentations (oral or written) or publications arising from the Services under this Agreement would be submitted to Zoetis before submission to a publisher for review. Zoetis shall have been furnished copies of any proposed

manuscript intended for journal publication sixty (60) days in advance of such proposed disclosure and shall be furnished a copy of an abstract intended for presentation at a meeting or conference. Prior to the end of the review period, Zoetis may request and Zoo will comply to delete all Zoetis Confidential Information. These periods may be extended for an additional thirty (30) days when Zoetis discloses reasonable need for such extension in order for patent protection to be filed.

## **VI. REPORTING REQUIREMENTS AND ADVERSE REACTIONS**

Zoo understands that accidental human exposure is a potential risk with the administration of any vaccine to animals. Human exposure is considered a Significant Adverse Event for purposes of reporting regardless of medical severity. In case of any accidental human exposure to the experimental vaccine, immediately contact the Rocky Mountain Poison and Drug Safety (888-747-1999) for advice on the recommended emergency medical treatment. A copy of the Safety Data Sheet for the experimental vaccine will be on file with the Rocky Mountain Poison and Drug Center.

Zoo agrees to immediately report any significant adverse reactions in the dosed animals that may suggest significant safety hazards or any accidental human self-injection or needle-stick exposures to Dr. John Hardham ([john.m.hardham@zoetis.com](mailto:john.m.hardham@zoetis.com)) using Form from Attachment 3.

The United States Department of Agriculture (USDA) requires notification of any Significant Adverse Events within three (3) days of discovery. The USDA has also requested that vaccinations administered in the field be reported. Therefore, Zoo shall submit a monthly report attached hereto as Attachment 4, to Zoetis who will provide this information to the USDA.

### **READ BEFORE SIGNING**

DATED: \_\_\_\_\_

By: \_\_\_\_\_

Signature: \_\_\_\_\_

Duly Authorized Representative of  
Zoo

DATED: \_\_\_\_\_

By: \_\_\_\_\_

Signature: \_\_\_\_\_

Title: \_\_\_\_\_

Duly Authorized Representative of Zoetis LLC

## **ATTACHMENT 1**

### **Animal List**

Families to be vaccinated:

Primate

Felid

Cervid

## ATTACHMENT 2

# Experimental SARS-CoV-2 Vaccine User Guide for Zoos, Conservatories, Aquariums, Academic Institutions, and similar Organizations in the United States

### **Intended Storage, Use, Disposal, and Reporting Information**

Zoetis is developing a vaccine for against the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus and is working with the USDA towards licensure. However, this licensed vaccine will likely not be available until early 2022. Due to the extraordinary circumstances of the SARS-CoV-2 pandemic, Zoetis is being allowed to offer the experimental Coronavirus Vaccine, Subunit to Zoos, Conservatories, and similar organizations caring for Zoological animals to vaccinate susceptible animals in order to mitigate the potential impacts of SARS-CoV-2 infection. The experimental vaccine is being provided in a 10-dose, single use bottle with no preservatives. As this is an experimental vaccine, there is no established expiration date for this product.

The below information contains concise instructions for the vaccine use.

- **Storage**
  - Vaccine should be immediately refrigerated (2-8 °C) upon arrival and stored there until use
- **Use**
  - Vaccine should be administered twice, subcutaneously, as 1.0 mL doses separated by approximately 3 weeks (21 days)
  - Once the vaccine bottle seal is broken, the product should be used in its entirety within 24 hours
- **Disposal**
  - As with licensed vaccines, all unused vaccine for this experimental unlicensed product empty bottles should be disposed of by incineration
- **Reporting Requirements**
  - We are required to communicate any significant adverse events to the USDA within 3 days
  - Significant adverse events should be reported immediately using the “Adverse Event Reporting Form” provided below
    - Email: [john.m.hardham@zoetis.com](mailto:john.m.hardham@zoetis.com)
    - Phone: 269-492-5253
- **Human Exposure**
  - Human exposure is considered a Significant Adverse Event for purposes of reporting regardless of medical severity
  - In case of any accidental human exposure to the experimental vaccine, immediately contact the Rocky Mountain Poison and Drug Safety (888-747-1999) for advice on the recommended emergency medical treatment
  - A copy of the Safety Data Sheet for the experimental vaccine will be on file with the Rocky Mountain Poison and Drug Center

- The event should be reported immediately using the “Adverse Event Reporting Form” provided below
  - Email: [john.m.hardham@zoetis.com](mailto:john.m.hardham@zoetis.com)
  - Phone: 269-492-5253
- **Vaccine Shipment Temperature Tracking**
  - As a component of the package you received, you will find a Temp Tale® Ultra temperature monitor
  - Since the material you are receiving requires refrigerated storage/shipment conditions, we have included this monitor to assure the package maintained the desired 2-8°C during shipment
  - Please remove the Temp Tale® monitor and follow the enclosed instructions to download the information from the device and email the data to [mark.g.johnson@zoetis.com](mailto:mark.g.johnson@zoetis.com) and [Jennifer.laaksonen@zoetis.com](mailto:Jennifer.laaksonen@zoetis.com)
  - Should you see an “X” on the monitor screen, please do not use the included vaccine until you’ve downloaded the data and received feedback from Zoetis on whether or not the material should be used
  - If you see a “√”, the materials have stayed in the desired temperature condition during transport and you may begin using under the guidelines of this agreement

Regardless of whether you see a “√” or an “X”, please download the data and email to the stated email addresses for our records

The TempTale® Ultra temperature monitor can be programmed with custom start-up delays, measurement intervals, and time-temperature alarm settings.

