Instructional Guidance for PV Express II for Public Submissions

NOTE: If you provide Personal Information when you submit an Adverse Event Report:

If you choose to provide us with personal information as in an email to one of our online email boxes, or by filling out a form with your personal information and submitting it to us through our website, we use that information to respond to your message and to help us get you the information you have requested. We do not collect personal information for any purpose other than to respond to you. We collect personally identifiable information (name, email address, or another unique identifier) only if specifically and knowingly provided by you. We only share the information you give us with another government agency if your inquiry related to that agency, or as otherwise required by law. Moreover, we do not create individual profiles with the information you provide or give it to any private organizations. We do not collect information for commercial marketing.

The PV Express II web-based form is the approved electronic method the public may use to submit individual adverse event reports (AER) for veterinary biological products to the Center for Veterinary Biologics (CVB). The PV Express II web-based form can be accessed here. The other approved methods the public may use to submit adverse event reports to the CVB is through hard copy submissions (email, mail, and fax).

The step-by-step instructions provided in this guidance document are to aid the public in completing the PV Express II web-based form.

NOTE: ALL FIELDS on the PV Express II web-based form should be completed if known by you. All date fields appear on the form as European dates (DD-MM-YYYY). To delete a case already submitted, contact CVB.

NOTE: Please consider reporting your adverse event report to the biological manufacturer. As of February 17, 2021, manufacturers are required to report all adverse event reports they receive to the CVB. If the case you are reporting has already been submitted to the manufacturer, there is no benefit to also filing the case with the CVB.

Should you have any questions, need assistance or need to report system problems, please contact CVB.Pharma@usda.gov or at (515) 337-6100.

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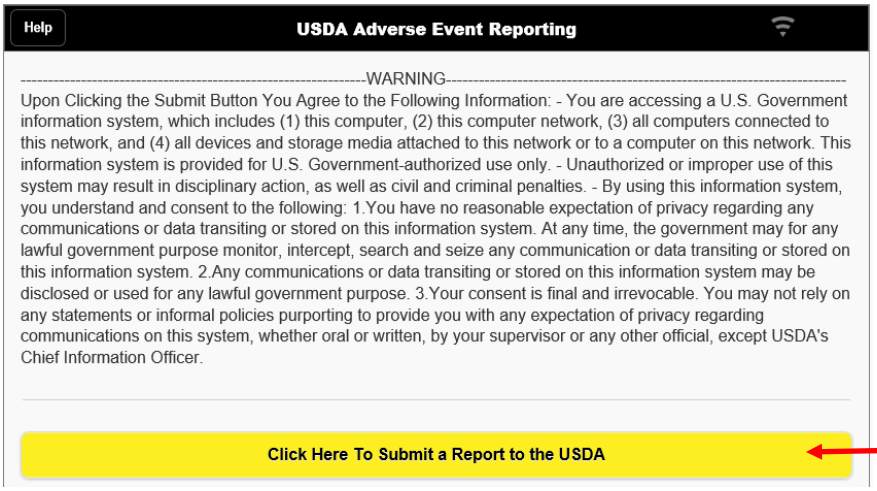
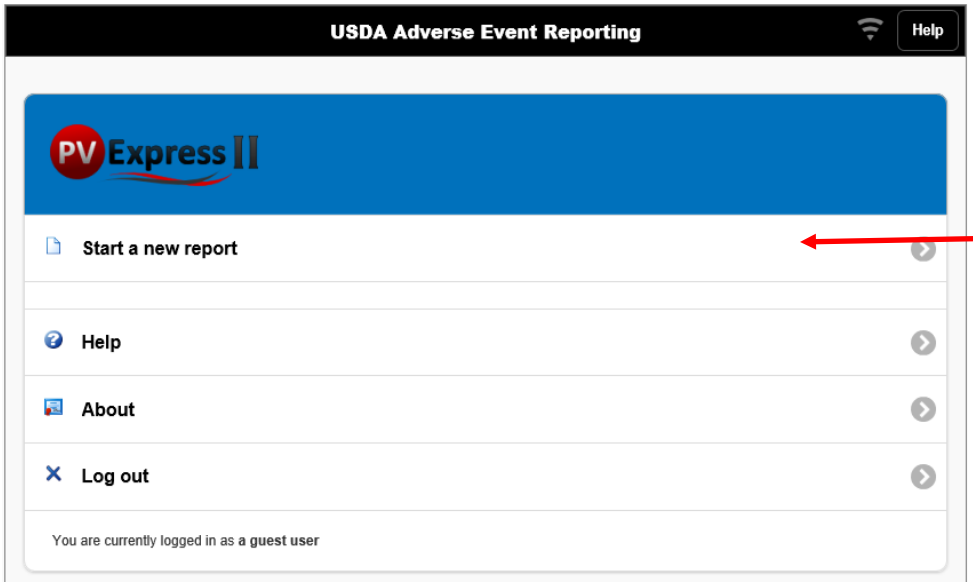
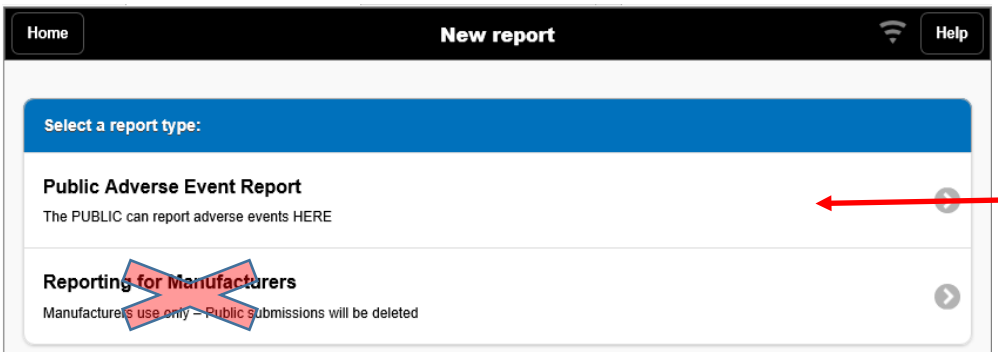
https://cvbpv.aphis.usda.gov/PVXClient/index.html ← URL to initiate an adverse event report.



Start the AER by clicking here.

