

#188

Guidance for Industry

Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine

(This guidance replaces the version dated October 2013. The document has been revised to correct numbering of some field data elements.)

Submit comments on this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All written comments should be identified with the Docket No. FDA-2010-D-0241.

For further information regarding this document, contact the Division of Veterinary Product Safety (HFV-240), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, Email: CVMAESupport@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm123602.htm> or <http://www.regulations.gov>

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Center for Veterinary Medicine
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Guidance for Industry

Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine¹

This guidance represents the Food and Drug Administration's (FDA or Agency) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance using the contact information on the title page of this guidance.

I. PURPOSE

The purpose of this guidance is to assist applicants (referred to as Marketing Authorization Holder (MAH) in this guidance) and nonapplicants with filling out Form FDA 1932, "Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report." As required by Food and Drug Administration (FDA) regulations at 21 CFR 514.80, an applicant must report adverse drug experiences² (ADEs) and product/manufacturing defects on Form FDA 1932. Firms named on the label as a manufacturer, packer, or distributor may also use this form.

As part of FDA's ongoing effort to harmonize the Agency's adverse event (AE) regulatory reporting data elements with those of other nations as well as streamline reporting for product and manufacturing defects, FDA revised Form FDA 1932.³ The changes to Form FDA 1932 are the product of discussions undertaken between the United States, Japan, and the European Union as part of the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). FDA revised Form FDA 1932 to bring the AE reporting data elements on the form more in line with the data elements developed as a result of the VICH discussions.⁴ In addition, the Agency has included new data elements to gather information specific only to the FDA. This information will enable FDA to process and review electronic and paper reports.

¹ This title harmonizes this guidance, to the extent consistent with FDA regulations, with the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) draft guidance document, "Pharmacovigilance of Veterinary Medicinal Products Data Elements for Submission of Adverse Event Reports" (VICH GL42), but identifies it as having some FDA-specific application. Certain terms, such as Marketing Authorization Holder (MAH) and Veterinary Medicinal Product (VMP) originate from this harmonization.

² The terms *adverse drug event* and *adverse drug experience* may be used interchangeably.

³ On November 20, 2009, FDA published a notice in the Federal Register (74 FR 60265) announcing its intention to revise Form FDA 1932, among other things. The notice gave the public an opportunity to comment on proposed data elements to be included on a revised version of Form FDA 1932. Form FDA 1932 was revised January 2010 (OMB Control No. 0910-0645) and again in January 2013 (OMB Control No. 0910-0645).

⁴ This guidance (VICH GL42) is available on the Internet at <http://www.vichsec.org/>

Contains Nonbinding Recommendations

This document is intended to provide guidance on how to complete Form FDA 1932. Form FDA 1932 can be completed as follows:

- through the Rational Questionnaire⁵;
- through the FDA Electronic Submissions Gateway (ESG) for gateway-to-gateway reporting; or
- by filling out the paper form.

This guidance document is not intended to provide guidance on how to electronically transmit the Form FDA 1932 to FDA. FDA intends to provide additional guidance on the electronic transmission of the information in a separate document. If you need additional information for appropriate transmission of the information based on the FDA electronic transmission standard, please refer to Guidance for Industry #108, “How to Register with the CVM Electronic Submission System to Submit Information in Electronic Format using the FDA Electronic Submissions Gateway.” Furthermore, this guidance does not address voluntary reporting on Form FDA 1932a.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance documents means that something is suggested or recommended, but not required.

II. BACKGROUND

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(l)) requires applicants to establish and maintain records and make such reports of data relating to experience with uses and other data or information received or obtained by the applicant with respect to such drug as required by regulation or order. Section 514.80(b) (21 CFR 514.80(b)) of FDA regulations requires applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report ADEs and product and manufacturing defects. In addition, nonapplicants, defined at 21 C.F.R. 514.3 as “any person other than the applicant whose name appears on the label and who is engaged in manufacturing, packing, distribution, or labeling of the product” must report ADEs to the applicant but may also report them to the FDA (see Section 21 CFR 514.80(b)(3)). This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA’s Center for Veterinary Medicine (CVM) obtains information regarding potential problems with the safety and effectiveness of marketed approved new animal drugs as well as potential product/manufacturing problems.

⁵ The Rational Questionnaire is a user-friendly, web-based questionnaire that displays a series of questions to be answered by the person submitting the report. These questions are intended to ensure proper collection of the information that is needed by FDA to appropriately evaluate the reported incident. The Rational Questionnaire is part of the FDA-National Institutes of Health Safety Reporting Portal (the Safety Reporting Portal).

Contains Nonbinding Recommendations

CVM relies on adverse event reports (AERs) to facilitate a determination under section 512(e) of the FD&C Act (21 U.S.C. 360b(e)) as to whether there may be grounds for suspending or withdrawing approval of the NADA or ANADA (21 CFR 514.80(a)(3)). In addition, the information contained in veterinary AERs assists CVM in working with firms to minimize ADEs due to manufacturing problems; previously unidentified or uncommon side effects; and off-label (also known as extralabel) use of animal drugs.

- Manufacturing/product defect cases must be reported as a *Three-day NADA/ANADA Field Alert Report* if they may result in serious adverse drug events (See 21 CFR 514.80(b)(1)).
- Adverse drug event cases must be reported as a *Fifteen-day NADA/ANADA Alert Report* if they are serious and unexpected. (See 21 CFR 514.80 (b)(2)).
- If the manufacturing/product defect is associated with a serious and unexpected adverse drug event, the applicant must submit a *Fifteen-day NADA/ANADA Alert*.
- All other adverse drug events and manufacturing/product defects should be submitted in a periodic report as described in 21 CFR 514.80 (b)(4)(iv).
- If a nonapplicant elects to report directly to FDA (after forwarding reports of ADEs to the applicant within 3 days after receiving information about the event), the nonapplicant should submit the report on Form FDA 1932, pursuant to 21 CFR 514.80(b)(3).

III. GUIDANCE AND INSTRUCTIONS

1. Guidance for Completing Form FDA 1932

Under FDA regulations, Form FDA 1932 must be used for the reporting of ADEs and product/manufacturing defect(s) (see 21 CFR 514.80(d)). The paper and electronic versions of Form FDA 1932 contain data elements necessary for us to process and access the report.⁶ However, not every data element will be applicable for every report. For example, if the ADE only involved a human, there may not be a data entry for data elements asking about the animal involved (i.e., breed, production class, reproductive status of the animal, etc.)

Complete all applicable data elements if the information is available. The data elements that are required to be filled out by everyone are marked on Form FDA 1932 with a single asterisk. Although there are data elements that are not marked with an asterisk, we strongly encourage you to submit that information, because it will help FDA process and review the report. It is expected that all available information supplied by the reporter will be provided to CVM.

⁶ The third option for submission, gateway-to-gateway electronic transmission, collects the same information in Form FDA 1932, but it is not considered an electronic version of the form. CVM intends to exercise enforcement discretion if firms choose to submit reports via gateway-to-gateway electronic transmission to satisfy their reporting obligation under 21 CFR 514.80(d).

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FDA has indicated which data elements are minimum requirements for acceptance of the ADE report as follows:

- The required elements for the paper form are indicated on the paper form itself;
- The required data elements for the gateway-to-gateway electronic transmissions are indicated in the technical specification documents; and
- The required data elements for the web-based Rationale Questionnaire are indicated on the screen during data entry and also through software functionality (e.g., upon submission of the report, the system will notify the reporter if a required field is empty).

According to 21 CFR 514.80(b)(1), the applicant must submit a three-day NADA/ANADA field alert report providing for information pertaining to product and manufacturing defects that may result in serious ADEs. This provision of the regulation can be satisfied by submitting Form FDA 1932 (paper form) to the appropriate FDA District Office or local resident post (see 21 CFR 514.80(b)(1)). Currently, FDA does not have the electronic capability to share with the FDA District Office or local resident post electronic reports submitted through the web-based Rationale Questionnaire or a gateway-to-gateway electronic submission. If the MAH elects to submit a three-day NADA/ANADA field alert report directly to FDA's CVM, the MAH may use any of the three previously-mentioned methods for providing the information. However, if the MAH chooses to submit this report directly to FDA's CVM, this does not alleviate the MAH's responsibility to submit this report (via telephone or other telecommunication means, and paper form) to the FDA District Field Office or local FDA resident post (see 21 CFR 514.80(b)(1)).

2. Instructions for Completing Form FDA 1932

Type or print all entries in a font no smaller than 8 point.

Complete all fields if the information is available.

The values and codes for the lists of categories will be specified in FDA technical specification for electronic transmission and can be obtained from the CVM [Veterinary Adverse Event Reporting for Manufacturers](#) webpage.

The values for U.S. state codes and the 3-character International Organization for Standardization (ISO) 3166 code can be found in the List of U.S. States & Territory Codes and List of ISO 3-character Country Codes, respectively.

Electronic submissions require a compliant xml format to avoid rejection of the submission. Do not use any special symbols, such as single or double quotation marks and ampersands, in the free text fields. Do not include any accent marks, such as ö, ñ, é, è, â, Ç and so on in the free text fields.

Contains Nonbinding Recommendations

PART A - ADMINISTRATIVE AND IDENTIFICATION INFORMATION

A.1 Regulatory Authority (RA) (Open Ended Text)

The RA is the government agency or authority to which this AER is to be submitted initially based on which RA has the authority to regulate the product.

Enter the RA name, street address, city, state/county, mail/zip code, and country (3-character ISO 3166 code). The RA for Veterinary Medicinal Products (VMPs) in the United States is the FDA, Center for Veterinary Medicine, entered as follows:

RA Name: Food and Drug Administration, Center for Veterinary Medicine
Street Address: 7500 Standish Place (HFV-199), Room 403
City: Rockville
State/County: MD
Mail/Zip Code: 20855
Country: USA

A.2 Marketing Authorization Holder (MAH)

The MAH is the applicant (sometimes referred to as the company or the firm) or the nonapplicant (such as the firm's distributor). The MAH is responsible for reporting the AE information to the RA who is responsible for regulating the veterinary medicinal product (VMP). For purposes of this guidance document, the term veterinary medicinal product has the same meaning as "new animal drug," as defined in section 201(v) of the FD&C Act, 21 U.S.C. 321(v).