#### Starting a TempTale® Ultra Monitor

- Press and hold the Start button (1 – 3 seconds) until the Sunshine icon ☀ appears in the upper left corner of the LCD screen (1). The LED (2) will blink GREEN (if LED startup option was programmed) to indicate that the monitor has started.
- The TempTale Ultra will begin to record data after the programmed start-up delay period has passed.



#### Marking an Important Event (Date Stamp)

- To mark an event while the monitor is recording, press and release the Start button. An Arrow ↑ icon will appear briefly in the top of the LCD screen and trip summary data will appear.
- Press and release the Start button to cycle through the trip summary data. Data appears in the following order:
  - Average temperature
  - Min. recorded temperature
  - Max. recorded temperature
  - Total time above high limit
  - Total time below low limit
  - Current temperature reading (This is a programmable option.)

#### Alarming

When the TempTale Ultra monitor is exposed to temperatures outside the programmed alarm limits, an X will appear at the top of the screen. The ▲ icon will display if the high alarm was triggered, the ▼ icon will display if the low alarm was triggered.

#### Stopping a TempTale Ultra Monitor

There are two ways to stop a TempTale Ultra monitor:

- Press and hold the Stop button (1 – 3 seconds) until the Stop icon ● appears in the upper right corner of the screen.
- Plug the monitor into a USB port on a computer or printer.

#### Receiving a TempTale Ultra Monitor

- Recover the TempTale Ultra monitor, then press and hold the RED Stop button (1 – 3 seconds) to manually stop the unit.
- NOTE: If the monitor is not stopped manually, the TempTale Ultra monitor will continue to record data until it is plugged into a USB port on the computer or until the programmed trip length is reached.

- Verify the "Stop" icon ● is visible on the display.

#### Retrieving TempTale Ultra Monitor Data Files

- Plug the monitor into a USB port on the computer. The LED will blink RED while the Adobe® PDF report and TTV data file are being created. When the RED LED stops blinking and displays solid GREEN, the file generation process is complete. The files are now accessible on a removable drive (Windows® 7, 8.1, and 10).

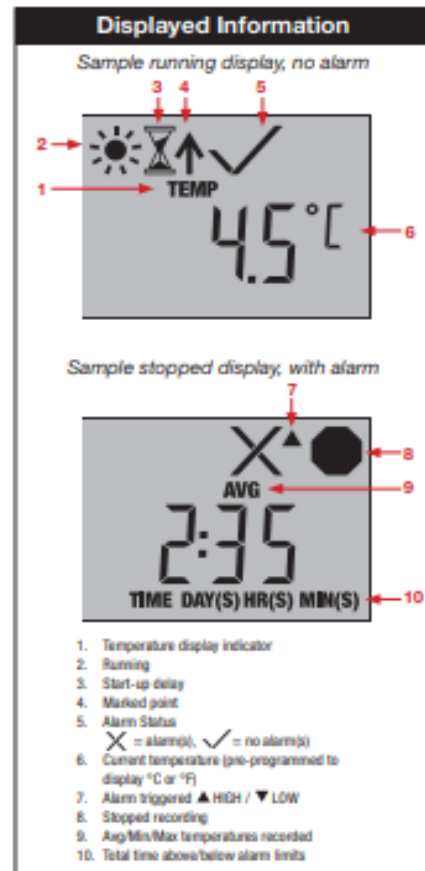
NOTE: Do not disconnect the monitor from the USB port while the RED LED is blinking.

#### Managing and Viewing TempTale Ultra Monitor Files

- If the computer has Adobe PDF compatible reader software installed, double-click the PDF file icon to open and view the PDF file.
- If the computer has Sensitech's TempTale Manager, Desktop Software installed (8.0 or higher), double-click the TTV file icon to open and view monitor configuration information, summary statistics, and time-temperature data graph.
- Both the PDF and TTV files can be copied, saved, or emailed as an attachment.

#### Direct USB Printing of PDF Reports

- To place the monitor in Direct Print mode, press and hold the Start and Stop buttons simultaneously until the RED LED starts blinking. The monitor is now in Direct Print mode.
- NOTE: Direct Print times out after approximately 10 seconds. If time out occurs before the monitor is connected to a USB port, repeat the previous step.
- While the LED is blinking, plug the monitor into the USB port located on the exterior of a USB-enabled printer, and then print the PDF report.
- NOTE: Not all USB printers support USB-direct printing of PDF documents. Consult your printer's user manual for support.



**ATTACHMENT 3**

**ADVERSE EVENT REPORTING FORM**



# SARS-COV-2 CORONAVIRUS EXPERIMENTAL VACCINE REACTION GUIDANCE FORM FOR ADVERSE EVENT REPORTING

**Today's Date:** \_\_\_\_\_

**Reporter/Producer's Information:**

Organization Name \_\_\_\_\_

First and Last Name \_\_\_\_\_

Address \_\_\_\_\_

City/State/Zip \_\_\_\_\_

Phone \_\_\_\_\_

**Event Details:**

Date of Administration \_\_\_\_\_

Date of Adverse Event \_\_\_\_\_

Onset \_\_\_\_\_

Age (if known, Juvenile or \_\_\_\_\_

Geriatric if not) \_\_\_\_\_

Vaccine Serial Number \_\_\_\_\_

Number of animals \_\_\_\_\_

vaccinated \_\_\_\_\_

Number of animals reacted \_\_\_\_\_

<b>Description of Event*</b> (Please give a detailed description of event including other concomitant medications given, treatment details, and first/second experimental SARS-COV-2 vaccine dose):

## MONTHLY REPORT

Reports shall be submitted and saved with the naming convention below:

[illegible]