
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

PERMISSIBLE STARS ACTION CODES FOR STARS SUBMISSIONS

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I. PURPOSE

This document describes permissible non-final and final Submission Tracking and Retrieval System (STARS) action codes for each Investigational New Animal Drug (INADs)/Generic Investigational New Animal Drug (JINAD) submission type and each New Animal Drug Applications (NADA)/Abbreviated New Animal Drug Application (ANADA) submission type.¹

If you have any questions about which of the permissible action codes to use for a particular submission type, contact your team leader or division director. Please contact a member of the policy team if there is still any uncertainty about which action code to use.

¹ This document addresses only the submission types that are in current use. A more complete description of current submission types, and those no longer in use, is available in P&P 1243.2580.

II. PERMISSIBLE ACTION CODES FOR INAD/JINAD SUBMISSIONS

A. Description of STARS action codes

| STARS Action Codes | | |
|--------------------------|------|--|
| Abbreviation | Code | Complete Name |
| Non-Final Actions | | |
| RTC | 008 | Due date reset; letter sent (<i>reset the clock</i>) |
| EXPED/GRNT | 040 | Expedited review status granted; letter sent |
| EXPED/DENY | 041 | Expedited review status denied; letter sent |
| EXPED/END | 049 | Expedited review status ended |
| Final Actions | | |
| FNR | 007 | Submission filed with no review documentation; no letter sent |
| FNR/MEMO | 009 | Submission filed with review documentation; no letter sent |
| TERM/AGNCY | 027 | File terminated by agency; letter sent, if appropriate |
| TERM/SPNSR | 028 | File terminated by sponsor; letter sent |
| AUTH GRNT | 030 | Food use authorization granted; letter sent |
| AUTH DENY | 031 | Food use authorization denied; letter sent |
| ACK/AUTH | 032 | Food use authorization granted; additional comments (acknowledgement letter); two letters sent |
| ACK | 033 | Submission reviewed; letter sent (<i>acknowledgement letter</i>) |
| WAVR GRNT | 034 | Granted waiver for bioequivalence; letter sent |
| WAVR DENY | 035 | Denied waiver for bioequivalence; letter sent |
| PROT CONCR | 045 | Protocol acceptable as submitted; letter sent |
| PROT NCONC | 046 | Protocol not acceptable as submitted; letter sent |
| REFUSE ACC | 063 | Refuse to accept submission for filing; acct in arrears; letter sent |
| REFUSE REV | 065 | Submission unacceptable for review; letter sent |
| STOP REV | 066 | Submission review terminated at sponsor request; letter sent |
| SPNSR CHNG | 070 | Sponsor name change acknowledged; letter sent; followed by publication if appropriate |
| SUSP by FP | 090 | Review suspended by fraud policy; letter sent |
| TS INC NOT | 201 | Technical section incomplete; submitted information not acceptable; letter sent |
| TS COMPLTE | 202 | Technical section complete; letter sent |
| TS INC OK | 203 | Technical section incomplete; submitted information acceptable; letter sent |
| QC CLOSOUT | 665 | Quality control closeout; action taken; submission lost |
| VOID SUB | 666 | Mark submission as void to preserve submission number |
| VOID AMEND | 668 | Mark amendment as void to preserve sequence number |

B. Non-final actions

| | | SUBMISSION TYPES | | | | | | | | | | | | | | | | | | | |
|---------------|------|------------------|---|---------------------|---|---|---|---|------|---|-----------|---|-----------|---|------------|---|---------------|-----|-----|-----|----------|
| | | Orig | | Drug / Animal Admin | | | | | Mtgs | | Food Auth | | Protocols | | Tech Sec'n | | Waivr Reqst * | Gen | CVM | EIR | Amend ** |
| Action Abbrev | Code | A | B | S | U | V | Z | Y | D | O | E | F | M | P | R | G | Q | K | T# | | |
| RTC | 008 | Y | Y | Y | - | Y | - | - | Y | Y | Y | Y | Y | Y | Y | Y | - | - | - | | |
| EXPED/GRNT | 040 | Y | - | - | - | - | - | - | Y | Y | Y | Y | Y | Y | - | Y | - | - | - | | |
| EXPED/DENY | 041 | Y | - | - | - | - | - | - | Y | Y | Y | Y | Y | Y | - | Y | - | - | - | | |
| EXPED/END | 049 | - | - | - | - | - | - | - | Y | Y | Y | Y | Y | Y | - | Y | Y | - | - | | |

Y - permissible action code; -- action code not permissible; * - for JINAD only; ** -amendments must be completed with parent submission