A.2.1 MAH Information (Open Ended Text)

Provide the business name, street address, city, state/county, mail/zip code, and country (3-character ISO code) of the MAH.

A.2.2 Person Acting on Behalf of the MAH (Open Ended Text)

Enter the title, first name, last name, telephone number, fax number, and e-mail address of the person acting on behalf of the MAH.

A.3 Person(s) Involved in the AER

Enter the name of the veterinarian involved in this AER as one of the reporters, if a veterinarian is involved in the AE.

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A.3.1 Primary Reporter (Open Ended Text)

The primary reporter is the person or organization, as determined by the MAH, who holds or provides the most pertinent information related to this AER.

Provide the last name, first name, telephone number, fax number, e-mail address, business name, street address, city, state/county, mail/zip code, and country code (3-character ISO 3166 code) of the individual or organization reporting the primary information for this AER.

If the telephone number, fax number, or e-mail address is not available, leave these fields blank.

If the reporter requests his/her name not be provided to the FDA, enter “Withheld” in the Last Name field.

A.3.1.1 Primary Reporter Category (Code List)

This field is a list of values regarding the role or involvement of the primary reporter. For an agent acting on behalf of the owner (e.g., horse trainer or pet sitter), choose “Animal Owner.” Choose “Patient” only when the affected species in the AE is a human. Only use “Physician” when the affected species in the AE is a human, unless a physician is reporting on an animal.

Enter a choice from the List of Reporter Categories.

A.3.2 Other Reporter (Open Ended Text)

The other reporter, as determined by the MAH, is the person or organization who also possesses pertinent information related to this AER. For example, if the primary reporter is the veterinarian, the other reporter may be the animal owner.

Provide the last name, first name, telephone number, fax number, e-mail address, business name, street address, city, state/county, mail/zip code, and country (3-character ISO 3166 code) of the other reporter.

If the telephone number, fax number, or e-mail address is not available, leave these fields blank.

If the reporter requests his/her name not be provided to the FDA, enter “Withheld” in the Last Name field.

A.3.2.1 Other Reporter Category (Code List)

This field is a list of values regarding the role or involvement of the other reporter. For an agent acting on behalf of the owner (e.g., horse trainer or pet sitter), choose “Animal Owner.” Choose “Patient” only when the affected species in the AE is a human. Choose “Physician” only when the affected species in the AE is a human, unless a physician is reporting on an animal.

Enter a choice from the List of Reporter Categories.

Contains Nonbinding Recommendations

A.4 AER Information

A.4.1 Unique Adverse Event Report Identification Number (Open Ended Text)

This globally unique AER identification number is designated by the MAH. It consists of a 3-character ISO 3166 country code, 8-character MAH identifier code, and a unique number assigned by the MAH. If the report originally was sent by an RA, this number may include the RA identifier code in place of the MAH identifier code.

- The country code specifies the country where the AE occurred.
- MAH identifier code: This is an 8-character code assigned by each MAH to identify itself.
- Unique number: This is a number, such as a case number, assigned by the MAH which would always allow retrieval of that report, including all of its follow-ups, in all future correspondence regarding the case.

Enter the unique AER identification number (e.g. *USA-GAPINDUS-000001*). If the case has a hospital case number or other nonapplicant case number, provide these numbers in the narrative B.3.1.

A.4.2 Original Receive Date (Date Field — Day, Month, Year)

For AERs submitted in accordance with 21 CFR 514.80 (b)(2)(i), (b)(3), and (b)(4)(iv)(A), the original receive date is the date of first receipt of information by the MAH responsible for reporting the AER to the FDA.

We interpret receipt of information to include the following factors:

- An identifiable reporter
- An identifiable animal(s) or human(s)
- An identifiable VMP
- One or more adverse events

For reports submitted in accordance with 21 CFR 514.80 (b)(1) and (b)(4)(iv)(A), the original receive date is the date that the MAH first became aware of the manufacturing/product defect.

Enter the date that the AER was received by your company. This date remains the same for follow-up or future submissions concerning this AER.

Contains Nonbinding Recommendations

A.4.3 Date of Current Submission (Date Field — Day, Month, Year)

Enter the date of the submission of this AER to the RA.

A.4.4 Type of Report

A.4.4.1 Type of Submission (Code List)

This field is a list of values regarding the type of report being submitted to the RA. Choose the values represented by this AER from the List of Type of Submission.

The “Expedited” (fifteen-day NADA/ANADA alert report) report provides information on each serious, unexpected adverse drug event. These reports should be submitted on Form FDA 1932 in accordance with 21 CFR 514.80 (b)(2)(i).

The Three-Day NADA/ANADA Field Alert Report contains information pertaining to the VMP that is the subject of the manufacturing/product defect(s) that may result in serious adverse events. These reports should be submitted on Form FDA 1932 in accordance with 21 CFR 514.80 (b)(1).

A “Follow-up” adverse event report provides additional information to a previously submitted initial AER. These reports should be submitted on Form FDA 1932 in accordance with 21 CFR 514.80 (b)(2)(ii).

“Nullification” is a specific type of follow-up report that describes why the initially submitted AER needs to be nullified.

A “Periodic” is an adverse event or manufacturing/product defect report included in the Drug Experience Report. These reports should be submitted on Form FDA 1932 in accordance with 21 CFR 514.80(b)(4).

A.4.4.2 Reason for Nullification Report (Text)

If “Nullification” was chosen in A.4.4.1, Type of Submission, provide a reason for the nullification of the report. The use of “Nullification” should be reserved for circumstances of inappropriate submission, such as mistaken submission to the wrong application. CVM will determine prior to nullifying the report if the reason provided is valid. CVM may notify the MAH if CVM does not agree with the reason for nullification.

A.4.4.3 Type of Information in Report (Code List)

This field is a list of values regarding the type of information in the AER. Choose the value represented by this AER from the List of Type of Information.

Contains Nonbinding Recommendations

SPONTANEOUS REPORTS

For purposes of this document, a *spontaneous report* is an AER that is voluntarily reported to the MAH for the identification of possible AEs following the use of a marketed VMP(s). The following terms and descriptions can be used for spontaneous reports.

“Safety Issue” is a spontaneous report that involves a perceived illness or other injury. This may refer to both animal and human AEs.

“Lack of Expected Effectiveness” is a spontaneous report that involves a lack of expected effectiveness (LOEE).

“Both Safety Issue and Lack of Expected Effectiveness” is a spontaneous report that represents both a safety issue and LOEE occurring in the same case.

NON-SPONTANEOUS REPORTS

For purposes of this document, a *non-spontaneous report* is an AER that is reported to the MAH for the identification of possible AEs following the use of a marketed VMP(s) in planned studies (such as clinical or marketing studies). The following terms and descriptions can be used for non-spontaneous reports.

“Safety Issue (Clinical Studies)” is a non-spontaneous report that involves a perceived illness or other injury that occurred in a planned study using an approved VMP, regardless of how or why the VMP is used.

“Lack of Expected Effectiveness (Clinical Studies)” is a non-spontaneous report that involves a lack of expected effectiveness (LOEE) that occurred during a planned study using an approved VMP, regardless of how or why the VMP is used.

“Both Safety Issue and Lack of Expected Effectiveness (Clinical Studies)” is a non-spontaneous report that represents both a safety issue and LOEE that occurred during a planned study using an approved VMP, regardless of how or why the VMP is used.

If the AER is associated with a planned study utilizing an approved VMP, provide the approved VMP name in B.2.1, Registered or Brand Name, and the NADA/ANADA number as part of the B.2.12, Registration Identifier.

Contains Nonbinding Recommendations

MANUFACTURING/PRODUCT DEFECTS

The following terms describe an AER where either humans or animals were exposed to the VMP that had a manufacturing/product defect and an AE occurred:

- MANUFACTURING/PRODUCT DEFECT (SAFETY)
- MANUFACTURING/PRODUCT DEFECT (LOEE)
- MANUFACTURING/PRODUCT DEFECT (BOTH SAFETY AND LOEE)

These terms apply to both spontaneous and non-spontaneous reports.

MEDICATION ERRORS

Medication errors are defined by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use." (www.nccmerp.org). FDA focuses on medication errors related to drug names, labeling and/or packaging of the product.

There is no CVM regulatory reporting requirement for medication errors. However, medication error reports are of great value to CVM because they can lead to label/package design improvements and may point to considerations about the product name and other potential sources of error. Evaluation of these reports is essential in CVM's efforts to protect animal and human health. Although there is no specific category for medication errors, such reports may be submitted for your convenience under the category of Manufacturing/Product Defect.

A medication error might be identified without any animal exposure, such as when an error almost occurred but was identified and exposure was prevented. Sometimes animal exposure occurs but without an adverse event, and the reporter wishes to alert the MAH to the potential of an adverse event.

Should you voluntarily choose to report a medication error, enter Type of Information as follows:

- If no animals were exposed, or if no adverse event occurred, designate the Type of Information as MANUFACTURING/PRODUCT DEFECT WITH NO ADVERSE EVENTS.
- If an adverse event occurred, designate the Type of Information as MANUFACTURING/PRODUCT DEFECT (SAFETY)

LACK OF EXPECTED EFFECTIVENESS (LOEE)

A LOEE is considered to be an AE. Complete Form FDA 1932 in the same manner as a safety report. Include the number of animals treated and affected.

Contains Nonbinding Recommendations

The “Expedited” (fifteen-day NADA/ANADA alert report) report provides information on each serious, unexpected ADE. An unexpected ADE is an adverse event that is not listed in the current labeling (21 CFR 514.3). Based on this definition, all LOEE events would be unexpected. Because all LOEE events are considered unexpected, the determination of whether it is an expedited or periodic report depends on the seriousness of the AE. Off-label use for indication or species should be reported, as such use often reflects common clinical practice or pending supplemental application.

PART B - DESCRIPTION OF THE AE

B.1 Animal Data

Except for B.1.1, data in Part B relates to the affected animals only. In the case of human exposure, conform the descriptive information to patient privacy laws as pertinent to the country of occurrence (e.g., Health Insurance Portability and Accountability Act Privacy Rule in the United States).