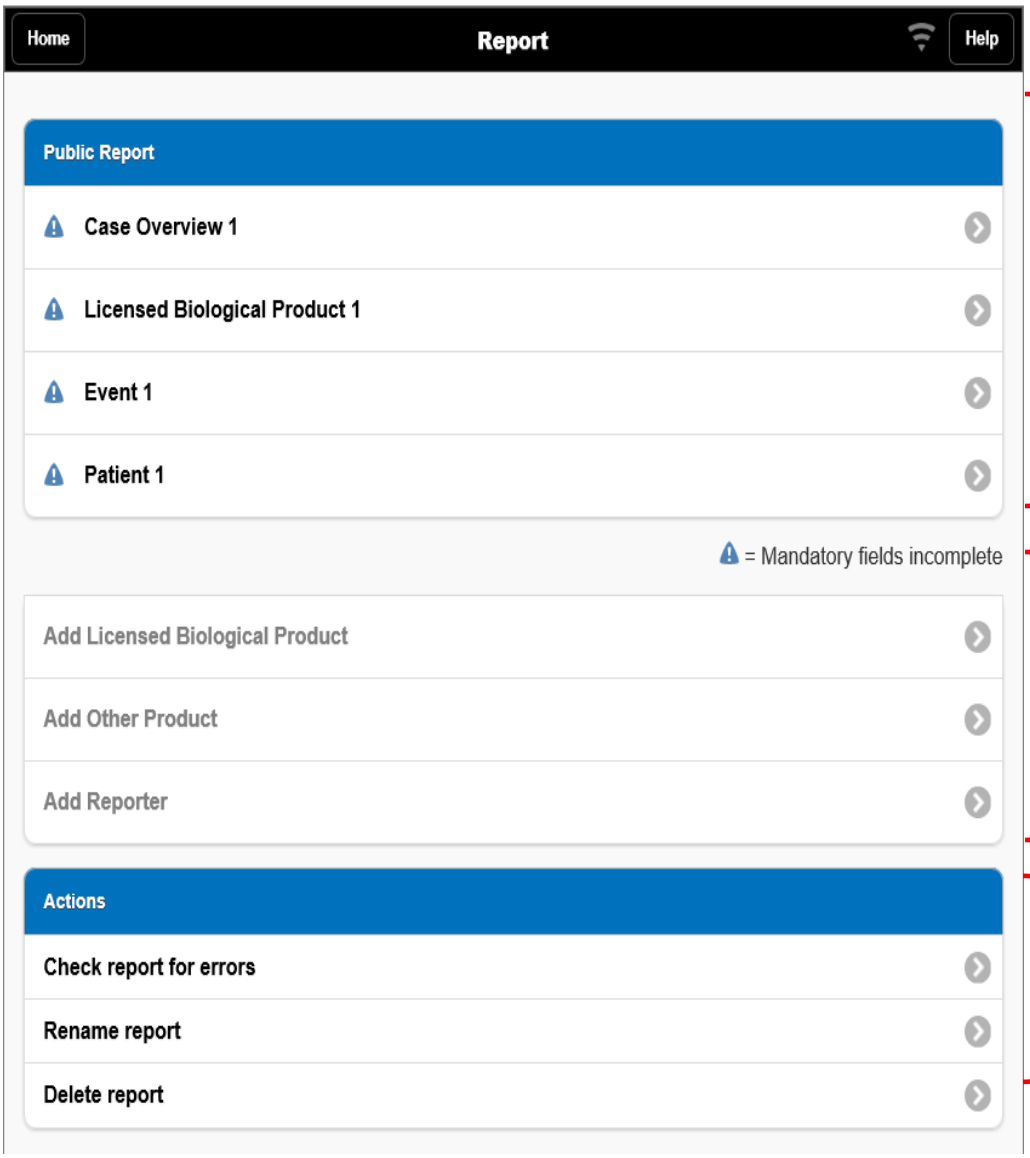


Then, clicking here.



Click on the Public Adverse Event Report.

NOTE: Do NOT use the "Reporting for Manufacturers" link as your entry may be deleted.

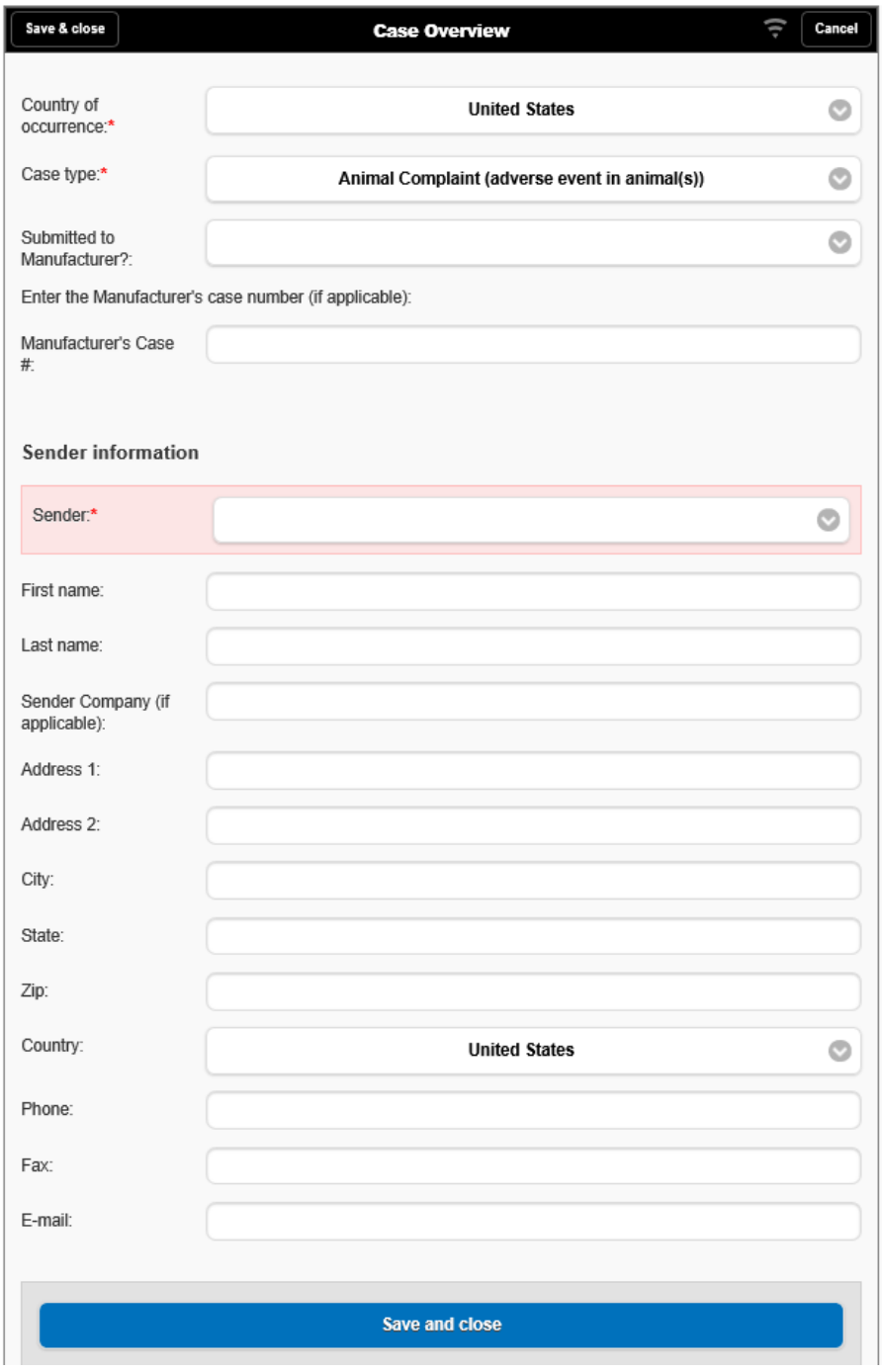


These 5 sections contain mandatory and optional requirements. Once the mandatory items are completed, the icon preceding the section name will change (eg. or). Instructions for completing each section will be covered in this document.

