

## Electronic Submission System (ESS) - Acceptance and Rejection Messages

The purpose of this document is to provide explanations for the acceptance and rejection messages for submissions to CVM's Electronic Submission System (ESS). Upon validation of all submissions received by the ESS, the system responds with an acceptance or rejection message.

### Acceptance Messages

The following is a list of the ESS acceptance messages

- A1: [Your submission has been accepted and has been forwarded for review.](#)
- A2: [Your submission has been accepted and has been forwarded for review. A document ID has been issued.](#)
- A3: [Your submission has been accepted as an amendment and has been forwarded for review.](#)
- A4: [Your submission has been accepted as an End Review Amendment \(ERA\) and has been forwarded for review.](#)
- A5: [Your submission has been received after CVM business hours; therefore it was logged in as received the next business day.](#)

### Rejection Messages

The following is a list of the ESS rejection messages

- R1: [Your submission has been rejected. CVM ONADE no longer accepts PDF Smart Forms as a viable solution for electronic submissions, please use eSubmitter.](#)
- R2: [Your submission has been rejected. The submitted file can not be processed for unknown reasons. Please contact CVM's eSubmitter staff for assistance at \[cvmesubmitter@fda.hhs.gov\]\(mailto:cvmesubmitter@fda.hhs.gov\).](#)
- R3: [Your submission has been rejected. The submission is not recognized as a valid eSubmitter format.](#)
- R4: [Your submission has been rejected. Only single file transmissions via FDA Gateway are allowed for eSubmitter file submission.](#)
- R5: [Your submission has been rejected. The digital signature in the submitted form does not contain an email address.](#)
- R6: [Your submission has been rejected. The stakeholder's digital signature was not validated because he/she is not registered or active in our system.](#)
- R7: [Your submission has been rejected. The Firm Name within the submission does not match our records.](#)

- R8: [Your submission has been rejected. The submission contains a Document ID that does not match our records.](#)
- R9: [Your submission has been rejected. The submission contains a Firm Name and Document ID that do not match our records.](#)
- R10: [Your submission has been rejected. The submission contains a Document ID that is not active.](#)
- R11: [Your submission has been rejected. A submission to establish the file or application \(A0000\) already exists for this Document.](#)
- R12: [Your submission has been rejected. Unable to amend previous submission because the submission number is invalid.](#)
- R13: [Your submission has been rejected. Unable to amend previous submission because it is closed](#)
- R14: [Your submission has been rejected. Unable to amend previous submission because our records indicate that a decision has already been made on the Protocol.](#)
- R15: [Your submission has been rejected. Our records indicate that additional documents are owned by your Firm. The number of additional documents is:](#)
- R16: [Your submission has been rejected. The submission contains Document ID\(s\) that do not match our records. These Document ID\(s\) are:](#)
- R17: [Your submission has been rejected. The submission contains a Firm Name and Document ID\(s\) that do not match our records. These Document ID\(s\) are:](#)
- R18: [Your submission has been rejected. The submission contains Document ID\(s\) that are not active. These Document ID\(s\) are:](#)
- R19: [Your submission has been rejected. Our records indicate that the application status is not Approved.](#)
- R20: [Your submission has been rejected. The referenced Technical Section submission number does not match our records.](#)
- R21: [Your submission has been rejected. The referenced Meeting Request submission number does not match our records.](#)
- R22: [Your submission has been rejected. The submission contains Document ID\(s\) and referenced Meeting Request submission numbers that do not match our records. These Document ID\(s\) are:](#)
- R23: [Your submission has been rejected. The submitted file is an invalid file format.](#)

## Acceptance Messages Details

The following list explains in detail the various acceptance messages.

**A1. Your submission has been accepted and has been forwarded for review.**

The submission has been accepted by the ESS and has been forwarded to the requested review division for review.

**A2. Your submission has been accepted and has been forwarded for review. A document ID has been issued.**

The submission has been accepted by the ESS and has been forwarded to the requested review division for review. No document ID was provided for the submission and one was issued by the ESS.

**A3. Your submission has been accepted as an amendment and has been forwarded for review.**

The submission has been accepted by the ESS as an amendment and has been forwarded to the requested review division for review.

**A4. Your submission has been accepted as an End Review Amendment (ERA) and has been forwarded for review.**

The submission has been accepted by the ESS as an End Review Amendment (ERA) and has been forwarded to the requested review division for review.