If the AE concerns a group of animals of the same species, where the variability among the animals is reasonably close so that a meaningful assessment of the AE can be made, you can use a single Form FDA 1932 to report the information for the group. A medically appropriate group exhibiting similar clinical signs can be included in a single report. Describe information concerning the group in the narrative in B.3.1.

If there is too much variability among animals in the group to allow reasonable assessment of the AE, then complete a separate Form FDA 1932 for each animal that does not conform to a group. Use a separate Unique AER Identification Number for each of these case reports and provide a cross-reference for each by entering the Unique AER Identification Number in the narrative in B.3.1.

B.1.1 Number of Animals Treated (Integer Field; 12 Characters)

This is the number of animals being directly treated by the VMP(s). This does not include animals being indirectly exposed to the use of the VMP(s). This number represents all animals treated, not just those affected by the treatment (as reported in B.1.2, Number of Animals Affected).

If the actual number is unknown, estimate the number of animals treated. Report a number greater than zero, rather than a percentage, for the number of animals treated.

When separate reports for each animal are being submitted for an AE involving multiple animals, the Number of Animals Treated is the number of animals referred to in the specific AER, rather than for the overall AE.

Provide the number of animals being directly treated by the VMP(s).

Contains Nonbinding Recommendations

B.1.2 Number of Animals Affected (Integer Field; 12 Characters)

This is the total number of animals affected by the AE, whether through direct or indirect exposure (e.g., treated during pregnancy or lactation, commingled, infectious spread, etc.). If the actual number of affected animals is unknown, estimate the number of animals affected. Use a number greater than zero, rather than a percentage of the number of animals treated. If the AE involved a lack of expected effectiveness, the number of animals affected is greater than zero.

When separate reports for each animal or animal group are being submitted for an AE involving multiple animals, the Number of Animals Affected is the number of animals referred to in the specific AER, rather than for the overall AE.

Since the number of animals affected in the AE represents the total number of animals affected, whether by direct or indirect exposure, the number of animals affected may be greater than the number of animals treated. The following are examples:

1. A pregnant dog is treated with a VMP. She has no clinical signs. Two of her puppies have adverse clinical signs. The number entered in B.1.1, Number of Animals Treated, would be “1.” The number entered in B.1.2, Number of Animals Affected, would be “2.”
2. Two cows are treated with a pour-on VMP. These 2 cows and 7 more cows corralled with them experience an adverse clinical sign of a rash. The number entered in B.1.1, Number of Animals Treated, would be “2.” The number entered in B.1.2, Number of Animals Affected, would be “9.”

Provide the number of animals adversely affected by the VMP(s).

B.1.2.1 Attending Veterinarian’s Assessment of Animal Health Status Prior to VMP (Code List)

This field is a list of values regarding the attending veterinarian’s assessment of the health status of the animal(s) involved in the AE prior to their exposure to the VMP. The definitions of these values will be left to the veterinarian’s medical opinion. “Unknown” may be chosen if the attending veterinarian does not provide the information, or if there is no attending veterinarian.

In the case of human exposure, this would be the assessment by the attending physician.

Choose the value for health status of the animal(s) from the List of Veterinarian’s Health Status Assessment.

Contains Nonbinding Recommendations

B.1.3 Species (Code List)

This field is a list of values regarding the species of animal affected. Select one species per AER. Choose the value for animal species represented in B.1.2, Number of Animals Affected, from the List of Species.

For AEs involving multiple species, make a separate report for each species and provide a description and a cross-reference for each case using the Unique AER Identification Number in the narrative in B.3.1.

The species list is not intended to be all-inclusive. If the species list does not contain a value for your animal, choose “Other” and describe the species in the narrative in B.3.1.

In the case(s) where the affected species in the AE is human, choose “human” as the species.

In the case of a hybrid, choose the appropriate “Other” category from the species list. Examples:

- Wolf/Dog Hybrid, choose “Other Canids” as the species and “Wolf Hybrid” as the breed
- Zebra/Horse Hybrid, choose “Other Equids” as the species and “Equine Hybrid” as the breed

B.1.4 Breed (Code List)

This field is a list of values regarding the breed(s) of animal(s) affected.

Choose the value for the breed of the animal(s) associated with the species chosen in B.1.3 from the List of Breeds.

Breed values have not been provided for every species listed in B.1.3. If the breed list does not contain a value for your animal, choose “Other” and describe the breed in the narrative in B.3.1. In the case of a human exposure, the breed is not applicable.

The term (Unspecified) allows identification of breed if the “general” breed could be identified but not the specific one, e.g. Poodle (Unspecified) because it is not known if this is a standard, miniature, or toy poodle.

B.1.4.1 Purebred Information

The “Purebred Information” identifies an animal made up of only one breed. For reports of herds with multiple purebred animals of different breeds, report the breed for each animal. The field is repeatable to allow the capture of several breeds in a herd.

Contains Nonbinding Recommendations

Enter information in the “Purebred Information” field to identify an animal made up of only one breed, and choose the correct breed from the Type of Breed list of values.

B.1.4.2 Crossbred Information

The “Crossbred Information” identifies an animal made up of more than one breed.

Enter information in the “Crossbred Information” and up to three breeds from the Type of Breed list of values to describe a crossbred animal.

Following are examples of how to populate these fields for specific animals of different species and breeds:

- Tennessee Walking Horse: Use B.1.4.1.1 to enter Tennessee Walking Horse
(This animal is a purebred Tennessee Walking Horse.)
- Horse of undetermined breeds: Use B.1.4.2.1 to enter Crossbred Equine/Horse
(This animal is a crossbred animal but the breed makeup is not known.)
- Labrador Retriever: Use B.1.4.1.1 to enter Labrador Retriever
(This animal is a purebred Labrador Retriever.)
- “Heinz 57” Dog: Use B.1.4.2.1 to enter Crossbred Canine/Dog
(This animal is a crossbred animal but the breed makeup is not known.)
- Labrador Retriever Mix: Use B.1.4.2.1 to enter Labrador Retriever
(This animal is a crossbred animal with Labrador Retriever being a known breed but the remainder of the breed makeup is not known)
- Labrador Retriever/German Shepherd Mix: Use two fields in B.1.4.2.1 to enter Labrador Retriever; German Shepherd
(This animal is a crossbred animal composed of at least 2 breeds with Labrador Retriever and German Shepherd being the known breeds)
- Poland China/Tamworth/Landrace: Use three fields in B.1.4.2.1 to enter Poland China; Tamworth; Landrace
(This animal is composed of 3 breeds with Poland China, Tamworth, and Landrace being the known breeds.)
- “Heinz 57” Cats are identified as Domestic Shorthair, Domestic Mediumhair, or Domestic Longhair according to the length of their hair coat.
If the cat has short hair: Use B.1.4.2.1 to enter Domestic Shorthair

Contains Nonbinding Recommendations

- Siamese/Domestic Shorthair Mix: Use two fields in B.1.4.2.1 to enter Siamese; Domestic Shorthair
(This animal is a crossbred animal with Siamese and Domestic Shorthair being the known breeds.)
- Persian Mix: Use B.1.4.2.1 to enter Persian
(This animal is a crossbred animal with Persian being the known breed but the remainder of the breed makeup is not known.)

Examples for herds:

- The herd consists of purebred Angus, Angus/Shorthorn mixes, and Charolais/Angus/Shorthorn mixes:

Use B.1.4.1.1 to enter Angus;

Use three fields in B.1.4.2.1 to enter Angus; Shorthorn; Charolais
- The herd consists of various types of purebreds but the individual breeds are not known: Use B.1.4.1.1 to enter Mixed
- The herd consists of various types of crossbreds, but their makeup is not known or there are a great many different contributing breeds: Use B.1.4.2.1 to enter Mixed

B.1.5 Gender (Code List)

This field is a list of values that describes whether the affected animal(s) is male or female. Choose the value for the gender of the animal(s) reported in B.1.2, Number of Animals Affected, from the List of Gender.

Choose “Mixed” where a group is reported, and the group represents both male and female animals. If “Mixed” is chosen, describe the gender of the animals involved in the narrative in B.3.1. Choose “Unknown” when the gender is not known for the single animal affected or when the gender is not known for all animals in the group. If “Unknown” is chosen, describe the known gender of any of the animals in the group in the narrative in B.3.1.

B.1.6 Reproductive Status (Code List)

This field is a list of values that describes whether the affected animal(s) is intact or neutered. Choose the value for the reproductive status of the animal(s) reported in B.1.2, Number of Animals Affected, from the List of Reproductive Status.

Contains Nonbinding Recommendations

Choose “Mixed” where group information is reported, and the group represents both intact and neutered animals. If “Mixed” is chosen, describe the reproductive status of the group in the narrative in B.3.1. Choose “Unknown” when the reproductive status is not known for the single animal affected or when the reproductive status is not known for all animals in the group. If “Unknown” is chosen, describe the known reproductive status of any of the animals in the group in the narrative B.3.1.

B.1.7 Female Physiological Status (Code List)

This field is a list of values that describes the pregnancy and lactation status of the affected female animal(s). Choose the value for the female physiological status of the animal(s) reported in B.1.2, Number of Animals Affected, from the List of Female Physiological Status.

Choose “Not Applicable” if there are only male animals and/or neutered female animals. For a mixed group of male and female animals, choose the physiological status appropriate for the female animals. If the group has multiple different physiological statuses, choose “Mixed” and describe the physiological status of the group in the narrative in B.3.1. If only one of the physiological factors is known, provide the physiological status of the animal in the narrative in B.3.1. Choose “Unknown” if the pregnancy and/or lactating status of the animal(s) is not known.

B.1.8 Weight

This field describes the weight of the animal(s) involved in the AE. Enter the weight in kilograms (kg).

B.1.8.1 Measured, Estimated, Unknown Weights (Code List)

This list describes how the weight of the affected animal(s) was determined.

- Measured — the animal was weighed.
- Estimated — the animal was not weighed but an estimation of its weight can be made.
- Unknown — the animal’s weight is not known.

If the weight is “Unknown”, then B.1.8.2, Minimum Weight, and B.1.8.3, Maximum Weight, can’t contain a numeric value.