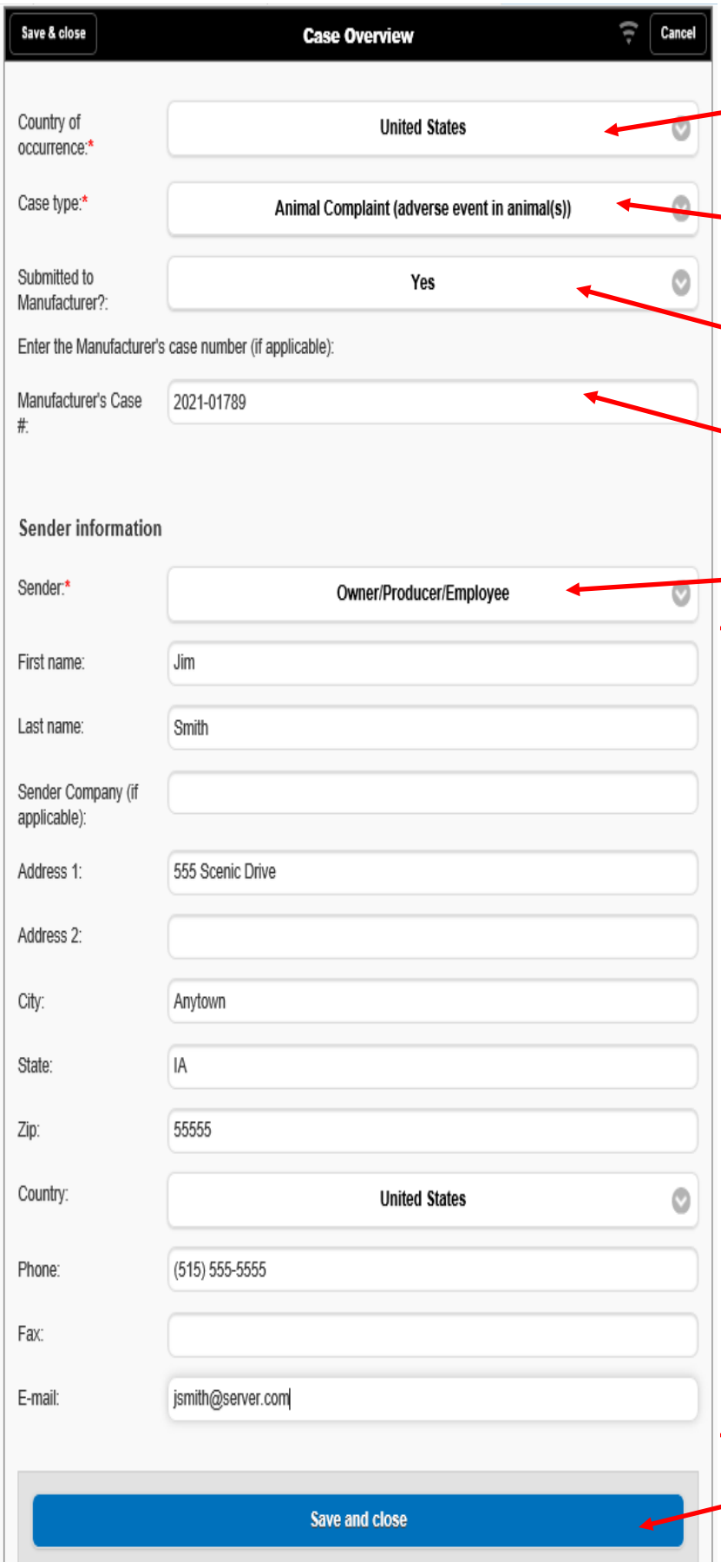
These 4 sections allow for the reporting of additional products and reporters.

This final grouping allows you to check the report for errors, rename the report, or delete the report.

Case Overview 1: **This is the screen as it initially appears. Mandatory fields are denoted with red asterisks (*). Remember, fill in ALL fields if they are known to you. Some fields have default values, which can be changed by selecting the down arrow at the right of the field. The down arrows at the right end of each field reveals a drop-down list to choose from.**



The next picture shows the fields completed:



The Country of Occurrence field defaults to United States

The Case Type field defaults to Animal Complaint. If necessary, you can select symptomatic human case.

Has the case been reported to the vaccine manufacturer? Select yes or no.

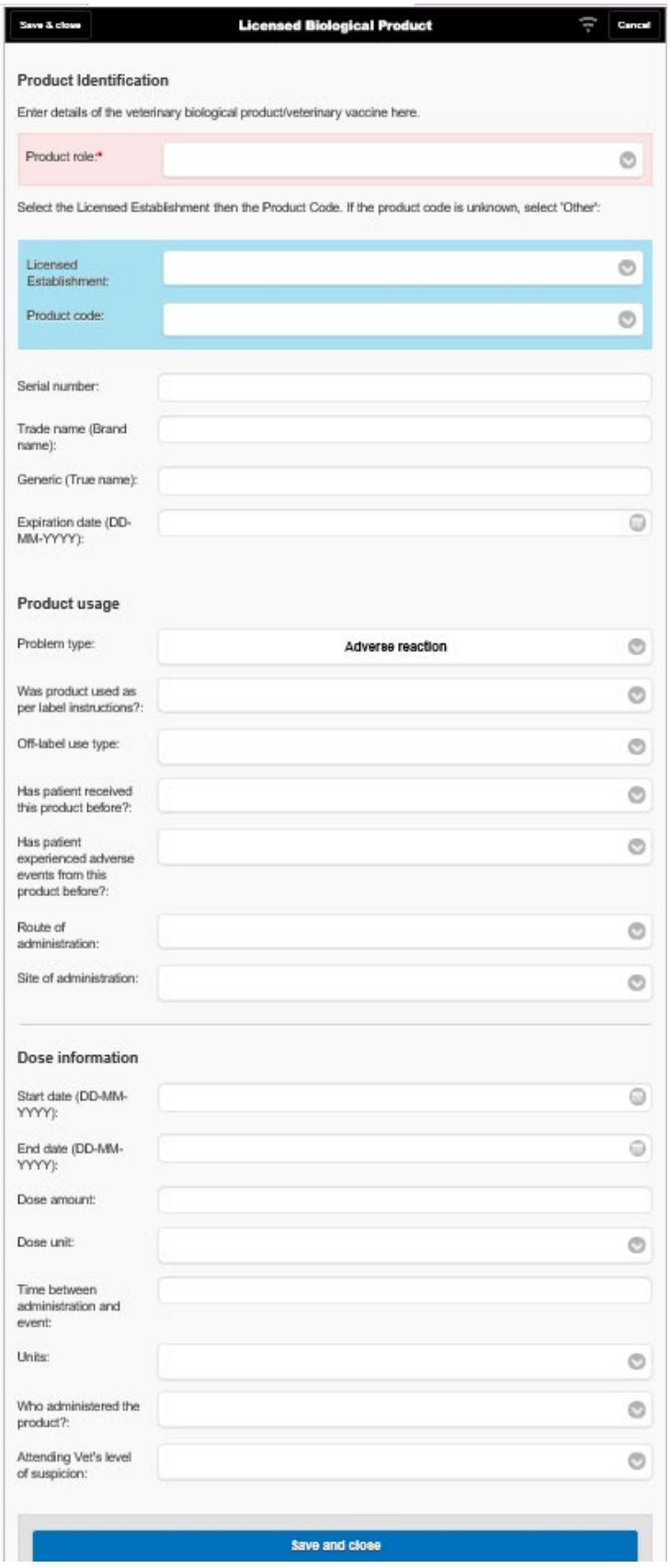
Enter the establishment-assigned AER case number, if known.