**A5. Your submission has been received after CVM business hours; therefore it was logged in as received the next business day.**

The submission has been accepted by the ESS after CVM business hours. The submission has been logged as being received by the ESS the next business day after it was accepted.

## Rejection Messages Details

The following list explains in detail the various rejection messages.

**R1. Your submission has been rejected. CVM ONADE no longer accepts PDF Smart Forms as a viable solution for electronic submissions, please use eSubmitter.**

A PDF Smart form is no longer supported by CVM. Please use eSubmitter to create electronic submissions to submit to CVM ONADE (click the link for information on the CVM eSubmitter Program <https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-program>).

**R2. Your submission has been rejected. The submitted file cannot be processed for unknown reasons. Please contact CVM's eSubmitter staff for assistance at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov).**

The submission was rejected because it could not be processed correctly by the ESS for undefined reasons and will need further investigation. Please contact CVM's eSubmitter staff for assistance at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

**R3. Your submission has been rejected. The submission is not recognized as a valid eSubmitter format.**

The submission has been rejected because the file format received is not supported by eSubmitter and not recognized as a valid file format by ESS. Listed below are several possible explanations and corrective actions:

1. You created an eSubmitter submission but transmitted the incorrect file (e.g., the submission report file). A valid eSubmitter generated submission package is contained within a ZIP file. Please review the submission packaging process within the CVM eSubmitter Quick Guide for additional information on generating a valid eSubmitter submission package.
2. You did not use eSubmitter to generate your submission package (e.g., submitted a document based on the earlier paper process, or used the eCTD format). Click the link for information on the CVM eSubmitter Program <https://www.fda.gov/industry/fda-esubmitter/cvm-esubmitter-program>
3. You tried to submit a Manage Form using the "eSubmitter" submission type and received this message; please select "electronic submission" in Webtrader when submitting a Manage Form.

**R4. Your submission has been rejected. Only single file transmissions via FDA Gateway are allowed for eSubmitter file submission.**

Only single file transmissions are accepted for eSubmitter submissions. Listed below is a possible explanation and corrective action:

You attempted to submit multiple eSubmitter submission packages (i.e., ZIP files) within a single ESG transmission. While the ESG supports multiple files to be transmitted in a single transmission, CVM only accepts a single eSubmitter submission package within a transmission.

**R5. Your submission has been rejected. The digital signature in the submitted form does not contain an email address.**

There is no email address contained within the digital signature provided. Listed below are several possible corrective actions:

1. When submitting a Manage Form, make sure the digital signature provided within the form contains an email address
2. When signing a submission within eSubmitter, make sure the digital signature used contains an email address and matches what is on file at CVM for the submitter

**R6. Your submission has been rejected. The stakeholder's digital signature was not validated because he/she is not registered or active in our system.**

The submission has been rejected by the ESS because the stakeholder digital signature provided within the submission is either not registered with the ESS or is not active. Listed below are several possible corrective actions:

1. To submit to CVM requires both an FDA ESG account and a CVM ESS account. If you have not yet registered with CVM ESS, follow the instructions in CVM GFI #108 on registering with ESS (click: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-108-registering-cvms-electronic-submission-system>)
2. ESS registration requires submitting a Manage Form with a digital signature included within section II of the form. The Manage Form is first submitted through ESG Test. Once CVM performs a validation, you will receive an ESG Production account. You must then submit the same Manage Form through ESG Production to activate the ESS account. Please verify you submitted the Manage Form a second time through ESG Production selecting "electronic\_submission" as the submission type to activate your ESS account.
3. If you are still having issues, please contact the CVM DCU mailbox at [cvmdu@fda.hhs.gov](mailto:cvmdu@fda.hhs.gov) or ESS registration questions or CVM's eSubmitter staff for general assistance at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

**R7. Your submission has been rejected. The Firm Name within the submission does not match our records.**

The Firm Name provided within the submission does not match exactly (including lack of punctuation) a Firm Name in the CVM system. Listed below are several possible corrective actions:

1. Ensure that the firm name does not include any punctuation as this will trigger a rejection since the CVM system does not include punctuation within firm names.
2. If you are unsure of the firm name to be included within the submission, contact CVM's eSubmitter staff for assistance at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

**R8. Your submission has been rejected. The submission contains a Document ID that does not match our records.**

The submission has been rejected by the ESS because the Document ID provided with the submission does not match a Document ID within the CVM system. Listed below are several possible corrective actions:

1. Verify the document number was correctly entered within the submission for the document type specified. If incorrect, revise and resubmit.
2. Verify the document number entered matches the appropriate document type. Every document number has an associated document type that must be specified correctly within each subsequent submission. A common mistake

when attempting to submit general correspondence information is to create a submission for a General Correspondence document type while using a document number for another document type (e.g., ANADA, NADA, JINAD, INAD, VMF). In this case, create a submission using the correct document type/number combination, while selecting general correspondence as the submission type (e.g., N123456-G-AD).