Choose the value from the List of Precision Categories.

Contains Nonbinding Recommendations

B.1.8.2 Minimum Weight (Numeric Field)

This is the minimum weight of the affected animals, or the weight of a single affected animal. If only a single animal is affected, enter its numerical weight in the minimum weight field. If a group of animals is affected, enter the numerical weight of the smallest individual animal or an average weight of a subgroup of the smallest animals within the group.

The field allows no more than 3 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

B.1.8.3 Maximum Weight (Numeric Field)

This is the maximum weight of the affected animals. Enter the numerical weight of the largest individual animal or an average weight of a subgroup of the largest animals within the group. Do not use this field if the case involves only a single animal.

The field allows no more than 3 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

B.1.9 Age

B.1.9.1 Measured, Estimated, Unknown Age (Code List)

This list describes the method used to determine the age of the affected animal(s).

- Measured — the age of the animal(s) is known.
- Estimated — the age of the animal(s) is not known, but an estimation of the age can be made.
- Unknown — the age of the animal(s) is not known.

If the age is “Unknown”, then B.1.9.2, Minimum Age, and B.1.9.3, Maximum Age, cannot contain numeric values.

Choose the value from the List of Precision Categories.

B.1.9.2 Minimum Age (Numeric Field)

This is the age of the youngest of the affected animals, or the age of a single affected animal. If only a single animal is affected, enter its numerical age in the minimum age field. If a group of animals is affected, enter the age of the youngest individual animal or an average age of a subgroup of the youngest animals within the group to represent the minimum age of the group.

Contains Nonbinding Recommendations

Enter the numerical minimum age for the animal(s) reported in B.1.2, Number of Animals Affected.

The field allows no more than 2 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

B.1.9.2.1 Minimum Age Units (Code List)

Choose the time units from the List of Units of Measurement associated with the numerical minimum age reported in B.1.9.2, Minimum Age.

B.1.9.3 Maximum Age (Numeric Field)

This is the age of the oldest of the affected animals. For groups of animals, either use the numerical age of the oldest individual animal or an average age of a subgroup of the oldest animals within the group. Do not use this field if the case involves only a single animal.

Enter the numerical maximum age for the animal(s) reported in B.1.2, Number of Animals Affected.

The field allows no more than 2 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

B.1.9.3.1 Maximum Age Units (Code List)

Choose the time units from the List of Units of Measurement associated with the numerical maximum age reported in B.1.9.3, Maximum Age.

B.2 VMP(s) Data and Usage

Fields B.2.1 – B.2.5.1 are repeatable for each VMP involved in the AE. Do not combine different VMPs within the same data fields. Use the repeatable function to describe each VMP separately.

Use fields B.2.6.1 – B.2.6.5 for AER involving product/manufacturing defects.

B.2.1 Registered or Brand Name (Open Ended Text)

Specifically, this is the name by which the product is presented by the MAH. This is known in various countries as the Registered, Brand, Proprietary or Trade Name of the product.

Contains Nonbinding Recommendations

If the reporting MAH does not own or is not responsible for the VMP, and if the registered or brand name(s) is not available, enter “Unknown” in this field and enter the active ingredient(s) in B.2.2.1, Active Ingredient.

For AEs related to more than one VMP held by the reporting MAH, if the primary reporter suspects that each may have contributed to the AE, submit separate reports under the Registration Identifier for each VMP. If the primary reporter does not believe the other VMPs contributed to the AE, additional reports need not be submitted.

Provide the complete/entire registered or brand name for the VMP(s) involved in the AE.

B.2.1.1 Product Code (Open Ended Text)

The product code is the National Drug Code (NDC) number for U.S. FDA-regulated products. This code is a combination of the labeler and product code components of the NDC number. The labeler code of the NDC number is a number containing up to 6 digits. The product code of the NDC number is either a 4- or 3-digit number. Separate the labeler code and product code of the NDC number by a dash (“-”) (e.g., 0123-1234, 0001-1234, 12345-123, or 12367-1234).

Provide the product code for the VMP(s) involved in the AE.

B.2.1.2 Registration Identifier (Open Ended Text)

The registration identifier is a combination of the 3-character ISO 3166 code for the country where the VMP is approved, the 8-character RA Identifier Code, and the registration number of the VMP involved in the AE.

- Registration Number: For FDA-regulated VMPs, the registration number is the 1-character application/file identifier followed by the 6 numbers assigned by FDA for that application/file (e.g., A200999, N199999, I999999).

The following table lists the 1-character application/file identifiers.

Application/File Type	1-Character Application/File Identifier
Abbreviated New Animal Drug Application	A
Generic Investigational New Animal Drug Application	J
Investigational New Animal Drug	I
New Animal Drug Application	N
MUMS Index File	Z
Unapproved Animal Drug Products	D

Contains Nonbinding Recommendations

Provide the registration identifier (application number) for your VMP(s). Choose the appropriate 3-character ISO 3166 Country Code and the RA Identifier code from the List of ISO 3-Digit Country Codes and List of Identifier Codes for Regulatory Authorities, respectively.

For the VMP(s) for which you are not responsible, provide the registration identifier, if known.

If the registration identifier cannot be determined due to insufficient information from the reporter, enter “Cannot Be Determined.”

Domestic Reports (Approved U.S. FDA Products)

Domestic reports are those AERs that involve an FDA-regulated VMP, regardless of the country in which the AE occurs.

For FDA-approved VMP(s), the registration identifier is the 3-character country code, 8-character RA Identifier Code, and FDA Application/File Number (e.g., USA-USFDACVM-N199999, USA-USFDACVM-I999999, USA-USFDACVM-A200999). Following are some examples of domestic reports:

- An AE occurring in the United States with an FDA-approved VMP.
- An AE occurring in Germany with an FDA-approved VMP (e.g., U.S. military personnel bought the VMP on a military base in Frankfurt).
- An AE occurring in Japan with an FDA-approved VMP (e.g., Japanese visitor bought VMP in Hawaii and used product in Tokyo).

Unapproved Animal Drug Products

These are veterinary products that are not FDA approved but that are marketed in the U.S. and that are commonly used in veterinary practice. Some examples include: oral health care products, subcutaneous fluids, chemotherapeutic agents, injectable vitamins, and heparin. If the MAH chooses to submit a report for a VMP that is not FDA approved, we recommend Form FDA 1932 be used to submit the report.

Contact the Pharmacovigilance Liaison in CVM’s Division of Veterinary Product Safety at CVMAESupport@fda.hhs.gov for a “D Number” for use as part of the registration identifier to which this product would be submitted.

Foreign Reports

Foreign reports are those AERs that involve a VMP that is the same as or similar to an FDA-regulated VMP but that is not the FDA-approved product (i.e., may have different labeling, different brand name, etc.). If the MAH chooses to submit a report for a VMP that is the same as or similar to an FDA-approved product, we recommend Form FDA 1932 be used to submit the report.

Contains Nonbinding Recommendations

- Same pharmaceutical VMP: The VMP originates from the same MAH with the same active ingredient(s) and formulation as the product approved in the United States. For example, the product has a different name, or the label is in a different language, or the product has different indications than the FDA-regulated VMP.

Example: the FDA-approved VMP named “Newcomer” is registered with the European Medicines Agency as “Forthright.” The registration identifier is GBR-EUEMEA00-xxxxxxx.

- Similar pharmaceutical VMP: The VMP is from the same MAH, containing the same active ingredient(s), major excipients with the same or similar pharmaceutical function, and at least one common registered species as the product approved in the United States. For example, the product has a different strength, formulation, or is a product not approved in the U.S.

Example: the FDA-approved VMP contains the active ingredient at 50 milligrams (mg)/milliliter (ml). The Canadian-approved VMP contains the active ingredient at 70 mg/ml. The registration identifier is CAN-CANHCVDD-xxxxx.

If the registration identifier cannot be determined due to insufficient information from the reporter, enter “Cannot Be Determined.”

B.2.1.3 Anatomical Therapeutic Chemical Vet (ATCvet) Code (Open Ended Text)

The ATCvet code is an Anatomic Therapeutic Chemical system for the classification of substances intended for therapeutic use, and can serve as a tool for the classification of VMPs. More information about the ATCvet code is available at <http://www.whooc.no/atcvet/>.

If your VMP does not have an ATCvet code, you can request it through the website given above. Use the free text Unknown in this ATCvet Code text field until your ATCvet code is supplied. Please notify CVM of your ATCvet code when it is supplied to you.

B.2.1.4 Company or MAH (Open Ended Text)

Provide the name(s) of the company or MAH that owns the VMP(s) involved in the AE.

B.2.1.5 MAH Assessment (Open Ended Text)

This is the assessment by the MAH of the association between the use of the VMP and the AE. Each VICH region may have its own requirements for this assessment.

Contains Nonbinding Recommendations

B.2.1.6 RA Assessment

B.2.1.6.1 *RA Assessment Term (Code List)*

This is the assessment by the RA of the association between the use of the VMP and the AE. Each RA may have its own requirements for this assessment.

Choose a value from the List of RA Assessment Categories

B.2.1.6.1.1 Explanation Relating to Assessment (Open Ended Text)

This is the explanation of the assessment provided by the MAH or the RA about the association between the use of the VMP and the AE.

Enter the explanation of the assessment provided by the MAH or the RA.

B.2.1.7 Route of Exposure (Code List)

This is the route by which the VMP was administered. Field B.2.1.7, Route of Exposure, and subfields are repeatable for each route of exposure for any given VMP.

Choose from the List of Route of Exposure the route of exposure for the VMP(s).

B.2.1.7.1 Dose per Administration

This is the actual dose administered to the animal involved in the AE. Field B.2.1.7.1, Dose per Administration, and subfields are repeatable if different doses of the VMP are given over time.

The denominator field allows description of the dose recipient on the basis of an individual animal or enclosure in a herd situation, rather than requiring complicated calculation of an average dose based on the weight of the animals.

Complex situations, such as premixes for multiple animals, should be described in the narrative.