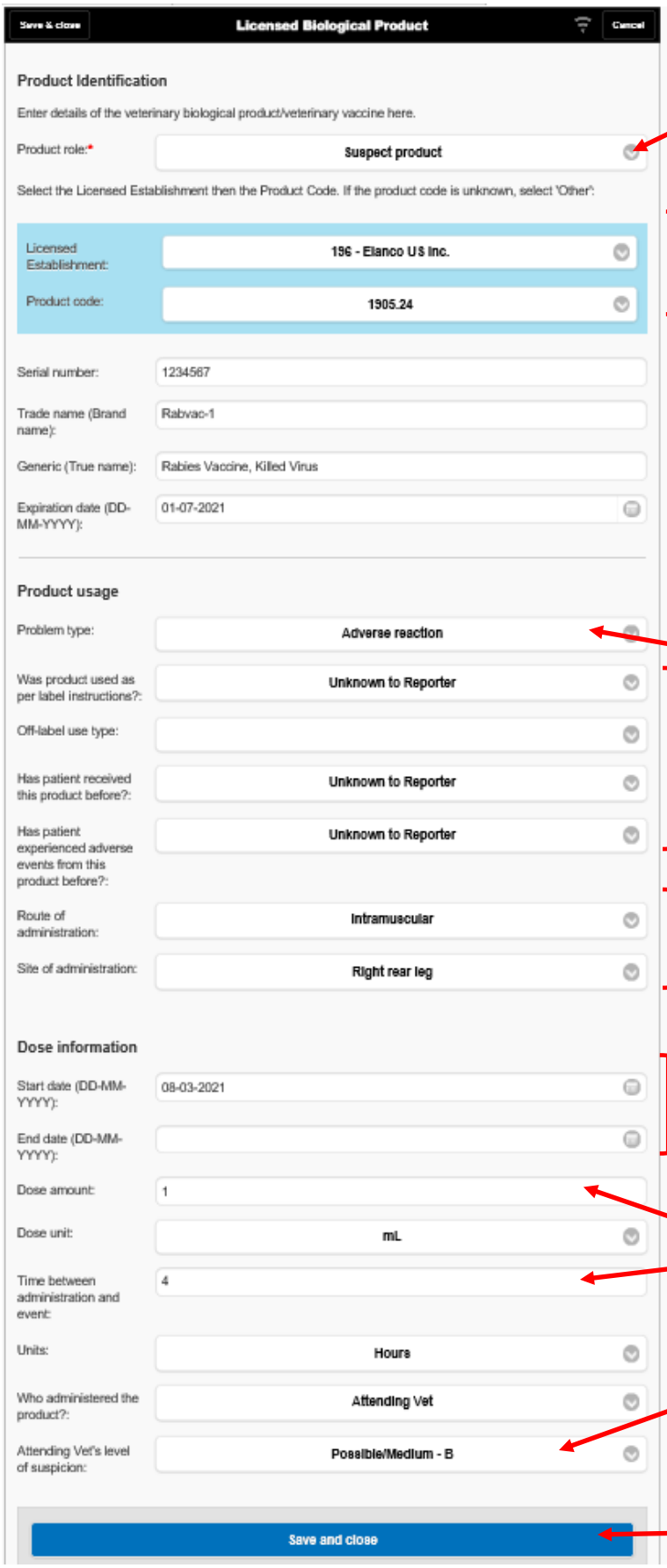
Choose from the drop-down list an appropriate reporter role, usually 'Owner/Producer/Employee' or 'Attending Veterinarian.'

This section should contain information about the reporter, in this case Jim Smith.

Once all information is entered, click "Save and close." Note you can click here or on the top left corner of the screen.

<u>Licensed Biological Product 1:</u> This screen is as it initially appears. Enter information on this screen for your Establishment's licensed product involved in this adverse event report. The down arrows at the right end of each field reveals a drop-down list to choose from.





Choose a Product Role, usually 'Suspect product.'

Establishment and Product Code for the product involved with this adverse event report. The Licensed Establishment information is available on the product label or from your veterinarian.

True name, Trade name, Serial number (if known) and expiration date of the product. This information is available on the product label or from your veterinarian. **NOTE** - expiration date is in European format.

Problem Type will usually be 'Adverse reaction.'

Choose the most appropriate response to these questions from the drop-down list.

Choose the route of administration and the site on the animal where administered.

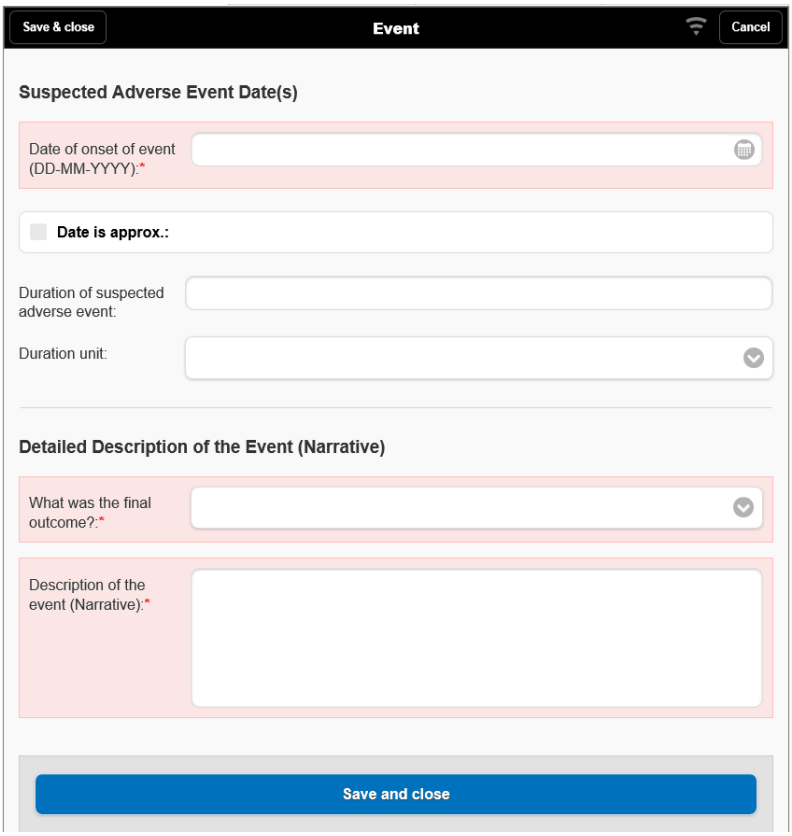
Start date = date of administration. End date is used when vaccination extends over a period of time (vaccinating 500 calves over two days, for example). If part of a series of immunizations for an individual animal, please explain in the case narrative.