**R9. Your submission has been rejected. The submission contains a Firm Name and Document ID that do not match our records.**

Please refer to R8 for guidance.

**R10. Your submission has been rejected. The submission contains a Document ID that is not active.**

Document ID numbers not currently active with CVM will be rejected. Ensure the Document ID is active and on file with the CVM.

**R11. Your submission has been rejected. A submission to establish the file or application (A0000) already exists for this Document.**

The document already exists in CVM's system. Only one A0000 submission type is permissible for each document. Please submit a different submission type. You may contact CVM at [cvmsubmitter@fda.hhs.gov](mailto:cvmsubmitter@fda.hhs.gov)

**R12. Your submission has been rejected. Unable to amend previous submission because the submission number is invalid.**

You need to verify and enter the submission number of the original submission you are amending. Please look at the acknowledgement letter for the original submission number. Reference the number between submission type and classification code.

**R13. Your submission has been rejected. Unable to amend previous submission because it is closed**

You can only amend an open submission, not a closed submission. A submission is considered closed when the review is completed, and a final letter sent back to the sponsor (Note: there are certain submission types that do not generally result in a response letter). Therefore, you need to create a new submission. Change the answer to the amendment question to "No". For CVM, amending a submission means it is still pending in CVM's system.

**R14. Your submission has been rejected. Unable to amend previous submission because our records indicate that a decision has already been made on the Protocol.**

You cannot amend a submission that is closed. You can only amend a pending submission.

**R15. Your submission has been rejected. Our records indicate that additional documents are owned by your Firm. The number of additional documents is:**

Contact CVM to determine what additional documents need to be included in the submission.

**R16. Your submission has been rejected. The submission contains Document ID(s) that do not match our records. These Document ID(s) are:**

Please refer to message R8 for guidance.

**R17. Your submission has been rejected. The submission contains a Firm Name and Document ID(s) that do not match our records. These Document ID(s) are:**

Please refer to message R8 for guidance.

**R18. Your submission has been rejected. The submission contains Document ID(s) that are not active. These Document ID(s) are:**

Please refer to message R8 for guidance.

**R19. Your submission has been rejected. Our records indicate that the application status is not Approved.**

Contact CVM for further information at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

**R20. Your submission has been rejected. The referenced Technical Section submission number does not match our records.**

The referenced submission number needs to be revised. If you need assistance in determining the correct submission number, please contact CVM at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

**R21. Your submission has been rejected. The referenced Meeting Request submission number does not match our records.**

The referenced submission number needs to be revised. If you need assistance in determining the correct submission number, please contact CVM at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

**R22. Your submission has been rejected. The submission contains Document ID(s) and referenced Meeting Request submission numbers that do not match our records. These Document ID(s) are:**

The referenced submission number needs to be revised. If you need assistance in determining the correct submission number, please contact CVM at [cvmesubmitter@fda.hhs.gov](mailto:cvmesubmitter@fda.hhs.gov)

**R23. Your submission has been rejected. The submitted file is an invalid file format.**

Your submission did not contain the manage form. You created a valid eSubmitter submission package but selected "electronic\_submission" as the submission type when transmitting through the ESG. The "electronic\_submission" submission type is for transmitting ESS Manage Forms, not eSubmitter submissions. Please resubmit selecting "eSubmitter" as the submission type.

## APPENDIX A: ACRONYMS

The following table provides definitions and explanations for acronyms relevant to the content presented within this document.

*Table A: Acronyms*

<b>Acronym</b>	<b>Definition</b>
ANADA	Abbreviated New Animal Drug Application
CVM	Center for Veterinary Medicine
DCU	Document Control Unit
ERA	End Review Amendment
ESG	Electronic Submission Gateway
ESS	Electronic Submission System
FDA	Food and Drug Administration
GC	General Correspondence
GFI	Guidance For Industry
INAD	Investigational New Animal Drug
IT	Information Technology
JINAD	Generic Investigational New Animal Drug
NADA	New Animal Drug Application
ONADE	Office of New Animal Drug Evaluation
PDF	Portable Document Format
VMF	Veterinary Master File