B.2.1.7.1.1 Numeric Value for Dose (Numerator) (Numeric Field)

This is the quantity/volume of the actual dose given, e.g., number of tablets, number of boluses, amount of feed, quantity of solution, etc. For example, the veterinarian gives the animal 10 ml of the VMP, which has strength of 13 milligrams (mg)/ml (as reported in B.2.2.1.1 – B.2.2.1.1.1). The numeric value reported in this field would be “10.”

Contains Nonbinding Recommendations

Enter the numeric value for the dose administered.

(The field allows no more than 4 places to the right of the decimal and a total of 12 characters (which includes the decimal point)).

B.2.1.7.1.1.1 Units of Value for Dose (Numerator) (Code List)

These are the units that qualify the numeric value for dose.

Choose from the list of values for List of Units of Measurement or List of Units of Presentation the unit associated with the numeric value for dose entered in B.2.1.7.1.1, Numeric Value for Dose.

B.2.1.7.1.2 Numeric Value for Dose (Denominator) (Numeric Field)

This describes the recipient of the dose by individual animal, weight, volume, etc.

The field allows no more than 4 places to the right of the decimal and a total of 12 characters (which includes the decimal point)).

B.2.1.7.1.2.1 Units of Value for Dose (Denominator) (Code List)

These are the units that qualify the numeric value for dose.

Choose from the list of values for List of Units of Measurement or List of Units of Presentation, or Dose Denominator Qualifiers the unit associated with the numeric value for dose entered in B.2.1.7.1.2, Numeric Value for Dose.

Examples of how to enter information for Dose and Dose Unit:

The owners give 3 tablets to their dog.

Numeric value for dose (numerator)	3
Units of value for dose (numerator)	tablets
Numeric value for dose (denominator)	1
Units of value for dose (denominator)	animal

Contains Nonbinding Recommendations

The veterinarian gives each animal in the herd 10 ml of the VMP per kg of body weight.

Numeric value for dose (numerator)	10
Units of value for dose (numerator)	ml
Numeric value for dose (denominator)	1
Units of value for dose (denominator)	kg

The pond of 100,000 fish is administered a one liter container of a 100 mg/L strength liquid tetracycline at a dose of 100 mg/1000 L.

Numeric value for dose (numerator)	1
Units of value for dose (numerator)	container
Numeric value for dose (denominator)	1000
Units of value for dose (denominator)	L

Or

Numeric value for dose (numerator)	1
Units of value for dose (numerator)	L
Numeric value for dose (denominator)	100,000
Units of value for dose (denominator)	animals

A cow is infused with 1 tube of VMP in her right front quarter.

Numeric value for dose (numerator)	1
Units of value for dose (numerator)	tube
Numeric value for dose (denominator)	1
Units of value for dose (denominator)	quarter

A goat is infused with 1 tube of VMP in her left mammary gland.

Numeric value for dose (numerator)	1
Units of value for dose (numerator)	tube
Numeric value for dose (denominator)	1
Units of value for dose (denominator)	teat

B.2.1.7.1.3 Interval of Administration

This is the frequency of administration of the VMP(s) involved in the AE. Field B.2.1.7.1.3, Interval of Administration, and subfields are repeatable if there are multiple frequencies of administration for the same given dose per administration.

Contains Nonbinding Recommendations

B.2.1.7.1.3.1 Numeric Value for Interval of Administration (Integer Field)

This is a number that characterizes the frequency of administration of the VMP(s). Enter the numeric value for the interval of administration.

- Enter the number “1” in B.2.1.7.1.3.1, Numeric Value for Interval of Administration, to represent “once.”

B.2.1.7.1.3.1.1 Units of Value for Interval of Administration (Code List)

These are the units that qualify the numeric value of the interval of administration. Do not use this field unless a value is provided in B.2.1.7.1.3.1, Numeric Value for Interval of Administration.

Use the time unit from the List of Units of Measurement) for interval of administration associated with the numeric value provided in B.2.1.7.1.3.1, Numeric Value for Interval of Administration.

- If a value is entered for the Numeric Value for Interval of Administration, choose “Years” to represent the situation where the VMP was given only once.

B.2.1.7.1.3.2 Date of First Exposure (Date Field — Day, Month, Year)

This field request information regarding the date on which the animal was first treated with the VMP. Enter the “Day,” “Month,” and “Year” for the date of first exposure for each VMP, if multiple VMPs are involved in the AE.

Enter the date on which the animal was first exposed to the VMP. If the actual day of first exposure cannot be supplied, just enter the “Month” and the “Year.” If the month of first exposure cannot be supplied, just enter the “Year”.

B.2.1.7.1.3.3 Date of Last Exposure (Date Field — Day, Month, Year)

This is the date on which the animal was last treated with the VMP. Enter the “Day,” “Month,” and “Year” for the date of last exposure for each VMP, if multiple VMPs are involved in the AE. If the treatment with the VMP is still ongoing, enter the date the report was received by the MAH.

Enter the date on which the animal was last exposed to the VMP. If the actual day of last exposure cannot be supplied, just enter the “Month” and the “Year.” If the month of last exposure cannot be supplied, just enter the “Year”.

Contains Nonbinding Recommendations

Examples of how to enter information for Interval of Administration Fields and Exposure Dates

A tablet given once on August 1, 2006, is entered as follows:

- Enter the number “1” in B.2.1.7.1.3.1, Numeric Value for Interval of Administration, to represent “once.” Choose the unit “years” for B.2.1.7.1.3.1.1, Units of Value for Interval of Administration. The “per” is understood and does not need to be entered.
- Enter the day “01” in the day field of B.2.1.7.1.3.2, Date of First Exposure.
- Enter the month “08” in the month field of B.2.1.7.1.3.2, Date of First Exposure.
- Enter the year “2006” in the year field of B.2.1.7.1.3.2, Date of First Exposure

A tablet given once per day from August 1, 2006, to February 10, 2007, is entered as follows:

- Enter the number “1” in B.2.1.7.1.3.1, Numeric Value for Interval of Administration, to represent “once.” Choose the unit “day” for B.2.1.7.1.3.1.1, Units of Value for Interval of Administration. The “per” is understood and does not need to be entered.
- Enter the day “01” in the day field of B.2.1.7.1.3.2, Date of First Exposure.
- Enter the month “08” in the month field of B.2.1.7.1.3.2, Date of First Exposure.
- Enter the year “2006” in the year field of B.2.1.7.1.3.2, Date of First Exposure.
- Enter the day “10” in the day field of B.2.1.7.1.3.3, Date of Last Exposure.
- Enter the month “02” in the month field of B.2.1.7.1.3.3, Date of Last Exposure.
- Enter the year “2007” in the year field of B.2.1.7.1.3.3, Date of Last Exposure.

A tablet given once per day from August 2006 to February 2007, but with unknown actual start and end dates, is entered as follows:

- Enter the number “1” in B.2.1.7.1.3.1, Numeric Value for Interval of Administration, to represent “once.” Choose the unit “day” for B.2.1.7.1.3.1.1, Units of Value for Interval of Administration. The “per” is understood and does not need to be entered.
- Leave blank the day field of B.2.1.7.1.3.2, Date of First Exposure.
- Enter the month “08” in the month field of B.2.1.7.1.3.2, Date of First Exposure.
- Enter the year “2006” in the year field of B.2.1.7.1.3.2, Date of First Exposure.
- Leave blank the day field of B.2.1.7.1.3.3, Date of Last Exposure.
- Enter the month “02” in the month field of B.2.1.7.1.3.3, Date of Last Exposure.

Contains Nonbinding Recommendations

B.2.2 Active Ingredient(s)

Provide the active ingredient(s) for your VMP(s).

Fields B.2.2.1 – B.2.2.1.2 are repeatable for each VMP involved in the AE. In cases where the user has altered the physical characteristics of the VMP prior to administration (e.g., mixing VMPs together, diluting the VMP, etc.), this field and its subfields are to be entered with the characteristics of the VMP as labeled. In such cases, leave the Dose per Administration field (B.2.1.7.1) blank and describe the dose administered in the narrative in B.3.1.

B.2.2.1 Active Ingredient(s) (Open Ended Text)

For VMP(s) where the reporting MAH does not own or is not responsible for the VMP(s), provide brand name(s) in B.2.1, Registered or Brand Name, or active ingredient(s) in B.2.2.1, Active Ingredient.

Provide the active ingredient(s) for your VMP(s).

B.2.2.1.1 Numeric Value for Strength (Numerator) (Numeric Field) and

B.2.2.1.2 Numeric Value for Strength (Denominator) (Numeric Field)

Strength is the concentration of the active pharmaceutical ingredient of the VMP(s) involved in the AE and is a ratio of the active pharmaceutical ingredient (numerator) to the units of the product (denominator), and is reported as a ratio of the 2 quantities. Complete the information for both the numerator and denominator.

Provide the numeric strength of the active ingredients for the VMP(s) for which the reporting MAH is responsible based on the labeled, approved strength. Report the strength and its associated strength unit for each active ingredient in the VMP. If the strength administered was not the concentration as labeled on the product, provide a description of the strength of the active ingredient(s) in the narrative in B.3.1

For VMP(s) for which the MAH is not responsible, provide the labeled, approved strength, if known. If the strength is not known, enter “1 Unknown” for the Strength and Strength Unit of both the Numerator and the Denominator.

Report terms typically used to describe premixes, such as parts per million (ppm) or grams (g)/ton, as g/kg, for example, 100 g/10 kg Type A Medicated Article.

The field allows no more than 4 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

Contains Nonbinding Recommendations

B.2.2.1.1.1 Units for Numeric Value for Strength (Numerator) (Code List)

For the numeric value of strength (numerator), choose the strength unit from the List of Units of Measurement.

B.2.2.1.2.1 Units for Numeric Value for Strength (Denominator) (Code List)

For the numeric value of strength (denominator), choose the strength unit from the List of Units of Measurement or List of Units of Presentation.