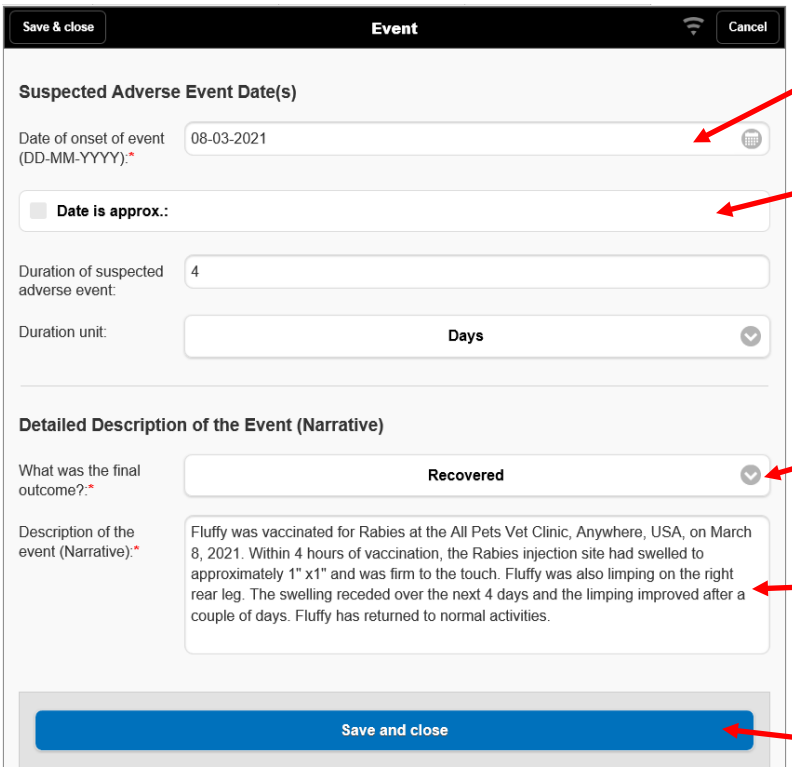
If this value is less than 1 (<1), you must enter a zero followed by the decimal, for example "0.5".

Enter the attending veterinarian's assessment of causality, if known.

Once all information is entered, click "Save and close." Note you can click here or on the top left corner of the screen.

Event 1: **This screen is as it initially appears. Enter information on this screen to describe the actual adverse event. Provide a complete, detailed narrative. The down arrows at the right end of a field reveals a drop-down list to choose from.**





The date the adverse event started.

If there is uncertainty about the date that the adverse event started, check this box.

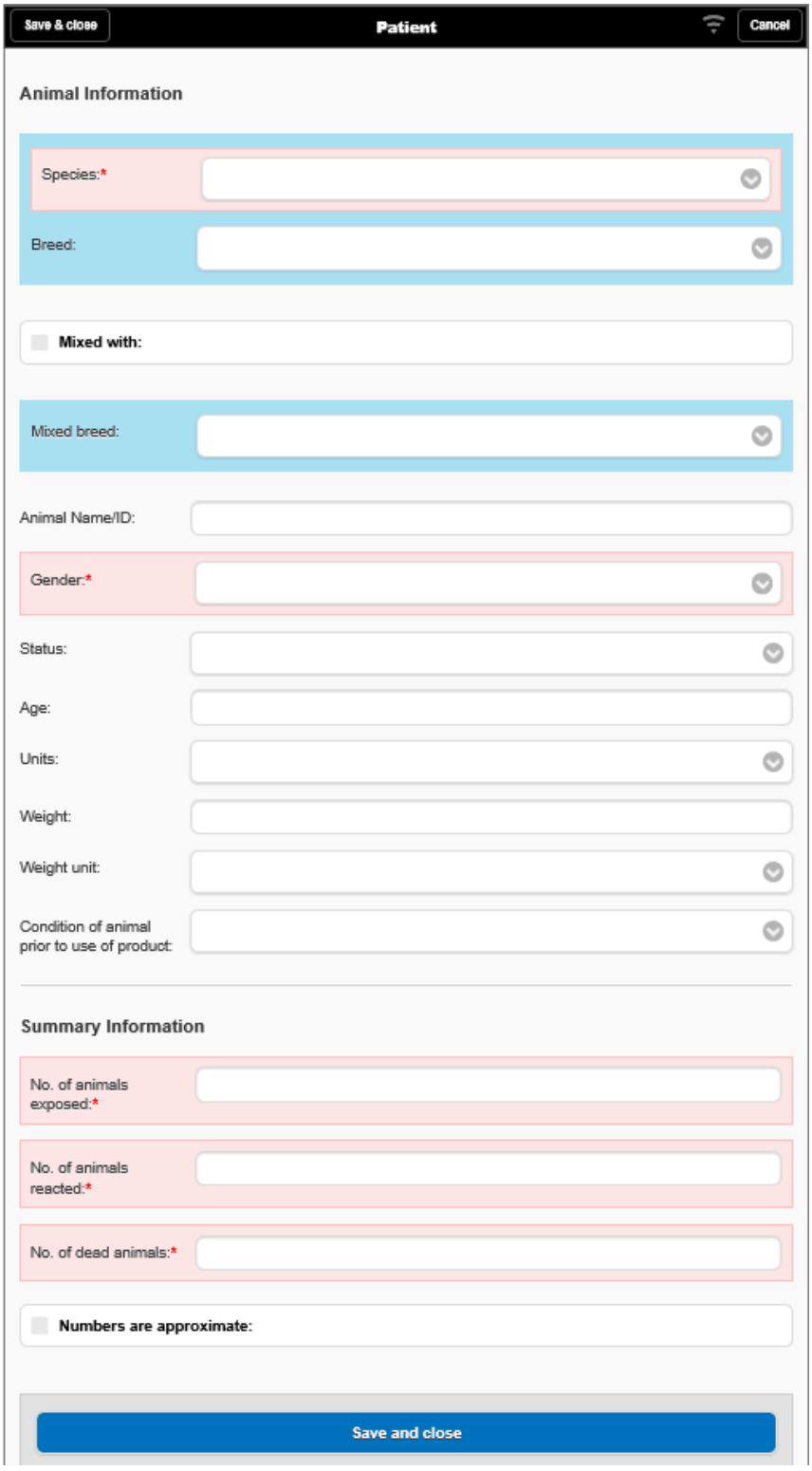
How long did the adverse event last?