C. Final actions

| | | SUBMISSION TYPES | | | | | | | | | | | | | | | | | | |
|-------------------------|------|------------------|---------------------|---|---|---|---|------|---|-----------|---|-----------|---|------------|---|---------------|-----|-----|-----|----------|
| | | Orig | Drug / Animal Admin | | | | | Mtgs | | Food Auth | | Protocols | | Tech Sec'n | | Waivr Reqst * | Gen | CVM | EIR | Amend ** |
| Action Abbrev | Code | A | B | S | U | V | Z | Y | D | O | E | F | M | P | R | G | Q | K | T# | |
| FNR | 007 | - | Y | Y | Y | Y | - | Y | - | - | - | - | - | - | - | Y | - | - | - | |
| FNR/MEMO | 009 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | Y | Y | - | - | |
| TERM/AGNCY | 027 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | Y | - | - | |
| TERM/SPNSR | 028 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | Y | - | - | - | |
| AUTH GRNT | 030 | Y | - | - | - | - | - | - | Y | Y | - | - | - | - | - | - | - | - | - | |
| AUTH DENY | 031 | Y | - | - | - | - | - | - | Y | Y | - | - | - | - | - | - | - | - | - | |
| ACK/AUTH | 032 | Y | - | - | - | - | - | - | Y | Y | - | - | - | - | - | - | - | - | - | |
| ACK | 033 | Y | Y | Y | - | Y | Y | Y | Y | Y | - | - | - | - | - | Y | Y | - | - | |
| WAIVR GRNT | 034 | - | - | - | - | - | - | - | - | - | - | - | - | - | Y | - | - | - | - | |
| WAIVR DENY | 035 | - | - | - | - | - | - | - | - | - | - | - | - | - | Y | - | - | - | - | |
| PROT CONCR | 045 | - | - | - | - | - | - | - | - | - | Y | Y | - | - | - | - | - | - | - | |
| PROT NCONC | 046 | - | - | - | - | - | - | - | - | - | Y | Y | - | - | - | - | - | - | - | |
| REFUSE ACC ² | 063 | Y | Y | Y | - | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | - | |
| REFUSE REV | 065 | Y | Y | Y | - | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | - | |
| STOP REV | 066 | Y | Y | Y | - | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | - | |
| SPNSR CHNG | 070 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | Y | - | - | - | |
| SUSP by FP | 090 | Y | Y | Y | - | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | |
| TS INC NOT | 201 | - | - | - | - | - | - | - | - | - | - | - | Y | Y | - | - | - | - | - | |
| TS COMPLTE | 202 | - | - | - | - | - | - | - | - | - | - | - | Y | Y | - | - | - | - | - | |
| TS INC OK | 203 | - | - | - | - | - | - | - | - | - | - | - | Y | Y | - | - | - | - | - | |
| QC CLOSOUT | 665 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | |
| VOID SUB | 666 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | |
| VOID AMEND | 668 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | Y | |

Y - permissible action code; -- action code not permissible; * - for JINAD only; ** -amendments must be completed with parent submission

² Only the ADUFA Team should use this final action code. They use this code to refuse to accept a submission for filing when the sponsor is not current on the fees owed under the provisions of the Animal Drug User Fee Act (ADUFA) of 2003.

III. PERMISSIBLE ACTION CODES FOR NADA/ANADA SUBMISSIONS

A. Description of STARS action codes

| STARS Action Codes | | |
|--------------------------|------|---|
| Abbreviation | Code | Complete Name |
| Non-Final actions | | |
| RTC | 008 | Due date reset; letter sent (<i>reset the clock</i>) |
| EXPED/GRNT | 040 | Expedited review status granted; letter sent |
| EXPED/DENY | 041 | Expedited review status denied; letter sent |
| EXPED/END | 049 | Expedited review status ended |
| CBE LTR | 192 | 30-day CBE unacceptable; letter sent |
| Final actions | | |
| FNR | 007 | Submission filed with no review documentation; no letter sent |
| FNR/MEMO | 009 | Submission filed with review documentation; no letter sent |
| ACK | 033 | Submission reviewed; letter sent (<i>acknowledgement letter</i>) |
| WITH/AGNCY | 020 | Document withdrawn by agency; letter sent |
| WITH/SPNSR | 021 | Document withdrawn by request of sponsor; letter sent |
| WITH/SUPL | 022 | Supplement withdrawn by request of sponsor; letter sent |
| INC APP | 024 | Incomplete application; letter sent |
| INC ADUFA | 026 | Incomplete application; acct in arrears; letter sent |
| SUP MIN LD | 050 | Minor supplement approved date of letter; letter sent |
| SUP SIG LD | 051 | Significant supplement approved date of letter; letter sent |
| ORG APP LD | 056 | Original application approved date of letter; letter sent |
| REFUSE APP | 060 | Refuse to file application; letter sent |
| REFUSE ACC | 063 | Refuse to accept submission for filing; acct in arrears; letter sent |
| REFUSE REV | 065 | Submission unacceptable for review; letter sent |
| STOP REV | 066 | Submission review terminated at sponsor request; letter sent |
| SPNSR CHNG | 070 | Sponsor name change acknowledged; letter sent; followed by publication if appropriate |
| SUSP by FP | 090 | Review suspended by fraud policy; letter sent |
| QC CLOSOUT | 665 | Quality control closeout; action taken; submission lost |
| VOID SUB | 666 | Mark submission as void to preserve submission number |
| VOID AMEND | 668 | Mark amendment as void to preserve sequence number |