Examples of how to enter information for Strength and Strength Unit:

1. 100 mg active ingredient to 1 kg of product = 100 mg/1 kg

Numeric value for strength (numerator)	100
Units of value for strength (numerator)	mg
Numeric value for strength (denominator)	1
Units of value for strength (denominator)	kg

2. 100 mg active ingredient in each tablet = 100 mg/1 tablet

Numeric value for strength (numerator)	100
Units of value for strength (numerator)	mg
Numeric value for strength (denominator)	1
Units of value for strength (denominator)	Tablet

3. The Strength is not known

Numeric value for strength (numerator)	1
Units of value for strength (numerator)	Unknown
Numeric value for strength (denominator)	1
Units of value for strength (denominator)	Unknown

B.2.2.1.3 Active Ingredient Code (Code List)

This is a list of values of the active ingredient substance associated with the unique ingredient identifier (UNII) codes. The UNII code is a non-proprietary, free, unique, unambiguous, non semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. The UNII code is generated by the joint FDA/United States Pharmacopeia (USP) Substance Registration System (SRS).

Click on the following link for the list of the codes:

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Contains Nonbinding Recommendations

- Scroll down to SPL Terminology Files for Validation and choose [Active Ingredient-Active Moiety Relationship/Basis of Strength](#)⁴⁴ (Excel)

Provide the AM UNII for your VMP(s) from the list of values.

If there are multiple UNII codes for the same active ingredient moiety, choose the same code used for your product in Structured Product Labeling.⁷

B.2.2.2 Dosage Form (Code List)

This is a list of values of the labeled dosage form of the VMP(s) involved in the AE.

Choose a value for the labeled dosage form of the VMP(s) involved in the AE from the List of Dosage Forms.

B.2.3 Lot Number (Open Ended Text)

Enter the lot number of the VMP(s) involved in the AE.

Use a separate field for each lot number. Fields B.2.3 – B.2.3.1 are repeatable if there are multiple lot numbers involved in the AE.

B.2.3.1 Expiration Date (Date Field — Day, Month, Year)

Enter the expiration date of the VMP(s) involved in the AE. If the actual day of expiration cannot be supplied, just enter the “Month” and the “Year.” If the month of expiration cannot be supplied, just enter the “Year”.

B.2.4 Who Administered the VMP(s) (Code List)

This field is a list of values describing the individual who administered the VMP(s) to the animal involved in the AE.

Choose from the List of Administrators of VMP the role of the person(s) who administered the VMP(s). For an agent acting on behalf of the animal owner, choose “Animal Owner.” For an agent acting on behalf of the veterinarian, choose “Other Health Professional.” In cases where multiple people administered the VMP(s) (e.g., the veterinarian administered the VMP at their place of business and the animal owner continued the treatment at home), choose “Multiple Administrators” and provide a detailed explanation of each person’s role in the narrative in

⁷ Structured Product Labeling (SPL) is the electronic format used by manufacturers to submit content of labeling to the FDA for drug establishment registration and drug product listing. You can find information on SPL at the following link: <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Contains Nonbinding Recommendations

B.3.1. Choose “Patient” for when the affected species in the AE is human and for cases where an animal inadvertently exposed itself to the VMP.

B.2.5 Use According to Label (Code List)

This is a list of values (Yes, No, or Unknown) describing whether the VMP(s) was used according to its labeled recommendations/directions of use.

Choose “Yes” if the VMP(s) was used according to its labeled recommendations/directions of use. Choose “No” if the VMP was used in an off-label use manner. Choose “Unknown” if the information is not available. If the VMP was used according to the label, and an AE involving human exposure results, choose “Yes.”

Examples:

- Human applied topical medication to cat according to label directions and now has a headache. Choose “Yes.”
- Human applied topical medication to cat according to label directions but accidentally splashed some on self and now has a skin rash. Choose “Yes.”
- Human accidentally ingested anti-anxiety medication prescribed for dog and now has a nervous twitch. Choose “No.”

B.2.5.1 Explanation for Off-Label Use

Provide information for this field if “No” was chosen in the Use According to Label field (B.2.5).

This field is a series of nine questions used to describe how the VMP was used in an off-label manner. Answer “Yes” to as many questions as applicable to characterize the manner of off-label use and provide a description of the off-label use in the narrative.

B.2.5.1.1 Was the target species Off-Label

B.2.5.1.2 Was the route of administration Off-Label

B.2.5.1.3 Was the animal overdosed

B.2.5.1.4 Was the animal underdosed

Contains Nonbinding Recommendations

B.2.5.1.5 Was the treatment regime Off-Label

B.2.5.1.6 Was the indication Off-Label

B.2.5.1.7 Was the storage condition Off-Label

B.2.5.1.8 Was the product expired

B.2.5.1.9 Was there any other Off-Label issue

B.2.6 Product/Manufacturing Defect Information

The fields within this subsection (B.2.6.1 – B.2.6.5) need only be completed for product/manufacturing defect AERs. Fields B.2.6.1–B.2.6.5 are repeatable if there are multiple manufacturers involved in the AE.

B.2.6.1 Manufacturing Site Identifier Number (Open Ended Text)

The manufacturing site identifier number identifies the site where the product/manufacturing defect issue occurred.

Enter the manufacturer's 7 to 10 digit FDA Establishment Identifier (FEI Number) or 9-digit Data Universal Numbering System (D-U-N-S®) Number.

B.2.6.1.1 Manufacturer's Identifier Type (Code List)

Identify the Manufacturing Site Identifier Number Type, i.e., whether it is an FEI or D-U-N-S number. Choose a code from the List of Manufacturer Site Identifiers (US Only).

B.2.6.2 Manufacturing Date (Date Field — Day, Month, Year)

The Manufacturing Date is typically set by each individual company's processes and documented internally.

Provide the date the VMP was manufactured.

Contains Nonbinding Recommendations

B.2.6.3 Number of Defective Items (Numeric Field)

Provide the number of defective items of the VMP described in the AE, based on the applicable retail unit. For example, if a product is sold as 20 syringes per carton, enter the number of defective syringes.

The field allows no more than 4 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

B.2.6.3.1 Defective Item Units (Code List)

Choose the unit from the List of Package Types (US Only) associated with the defective items from field B.2.6.3.

Examples of how to enter information for Number of Defective Items and Defective Item Units:

1. The product is sold in bottles. Twelve bottles in the shipped carton were leaking.
Number of Defective Items = 12
Defective Item Units = Bottles
2. The product is sold as 100 syringes per carton. Three cartons were shipped. Twenty of the syringes in the shipped cartons arrived crushed.
Number of Defective Items = 20
Defective Item Units = Syringes

B.2.6.4 Number of Items Returned (Numeric Field)

Provide the number of VMP items returned as described in the AE. For example, if a product is sold as 20 syringes per carton, enter the number of syringes returned.

The field allows no more than 4 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

B.2.6.4.1 Returned Item Units (Code List)

For the items reported in B.2.6.4, select the unit type from the List of Package Types (US Only).

Contains Nonbinding Recommendations

Examples of how to enter information for fields, Number of Items Returned, and Returned Item Units:

1. The product is sold in bottles. Twelve bottles in the shipped carton were leaking. One of the leaking bottles was returned.
Number of Returned Items = 1
Returned Item Units = Bottles
2. The product is sold as 100 syringes per carton. Three cartons were shipped. Twenty of the syringes in the shipped cartons arrived crushed. All twenty of them were returned.
Number of Returned Items = 20
Defective Item Units = Syringes

B.2.6.5 Office of Regulatory Affairs (ORA) District Field Office (Code List)

This field is a list of values for selecting the ORA District Field Office or local FDA resident post to which the product/manufacturing defect information is being submitted for three-day NADA/ANADA field alert reports.

Use the List of ORA District Field Offices (US Only) to provide the office to which the AE is being sent. Choose “Not Applicable” if the report was not sent to an FDA ORA District Field Office or local FDA resident post.

B.3 Adverse Event Data

B.3.1 Narrative of AE (Open Ended Text)

Provide a detailed narrative description of the AE, including a chronological history that clearly identifies relevant information, such as:

- relevant medical history
- reason for using the VMP(s)
- possible contributing factors
- sites of response
- severity of response
- pertinent laboratory and other diagnostic test results
- treatment of the AE
- date of death (if applicable)
- necropsy results, including accurate description of gross pathology and accurate description of histopathologic findings including a pathologist’s assessment
- comments on assessments from veterinarian or MAH
- other significant information pertaining to the adverse event

Contains Nonbinding Recommendations

If multiple laboratory tests were performed, the results for each relevant test date can be provided as an attachment. Provide a description of all attached documents at the end of the narrative.

If the AER was generated by a poison control center or other contract organization, provide the case number (if available). If the AER relates to an animal in a clinical or pilot study, provide the study number (i.e., approved animal study protocol number).

For VMP product/manufacturing defect reports, enter a detailed description of: 1) the defect and the investigation results; 2) actions taken by the MAH/manufacturer/distributor to address the problem, including any corrective actions taken; and 3) any notifications that have been issued to alert the vendor/manufacturer to the defect issues.

B.3.2 Adverse Clinical Manifestations (Code List)

These fields are lists of values for the clinical signs that occurred during the AE. There are three vocabulary lists for use in describing adverse clinical manifestations. You may choose terms from one or more of these lists to most completely and accurately describe the adverse event:

- VeDDRA Terms
- FDA CVM Internal Adverse Events Terms (US Only)
- FDA CVM Internal Product Problem/Medication Error Terms (US Only)

VeDDRA Terms

The VeDDRA Vocabulary is the VICH-harmonized list for submission of AE terms. Refer to the VeDDRA⁸ medical terminology to describe the adverse clinical manifestations. VeDDRA terminology for animal and human AEs is the clinical dictionary used to describe adverse clinical manifestations.

The most current list, as well as the full explanation and Guidance Notes on the Use of VeDDRA Terminology for Reporting Adverse Events in Animals, can be downloaded from the European Medicines Agency Website at

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000173.jsp&mid=WC0b01ac058002dea6

Choose the lowest level term as used in VeDDRA for each adverse clinical manifestation observed in the AE. In the case of human AEs, choose terms designated as “H” (Exclusively Human) or “C” (Common). For animal adverse events, choose terms designated as “A” (Exclusively Animal) or “C” (Common).