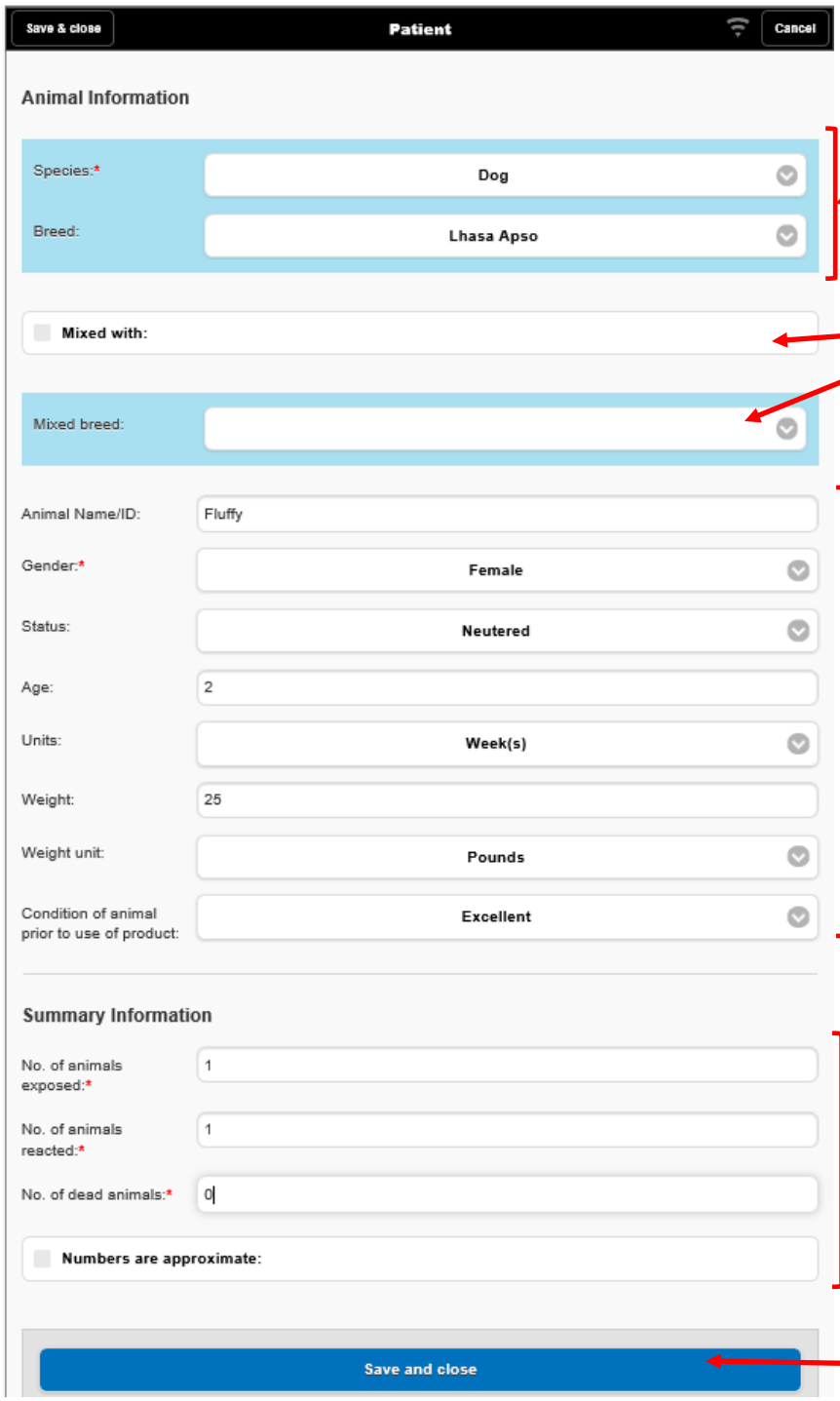
Click the drop-down arrow and select an outcome from the drop-down list.

Provide a **complete, detailed description (narrative)** of the adverse event.

Once all information is entered, click "Save and close." Note you can click here or on the top left corner of the screen.

Patient 1: **This screen is as it initially appears. Enter patient information. The down arrows at the right end of a field reveals a drop-down list to choose from.**





Choose the appropriate species and breed from the drop-down lists.

If a mixed breed, check this box, and provide the other breed.

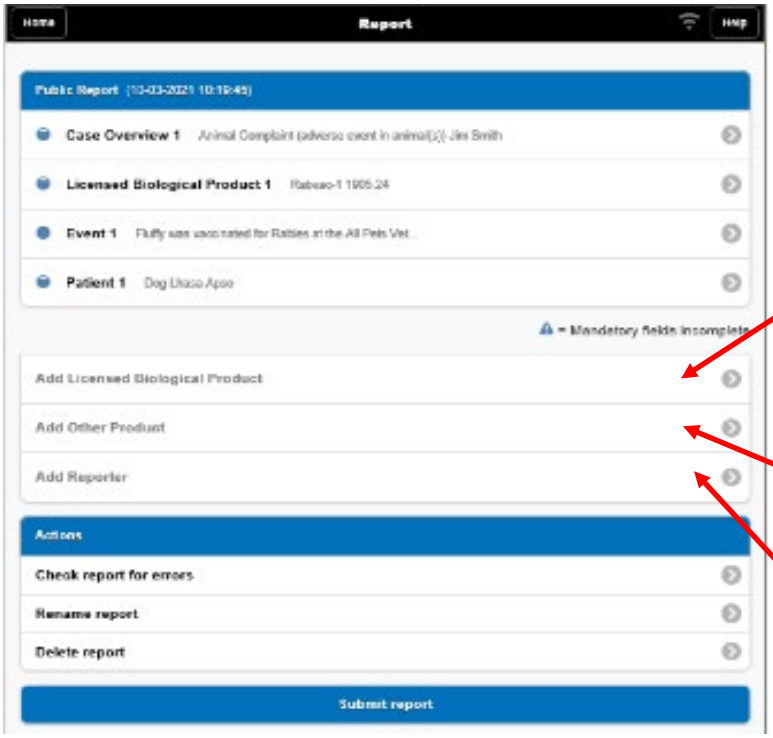
Provide the requested information regarding the animal.

Provide the number of animals exposed (vaccinated), the number reacted, and the number dead. If the numbers are approximations, check the box.

Once all information is entered, click "Save and close." Note you can click here or on the top left corner of the screen.

This completes the mandatory sections.

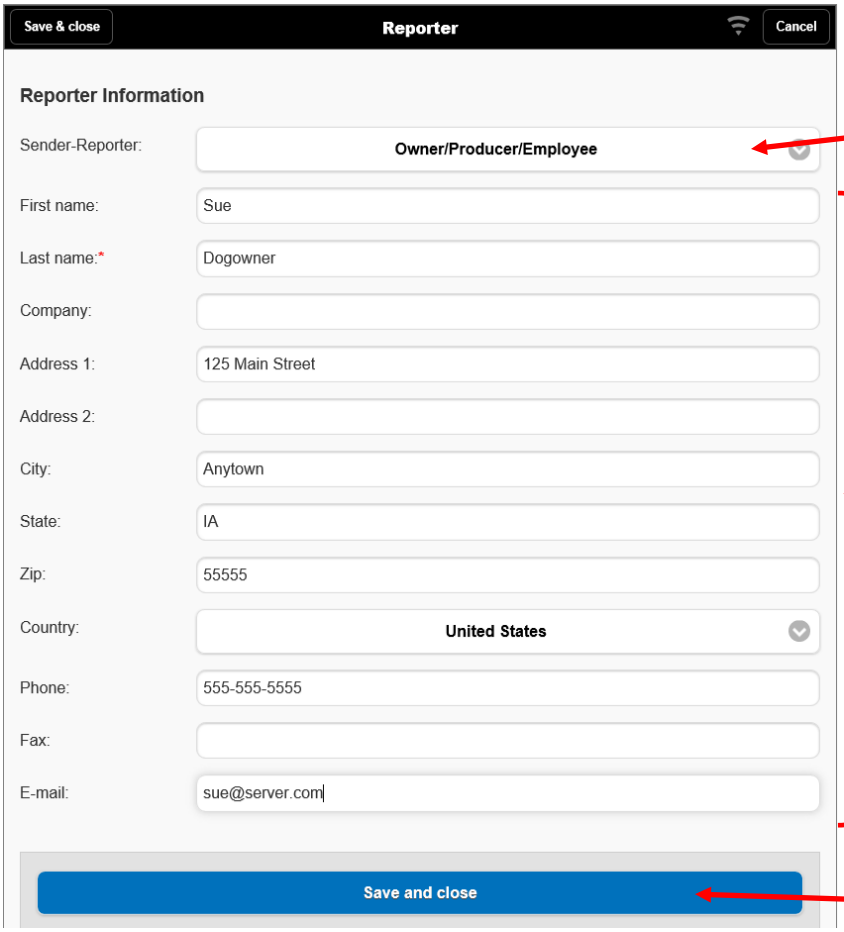
If necessary, add additional 'Licensed Biological Products' or 'Other Products' (such as pharmaceuticals, heartworm medication, or flea control products, for example).



