

# Food and Drug Administration



## Center for Veterinary Medicine

**ELECTRONIC SUBMISSION SYSTEM (ESS)  
ACCEPTANCE AND REJECTION MESSAGES**

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## Table of Contents

<b>1.0 INTRODUCTION .....</b>	<b>3</b>
1.1 Purpose .....	3
<b>2.0 ESS MESSAGE EXPLANATIONS.....</b>	<b>3</b>
2.1 Acceptance Messages .....	3
2.2 Rejection messages .....	4
<b>APPENDIX A: ACRONYMS.....</b>	<b>8</b>

## 1.0 INTRODUCTION

### 1.1 PURPOSE

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.

## 2.0 ESS MESSAGE EXPLANATIONS

### 2.1 ACCEPTANCE MESSAGES

The following table defines the ESS acceptance messages. These messages are in no particular order as an accepted ESS submission may receive only one of the following acceptance messages.

**Table 2.1: Acceptance Messages**

Message ID	Message	Message Explanation
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.

Message ID	Message	Message Explanation
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.

## 2.2 REJECTION MESSAGES

The following table defines the ESS rejection messages. Based on the order of the messages it can be assumed that validation for any preceding message has passed.

**Table 2.2: Rejection Messages**

Message ID	Message	Message Explanation
R001	Your submission has been rejected. CVM ONADE no longer accepts PDF Smart Forms as a viable solution for electronic submissions, please use eSubmitter.	The submission has been rejected by the ESS because CVM ONADE no longer accepts PDF Smart Forms. The submission should be submitted using eSubmitter.
R002	Your submission has been rejected. The submitted file can not be processed for unknown reasons. Please contact CVM's eSubmitter staff for assistance at <a href="mailto:cvmesubmitter@fda.hhs.gov">cvmesubmitter@fda.hhs.gov</a> .	The submission has been rejected by the ESS because the submission can not be processed for reasons unknown. The CVM eSubmitter staff should be contacted for further assistance with this rejection.
R003	Your submission has been rejected. The submission is not recognized as a valid eSubmitter format.	The submission has been rejected by the ESS because the file format is not valid.
R004	Your submission has been rejected. Only single file transmissions via FDA Gateway are allowed for eSubmitter file submission.	The submission has been rejected by the ESS because the submission contains multiple files. Only single files transmissions are accepted for eSubmitter submissions.

CVM ESS Acceptance and Rejection Messages

Message ID	Message	Message Explanation
R005	Your submission has been rejected. The digital signature in the submitted form does not contain an email address.	The submission has been rejected by the ESS because the digital signature provided with the submission does not contain an email address.
R006	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 with the submission is either not registered with the ESS or is not active.
R007	Your submission has been rejected. The Firm Name within the submission does not match our records.	The submission has been rejected by the ESS because the Firm Name provided with the submission does not match exactly (including punctuation, etc) a Firm Name in the system.
R008	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 in the system.
R009	Your submission has been rejected. The submission contains a Firm Name and Document ID that do not match our records.	The submission has been rejected by the ESS because the combination of the Firm Name and Document ID provided with the submission do not match any records in the system.
R010	Your submission has been rejected. The submission contains a Document ID that is not active.	The submission has been rejected by the ESS because the Document ID provided with the submission is not an active Document ID in the system.
R011	Your submission has been rejected. A submission to establish the file or application (A0000) already exists for this Document.	The submission has been rejected by the ESS because a submission to establish the file or application already exists for the Document in the system.
R012	Your submission has been rejected. Unable to amend previous submission because the submission number is invalid.	The submission has been rejected by the ESS because the system is unable to amend the previous submission because the submission number provided with the submission is invalid.
R013	Your submission has been rejected. Unable to amend previous submission because it is closed	The submission has been rejected by the ESS because the system is unable to amend the previous submission because the submission is closed in the system.

CVM ESS Acceptance and Rejection Messages

Message ID	Message	Message Explanation
R014	Your submission has been rejected. Our records indicate that an ERA was not requested.	The submission has been rejected by the ESS because the system does not indicate that an End Review Amendment (ERA) was requested for the submission.
R015	Your submission has been rejected. Our records indicate the ERA submission has already been received.	The submission has been rejected by the ESS because the system indicates the End Review Amendment (ERA) submission associated with the submission has already been received by the system.
R016	Your submission has been rejected. Our records indicate the ERA submission is overdue.	The submission has been rejected by the ESS because the system indicates that the End Review Amendment (ERA) submission associated with the submission is overdue.
R017	Your submission has been rejected. Unable to amend previous submission because our records indicate that a decision has already been made on the Protocol.	The submission has been rejected by the ESS because the system indicates that a decision has already been made on the Protocol associated with the submission and the system can not amend the previous submission.
R018	Your submission has been rejected. Our records indicate that additional documents are owned by your Firm. The number of additional documents is:	The submission has been rejected by the ESS because the system indicates that additional documents are owned by the Firm than those provided in the submission. The number of additional documents is included in the rejection message.
R019	Your submission has been rejected. The submission contains Document ID(s) that do not match our records. These Document ID(s) are:	The submission has been rejected by the ESS because the Document ID(s) provided with the submission do not match any records in the system. The Document ID(s) that do not match our system records are included in the rejection message.
R020	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:	The submission has been rejected by the ESS because the Firm Name and Document ID(s) provided with the submission do not match any records in the system. The Document ID(s) that do not match our system records are included in the rejection message.
R021	Your submission has been rejected. The submission contains Document ID(s) that are not active. These Document ID(s) are:	The submission has been rejected by the ESS because the Document ID(s) provided with the submission are not active in the system. The Document ID(s) found to be not active are included in the rejection message.

CVM ESS Acceptance and Rejection Messages

Message ID	Message	Message Explanation
R022	Your submission has been rejected. Our records indicate that the application status is not Approved.	The submission has been rejected by the ESS because the status of the application associated with the submission is not Approved.
R023	Your submission has been rejected. The referenced Technical Section submission number does not match our records.	The submission has been rejected by the ESS because the referenced Technical Section submission number provided with the submission does not match any records in the system.
R024	Your submission has been rejected. The referenced Meeting Request submission number does not match our records.	The submission has been rejected by the ESS because the referenced Meeting Request submission number provided with the submission does not match any records in the system.
R025	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 submission has been rejected by the ESS because the Document ID(s) and referenced Meeting Request submission numbers provided in the submission do not match the records in the system. The Document ID(s) with unmatched referenced Meeting Request submission numbers are included in the rejection message.

## 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
ERA	End Review Amendment
ESS	Electronic Submission System
FDA	Food and Drug Administration
GC	General Correspondence
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