⁸ Veterinary Dictionary for Drug Regulatory Activities

Contains Nonbinding Recommendations

FDA CVM Internal Adverse Event Terms (US Only)

CVM has a list of additional terms used internally to capture adverse clinical manifestations for which no term exists in VeDDRA. Examples include laboratory and pathology terms, as well as more specific types of reported lack of expected efficacy (LOEE). These terms are now available for use in AER submission to CVM, should you choose to use them.

If you prefer not to use the FDA CVM Internal AE Terms when reporting a LOEE, choose “Lack of Efficacy” from the VeDDRA vocabulary and describe the nature of the LOEE in the narrative in B.3.1.

FDA CVM Internal Product Problem/Medication Error Terms (US Only)

CVM has a list of additional terms used internally to describe product problems, as such terms do not exist in VeDDRA. Examples include problems related to manufacturing and shipping, as well as terms used to describe medication errors. These terms are now available for use in AER submission to CVM, should you choose to use them.

If you prefer not to use the FDA CVM Internal Product Problem/Medication Error Terms when reporting a VMP product/manufacturing defect, choose “Product problem” and describe the nature of the defect in the narrative in B.3.1.

B.3.2.1 Number of Animals (Integer Field)

Please make a reasonable attempt to provide the number of animals affected per clinical sign. When only percentages have been made available, convert this percentage into an integer and insert this value into B.3.2.1. The way in which the MAH arrives at the integer should be provided in the narrative in B.3.1. If the reporting party cannot or will not provide an integer value or a percentage estimate, please describe in the narrative.

B.3.2.1.1 Accuracy of the Number of Animals (Code List)

If a value is entered in the Number of Animals field, please indicate whether the integer provided under B.3.2.1 is an actual or estimated number. Choose a value from the List of Accuracy of the Number of Animals.

B.3.3 Date of Onset of AE (Date Field — Day, Month, Year)

Enter the date of onset of the AE. If the actual date is unknown, enter the approximate date information using the reporter’s description in the fields “Length of Time Between Exposure to VMP and Onset of AE” (B.3.4 below), and “Date of First Exposure” (B.2.1.7.1.3.2 above). If the actual day of onset cannot be supplied, just enter the “Month” and the “Year.” If the month of onset cannot be supplied, just enter the “Year”.

Contains Nonbinding Recommendations

B.3.4 Length of Time Between Exposure to VMP(s) and Onset of AE (Code List)

This field is a list of values for the length of time between the first exposure to the VMP and the onset of the AE. For cases where there is a clear time relationship between the administration of the VMP(s) and the onset of AE(s), choose a value from the List of Exposure and Onset Time. When a clear time relationship is difficult to determine, such as for a lack of expected effectiveness, choose “Unknown” from the List of Exposure and Onset Time.

B.3.5 Duration of the AE

This section describes the actual or approximate length of time the AE lasted.

B.3.5.1 Duration (Numeric Field)

This is the numeric value for the duration of the AE. For example, if the AE lasted 3 days, enter “3” in this field. If the AE is ongoing, enter the number based on the onset date entered in B.3.3, Date of Onset of AE, and the date entered in A.4.2, Date AER Received by MAH. In the case of the animal’s death, this field is not applicable.

Enter the numeric value for the duration of the AE.

The field allows no more than 4 places to the right of the decimal and a total of 12 characters (which includes the decimal point).

B.3.5.1.1 Duration Time Units (Code List)

This is a list of values for the unit associated with the numeric value for duration specified in B.3.5.1, Duration. For example, if the AE lasted 3 days, choose “Days.”

Choose the time units from the List of Units of Measurement associated with the numeric value for duration specified in B.3.5.1, Duration.

B.3.6 Serious AE (Code List)

This is a list of values (Yes or No) characterizing the seriousness of the AE.

“Serious,” as used in this document, means the AE was serious according to the following definition in FDA regulations at 21 CFR 514.3:

Contains Nonbinding Recommendations

Serious adverse drug experience is an adverse event that is fatal, or life-threatening, or requires professional intervention, or causes an abortion, or stillbirth, or infertility, or congenital anomaly, or prolonged or permanent disability, or disfigurement.

Choose “Yes” or “No” to answer whether or not the AE was serious.

B.3.7 Treatment of AE (Code List)

This is a list of values (Yes, No, or Unknown) describing whether or not the human or animal affected received treatment in response to the AE (e.g. pharmacological, physical rehabilitation, diet, etc.).

Select whether there was treatment for the AE. If the human or animal involved in the AE was treated, describe the treatment and the outcome from such treatment in the narrative in B.3.1.

B.3.8 Outcome to Date (Integer Field - B.3.8.1 – B.3.8.6)

This is the medical status of the animal(s) affected in the AER at the time the AE is reported to the RA. Fields B.3.8.1 – B.3.8.6 list the possible outcomes experienced by animals affected by the AER. In each field, enter the number of animals that experienced the listed outcome. The total number of animals entered in fields B.3.8.1 – B.3.8.6 should equal the number entered in B.1.2, Number of Animals Affected. We recommend that you do not enter percentages in these fields for group reports.

Determine and enter the number of animals for each of the categories below. If there are no animals represented by a given category, enter “0.”

B.3.8.1 Ongoing

Enter the number of animals described in the AER with ongoing clinical manifestations.

B.3.8.2 Recovered/Normal

Enter the number of animals described in the AER that have recovered or returned to normal health.

B.3.8.3 Recovered with Sequela

Enter the number of animals described in the AER that have recovered but are left with an altered health status.

B.3.8.4 Died

Enter the number of animals described in the AER that died (not including those that have been euthanized).

Contains Nonbinding Recommendations

B.3.8.5 Euthanized

Enter the number of animals described in the AER that were euthanized.

B.3.8.6 Unknown

Enter the number of animals with an unknown outcome.

B.3.9 Previous Exposure to the VMP (Code List)

This is a list of values (Yes, No, or Unknown) describing whether or not the affected animal(s) had been exposed to the VMP on a date previous to this AER. This field applies only to exposures outside the dates mentioned in B.2.1.7.1.3.2, Date of First Exposure, and B.2.1.7.1.3.3, Date of Last Exposure.

Select whether there was previous exposure to the VMP. If there was a previous exposure to the VMP, choose “Yes” and provide the dates of the previous exposure in the narrative in B.3.1. Choose “No” if there was no previous exposure. Choose “Unknown” if the information was not available from the reporter.

B.3.10 Previous AE to the VMP (Code List)

This is a list of values (Yes, No, Unknown, or Not Applicable) describing whether or not the affected animal(s) experienced an AE when exposed to the VMP on a date previous to this AER.

This field refers only to clinical manifestations identified during a previous exposure to the VMP.

Select whether there was a previous AE to the VMP. Choose “Yes” if there was a previous AE and “No” if there was not a previous AE to the VMP. If “Yes” is chosen, describe the clinical signs of the previous AE in the narrative in B.3.1. Choose “Unknown” if the information was not available from the reporter. Choose “Not Applicable” if there was no previous exposure, i.e., if “No” was selected in B.3.9, Previous Exposure to the VMP.

B.4 Dechallenge-Rechallenge Information

This section addresses dechallenges or rechallenges related to AEs involving a single VMP. Dechallenge is the removal, withdrawal, or discontinuance of a VMP from the animal’s therapeutic regimen. Dechallenge also includes a substantial dosage reduction. Rechallenge is the reintroduction of a VMP after the occurrence of a positive dechallenge. It also includes a substantial increase in dosage following a previous reduction which produced improvement in the clinical manifestations.

Use the narrative in B.3.1 to describe dechallenge-rechallenge information for multiple VMP AEs.

Contains Nonbinding Recommendations

B.4.1 Did AE Abate After Stopping the VMP (Code List)

This is a list of values (Yes, No, Unknown, or Not Applicable) for whether the AE abated after stopping the VMP. Choose a value for whether the AE abated after stopping the VMP. If the VMP is neither stopped nor re-introduced, choose “Not Applicable.” Choose “Unknown” if the information was not available from the reporter.

B.4.2 Did AE Reappear After Reintroduction of the VMP (Code List)

This is a list of values (Yes, No, Unknown, or Not Applicable) for whether the AE reappeared after re-introduction of the VMP. Choose a value for whether the AE reappeared after reintroduction of the VMP. If the VMP is neither stopped nor re-introduced, choose “Not Applicable.” Choose “Unknown” if the information was not available from the reporter.

B.5 Assessment of AE

B.5.1 Attending Veterinarian’s Assessment (Code List)

This is a list that describes the assessment of the attending veterinarian regarding the association between the VMP(s) and the AE (where the species affected is not human).

Choose from the List of Vet Causality Assessment the value that best describes the attending veterinarian’s assessment (if applicable). Choose “No Assessment” if a veterinarian has not been consulted about the AE. If the AE was evaluated by a physician, the value for the physician’s assessment may be entered here and details given in the narrative in B.3.1.

B.6 Report Number(s) of Linked Report(s)

This section should be used to identify reports that warrant being evaluated together, such as those for several animals in the same household, a cluster of events in one locality, or both a human and an animal adverse event after exposure to the same product.

B.6.1 Unique Adverse Event Report Identification Number (Open Ended Text)

Provide the Unique AER Identification Number of linked reports. Be sure to use the format specified in A.4.1 of this Guidance.

Contains Nonbinding Recommendations

B.6.1.1 Explanation for Linkage (Code List)

This is a list that describes possible reasons for the linked reports. Choose from the List of Explanation of Linkage the value that best describes the reason these reports should be evaluated together.

B.7 Supplemental Documents

The fields in this section can be voluntarily used by the MAH, or used by the MAH upon request from the RA for additional information on a specific AER. This section provides for the attachment of additional documents containing information relevant to the AE, such as medical record, radiology, clinical chemistry reports, newspaper articles, and letters.

If submitting by regular mail in hard copy, affix attachments to the paper form of Form FDA 1932. If submitting a CD, label the CD with the FDA CVM Application/File Type Number, the Unique Adverse Event Report Identification Number, and the date (see A.4.3) the AER was submitted to the FDA's CVM.

B.7.1 Attached Document Name(s) (File name(s) if Electronic) (Open Ended Text)

Specify the filename of the attached document, including the 3-character document type extension, such as:

- .pdf — Portable document format
- .jpg, .jpeg — Image file format
- .tiff — Tagged image file format
- .wpd — Word processing document format.