For the additional licensed biological products that were administered, select "Add Licensed Biological Product" and follow the instruction for Licensed Biological Product. Remember to select "Suspect product" for the Product role field.

For any other products (pharmaceuticals, etc.) that were administered, select "Add Other Product" and complete all fields to the best of your ability.

To add additional reporters (owner, vet clinic), select "Add Reporter." See example below.

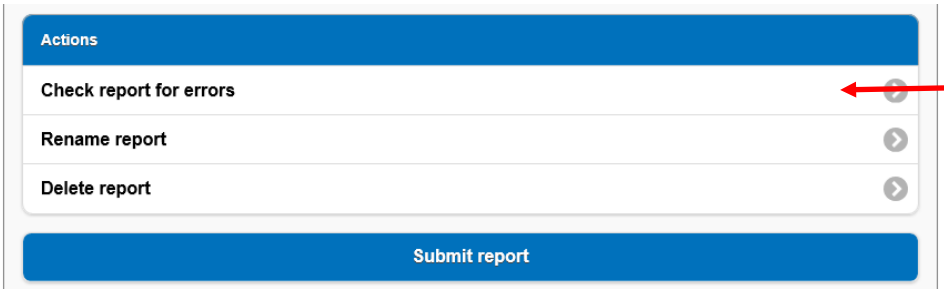


Select additional reporters from the drop-down list.

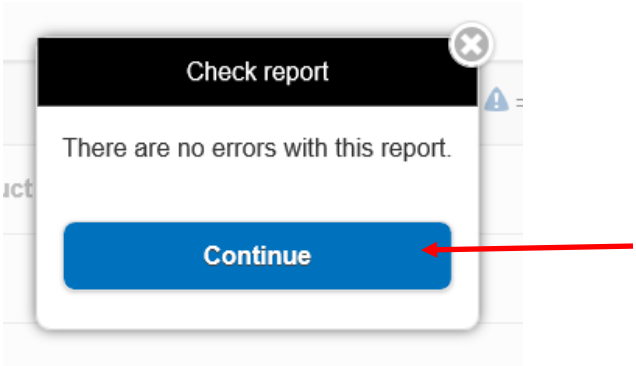
Fill out all the fields as completely and accurately as possible.

Once all information is entered, click "Save and close." Note you can click here or on the top left corner of the screen.

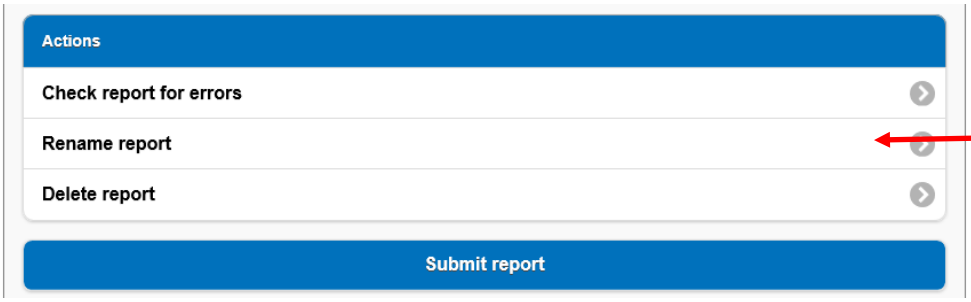
The final step involves checking the report for errors. If an error is found, you will be directed to correct the error and then allowed to submit the report.

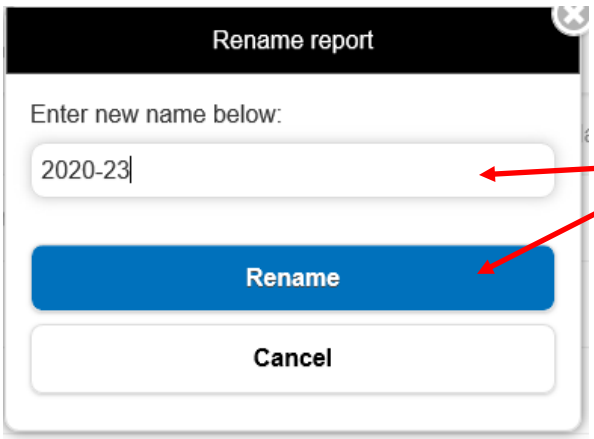


If there are no errors, select continue:



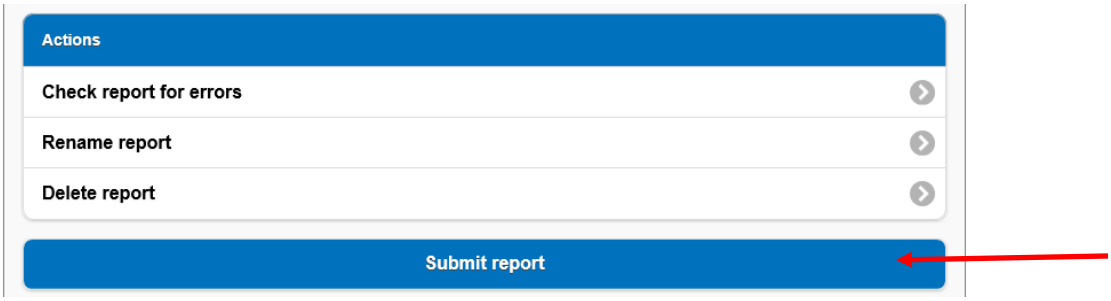
You can rename the report (not necessary).