B. Non-final actions

| | | SUBMISSION TYPES | | | | | | | | | | | |
|---------------|------|--------------------|---|----------------|---|----------|---|-----------------------|---|-----|-----|-----|---------------|
| | | Originals & Reacts | | Supps & Reacts | | Meetings | | Chem Reports & Reacts | | Gen | CVM | EIR | Amend(s) * |
| Action Abbrev | Code | A | E | C | R | Z | Y | B | F | G | Q | K | M, T, U, S |
| RTC | 008 | Y | Y | Y | Y | - | - | - | - | Y | - | - | - |
| EXPED/GRNT | 040 | Y | Y | Y | Y | - | - | - | - | Y | - | - | - |
| EXPED/DENY | 041 | Y | Y | Y | Y | - | - | - | - | Y | - | - | - |
| EXPED/END | 049 | - | Y | Y | Y | - | - | - | - | Y | Y | - | - |
| CBE LTR | 192 | - | - | Y | Y | - | - | - | - | - | - | - | - |

Y - permissible action code; -- action code not permissible; * - amendments must be completed with parent submission

B. Final actions

| | | SUBMISSION TYPES | | | | | | | | | | | |
|-------------------------|------|--------------------|---|----------------|---|----------|---|-----------------------|---|-----|-----|-----|---------------|
| | | Originals & Reacts | | Supps & Reacts | | Meetings | | Chem Reports & Reacts | | Gen | CVM | EIR | Amend(s) * |
| Action Abbrev | Code | A | E | C | R | Z | Y | B | F | G | Q | K | M, T, U, S |
| FNR | 007 | - | - | - | - | - | Y | Y | Y | Y | - | - | - |
| FNR/MEMO | 009 | - | - | - | - | Y | Y | Y | Y | Y | Y | - | - |
| ACK | 033 | - | - | - | - | Y | Y | - | - | Y | Y | - | - |
| WITH/AGNCY | 020 | - | - | Y | Y | - | - | - | - | - | Y | - | - |
| WITH/SPNSR | 021 | Y | Y | Y | Y | - | - | - | - | - | - | - | - |
| WITH/SUPL | 022 | - | - | Y | Y | - | - | - | - | - | - | - | - |
| INC APP | 024 | Y | Y | Y | Y | - | - | Y | Y | Y | - | - | - |
| INC ADUFA | 026 | Y | Y | Y | Y | - | - | - | - | - | - | - | - |
| SUP MIN LD | 050 | - | - | Y | Y | - | - | - | - | - | - | - | - |
| SUP SIG LD | 051 | - | - | Y | Y | - | - | - | - | - | - | - | - |
| ORG APP LD | 056 | Y | Y | - | - | - | - | - | - | - | - | - | - |
| REFUSE APP | 060 | Y | Y | Y | Y | - | - | - | - | - | - | - | - |
| REFUSE ACC ³ | 063 | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | - | - |
| REFUSE REV | 065 | - | - | - | - | Y | Y | - | - | Y | - | - | - |
| STOP REV | 066 | - | - | - | - | Y | Y | - | - | Y | - | - | - |
| SPNSR CHNG | 070 | - | - | - | - | - | - | - | - | Y | - | - | - |
| SUSP by FP | 090 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | - |
| QC CLOSOUT | 665 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| VOID SUB | 666 | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | - | - |
| VOID AMEND | 668 | - | - | - | - | - | - | - | - | - | - | - | Y |

Y - permissible action code; -- action code not permissible; * - amendments must be completed with parent submission

³ See footnote 2.

IV. REFERENCES

CVM Program Policy and Procedure Manual

1243.2580, Submission Identification System