Examples of filenames:

- Documents for Princess.pdf.
- Spreadsheet of Princess lab results.pdf
- Photographs of Princess before and after treatment.jpg
- Newspaper article about the product.pdf

Refer to the List of Attached Document Kind for a list of files that are acceptable for electronic submission.

B.7.1.1 Attached Document Type(s) (Code List)

This is a list of values that describes the type of document that is attached, e.g., medical record.

Choose from the List of Document Type(s).

Contains Nonbinding Recommendations

B.8 HL7 ICSR Wrapper Data Elements

The following are the data elements to be included in the submission of an electronic report. Only sections B.8.2.2.3 – B.8.2.2.8, B.8.2.5, and B.8.2.6 are relevant for submission of the paper form.

B.8.1 Batch Wrapper

B.8.1.1 Batch Number/Identifier

The Batch Number/Identifier information identifies the collection of reports in this batch as a complete submission. The concatenation of Batch Number/Identifier Root and Extension uniquely identifies each batch of reports. This is comparable to a cover letter identifying a paper submission. It is the sender's responsibility to define and assign this identifier, as each batch submission should have a unique identifier. A Batch Number/Identifier should be supplied even if only one AER or PPR is within the batch.

B.8.1.1.1 Batch Number/Identifier – Root (Open Ended Text)

This is the submitting organization's unique "sender identifier". This data element identifies the sender of the AER or PPR message, e.g., the MAH unique ID.

B.8.1.1.2 Batch Number/Identifier – Extension (Open Ended Text)

The Batch Number/Identifier Extension is a unique tracking number assigned to a specific batch file transmitted by the sender. The form and format of this element is designated by the creator of the batch submission.

B.8.1.2 Batch Sender

This information identifies the sender who is responsible for any technical communications between FDA CVM and sender regarding the batch submission of the AER or PPR report(s).

B.8.1.2.1 Batch Sender – Root (Open Ended Text)

This is the submitting organization's unique "sender identifier". This data element identifies the sender of the AER or PPR report.

Contains Nonbinding Recommendations

B.8.1.2.2 Batch Sender – Extension (Open Ended Text)

The Batch Sender Extension is a field that contains the sender's organization name.

B.8.1.2.3 Batch Sender – Title (Open Ended Text)

The Batch Sender Title is a field that contains the title of the sender who is responsible for any corresponding communications regarding the submission.

B.8.1.2.4 Batch Sender – Last name (Open Ended Text)

The Batch Sender Last name is a field that contains the last name of the sender who is responsible for any corresponding communications regarding the submission.

B.8.1.2.5 Batch Sender – First name (Open Ended Text)

The Batch Sender First name is a field that contains the first name of the sender who is responsible for any corresponding communications regarding the submission.

B.8.1.2.6 Batch Sender – Telephone (Open Ended Text)

The Batch Sender Telephone is a field that contains the telephone of the sender who is responsible for any corresponding communications regarding the submission.

B.8.1.2.7 Batch Sender – Fax (Open Ended Text)

The Batch Sender Fax is a field that contains the fax of the sender who is responsible for any corresponding communications regarding the submission.

B.8.1.2.8 Batch Sender – e-mail (Open Ended Text)

The Batch Sender e-mail is a field that contains the e-mail of the sender (or an equally functional group e-mail address) who is responsible for any corresponding communications regarding the submission.

B.8.1.3 Batch Receiver (Open Ended Text)

The Batch Receiver information identifies the receiver of the batch report. The "Batch Receiver" of the report will be "USFDA".

Contains Nonbinding Recommendations

B.8.1.3.1 Batch Receiver – Root (Open Ended Text)

This is the submitting organization's unique "receiver identifier". This data element identifies the receiver of the AER or PPR report. This will be the "USFDA".

B.8.1.3.2 Batch Receiver – Extension (Open Ended Text)

The Batch Receiver Extension is a field that contains the organization name. This will be the "US Food and Drug Administration".

B.8.1.4 Date of Batch Creation (Date Field)

The Date of Batch Creation indicates the date the batch report is created.

B.8.1.5 VICH AER Version Number (Open Ended Text)

The VICH AER Version Number indicates the AER Message Version and Release Number on which this batch is based, currently VICH AER 1.0.0.

B.8.2 Transmission Wrapper

B.8.2.1 Message Number (Open Ended Text)

The Message Number information identifies each individual report from any other report that the sender submits. The concatenation of Message Number Root and Extension uniquely identifies each report. The message creator should ensure that this uniquely assigned identifier will never be used in another report. It is the sender's responsibility to define and assign this number, as each report should have a unique number.

B.8.2.1.1 Message Number – Root (Open Ended Text)

The Message Number Root is the submitting organization's unique "sender identifier". This data element identifies the sender of the AER or PPR report, e.g., the MAH unique ID.

Contains Nonbinding Recommendations

B.8.2.1.2 Message Number – Extension (Open Ended Text)

This data element is a field that contains the uniquely assigned identifier for the specified report (this is not the Unique Adverse Event Report Identification Number). Each submitted message should have a unique identifier assigned regardless of the Type of Submission. This field format is up to the creator of the report.

B.8.2.2 Pharmacovigilance Contact Person for the MAH (Message Sender)

This section includes fields to enter information about the person within the United States who is acting on behalf of the MAH and is the contact person for the FDA for any Pharmacovigilance issues about the report.

B.8.2.2.1 Message Sender – Root (Open Ended Text)

This is the submitting organization's unique "sender identifier". This data element identifies the sender of the AER or PPR report, e.g., the MAH unique ID. However, this sender identifier can be different from the responsible MAH if the Pharmacovigilance Contact Person is a contractor of the MAH. If so, the sender identifier should be the contractor's unique sender identifier.

B.8.2.2.2 Message Sender – Extension (Open Ended Text)

The Message Sender Extension is a field that contains the organization name of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR report.

B.8.2.2.3 Title (Message Sender – Title) (Open Ended Text)

The Message Sender Title is a field that contains the title of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR report.

B.8.2.2.4 Last Name (Message Sender – Last name) (Open Ended Text)

The Message Sender Last name is a field that contains the last name of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR report.

B.8.2.2.5 First Name (Message Sender – First name) (Open Ended Text)

The Message Sender First name is a field that contains the first name of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR report.

Contains Nonbinding Recommendations

B.8.2.2.6 Telephone (Message Sender – Telephone) (Open Ended Text)

The Message Sender Telephone is a field that contains the telephone of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR report.

B.8.2.2.7 Fax (Message Sender – Fax) (Open Ended Text)

The Message Sender Fax is a field that contains the fax of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR report.

B.8.2.2.8 Email (Message Sender – e-mail) (Open Ended Text)

The Message Sender e-mail is a field that contains the e-mail of the message sender (or an equally functional group e-mail address) who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR report.

B.8.2.3 Message Receiver

B.8.2.3.1 Message Receiver – Root (Open Ended Text)

The Message Receiver Root is a field that contains the receiver of the AER or PPR report, e.g., the RA unique ID. This will be the “USFDACVM”.

B.8.2.4 Date of Message Creation (Date Field)

This is the date on which each report inside the batch was created. This date can be the same as the date of batch creation for electronic transmission.

B.8.2.5 Report Identifier (Open Ended Text)

The format for the report identifier is the 1-character application/file identifier followed by the 6-number identifier assigned by FDA for that application/file (e.g., A200999). The application/file number is the NADA or ANADA number to which the report is being sent.

The following table represents the 1-character application/file identifiers.

Contains Nonbinding Recommendations

Application/File Type	1-Character Application/File Identifier
Abbreviated New Animal Drug Application	A
New Animal Drug Application	N
MUMS Index File	Z
Unapproved Animal Drug Products	D

The report identifier is the same as the registration number segment in the Registration Identifier field (B.2.1.2).

- **Registration Number** — For FDA-regulated VMPs, the registration number is the 1-character application/file identifier followed by the 6 numbers assigned by FDA for that application/file (e.g., A200999, N199999, I999999).

Enter the Report Identifier.

B.8.2.6 Domestic vs. Foreign Report Category (Code List)

This field is a list of values for reporting either a U.S.-approved or a non U.S.-approved product that is the same as or similar to a U.S.-approved VMP(s).

Choose a value from the List of Domestic and Foreign Report Categories.

Domestic Reports

Domestic reports are those AERs that involve an FDA-regulated VMP, regardless of the country in which the AE occurs.

Foreign Reports

Foreign reports are those AERs that involve a VMP that is the same as or similar to an FDA-regulated VMP.

- **Foreign — Same [category]:** The VMP originates from the same MAH with the same active ingredient(s) and formulation as the product approved in the United States. For example, the product has a different name, or the label is in a different language, or the product has different indications than the FDA-regulated VMP.
- **Foreign — Similar [category]:** The VMP is from the same MAH, containing the same active ingredient(s), major excipients with the same or similar pharmaceutical function, and at least one common registered species as the product approved in the United States. For example, the product has a different strength, formulation, or is a product not approved in the U.S.

Contains Nonbinding Recommendations

The following are examples of the different domestic and foreign report categories.

Domestic:

U.S.-approved VMP and AE occurred in the United States

- Report is sent to the FDA
- Report Category = Domestic

U.S.-approved VMP and AE occurred in Germany (e.g., U.S. military personnel purchased product on a military base in Frankfurt)

- Report is sent to the FDA
- Report Category = Domestic

U.S.-approved VMP and AE occurred in Japan (e.g., Japanese visitor purchased product in Hawaii, used in Tokyo)

- Report is sent to the FDA
- Report Category = Domestic

Foreign — Same [category]:

Germany-approved product and AE occurs in Germany

- Report is sent to the United States because the MAH has a “same” VMP approved by FDA
- Report Category = Foreign — Same

Foreign — Similar [category]:

Canada-approved product and AE occurs in Canada

- Report is sent to the United States because the MAH has a “similar” VMP approved by FDA
- Report Category = Foreign — Similar

B.8.2.7 Profile Identifier (Open Ended Text)

The Profile Identifier (Profile ID) Code categorizes the details of the report as Adverse Event only; Adverse Event and Product Problem; or Product Problem only.