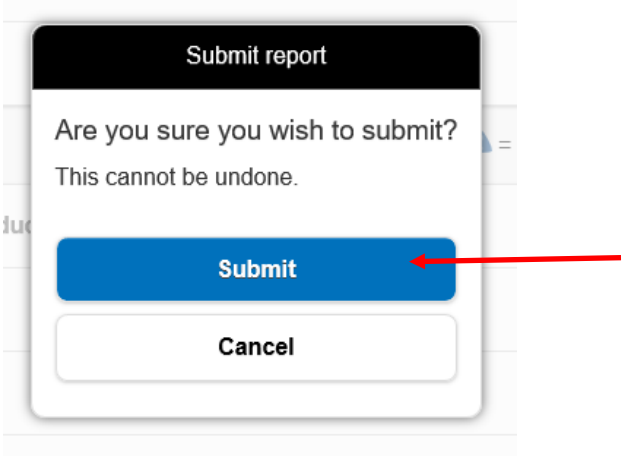




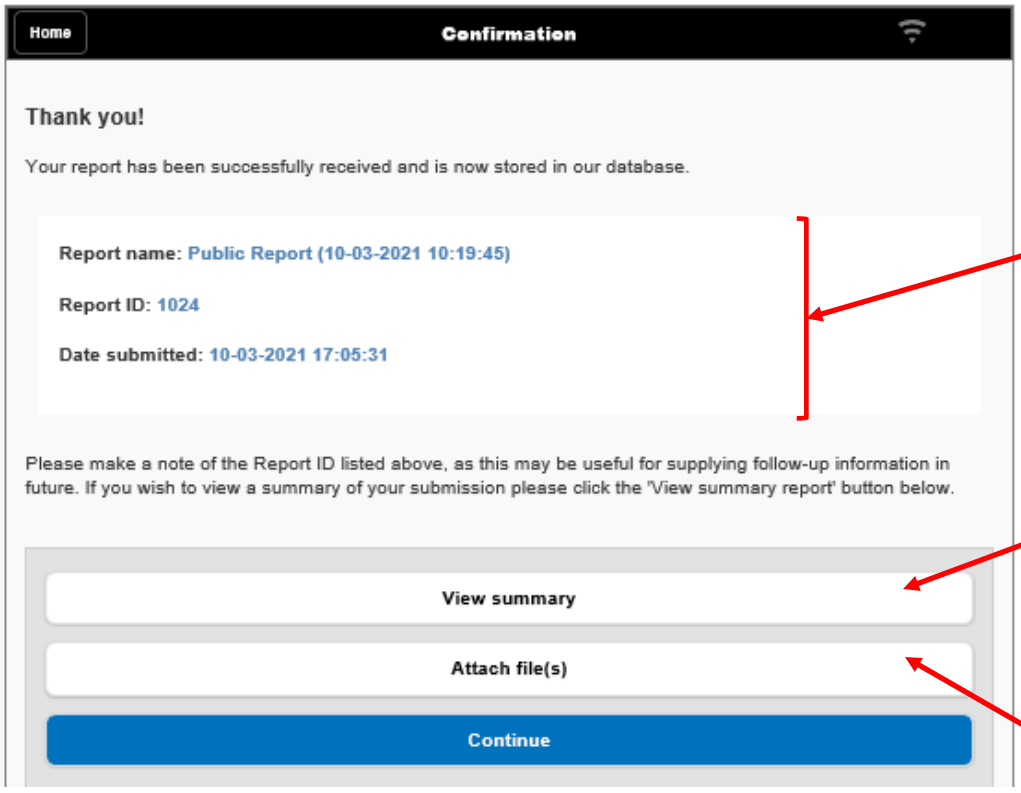
Enter a new name and then select "Rename."

Select "Submit report."





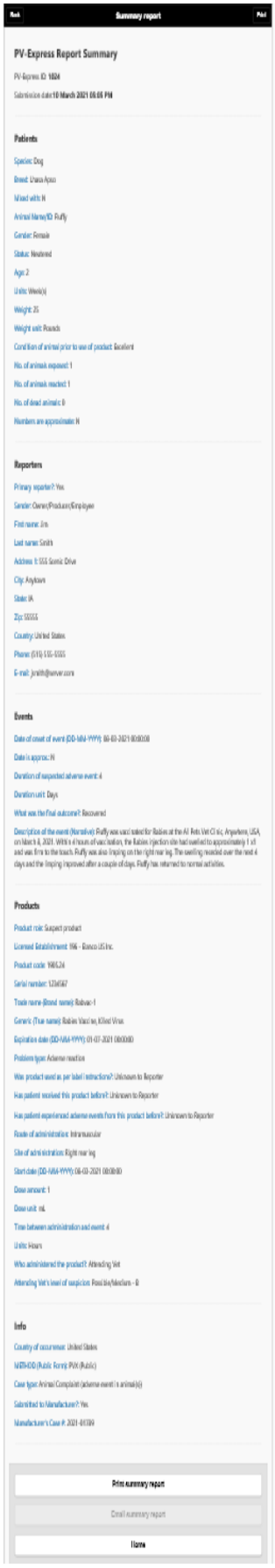
You will get a "confirmation" screen:



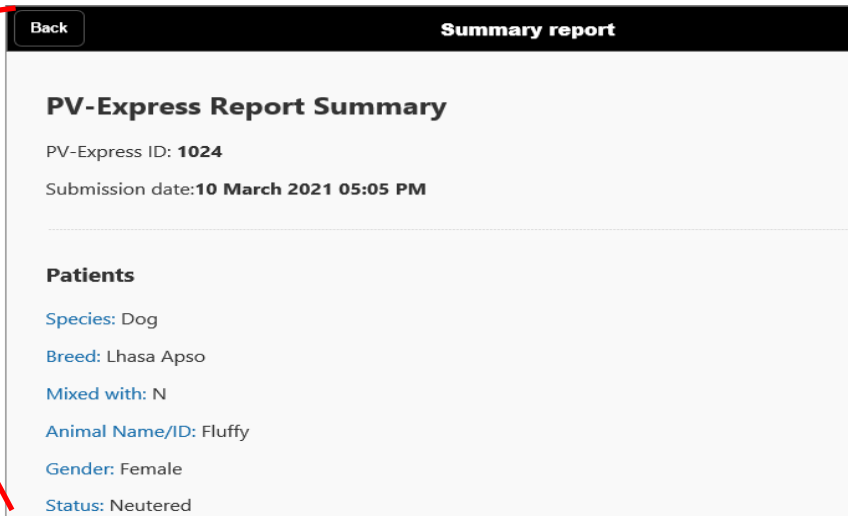
Note the Report default name is "Public Report" and the Report ID. The Report ID is a useful field for CVB to find your report.

Select View summary. This will allow you to see, save, and print the report. This provides documentation of the report.

Files can be attached to your report, such as veterinarian records, etc., if necessary.

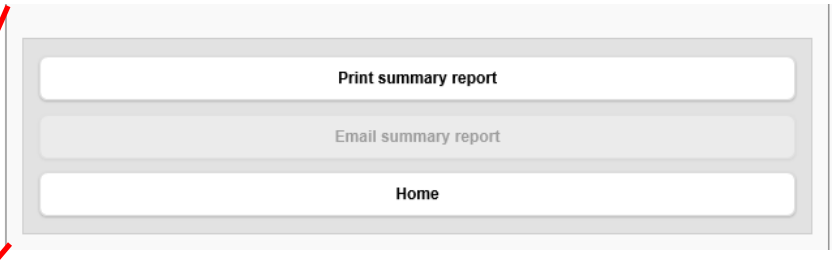


Enlarged view of beginning of report.



While too small to read in this picture, the summary contains all of the data you entered into the report.

Enlarged view of bottom of report.



If desired, you can print the summary report for your records.

Finally, select "Home" to start a new report or exit the AER web-based reporting application.