

Overrides Request

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Manual Overrides

A Few Tips from the SPL Office



Manual Overrides are Difficult and Time Consuming



Overrides are sometimes necessary to bypass the automated validations and allow certain corrections to be made to a record

An override bypasses ALL business validations

When an override request is received, the entire SPL file must be reviewed by the SPL office

The submitted file is compared to previous version to prevent other errors from being introduced

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Providing incorrect or incomplete data in your override request can cause significant delays in processing.

One Result from the Provision of the Wrong Core ID/Submission ID Metrics	
Number of Instances	Amount of Time Used by FDA SPL Team Which Does Not Beneficially Contribute to Manual Override Review
1	~Five minutes
12	Cumulatively represents one work hour
48	Cumulatively represents half of an eight-hour work day

Each time the SPL Team has to stop and look up records or wait for correct data to be emailed, processing is delayed for the current file and potentially others in the queue behind it.

Manual Overrides are Difficult and Time Consuming Continued



These are common causes of delays in processing:

- Discrepancies in the number of errors stated in the body of the e-mail message and the number of issues listed in the actual error message.*
- Providing a partial core ID or submission ID, OR, providing these values in a screenshot which cannot be copy and pasted or clearly read*
- Duplicate requests - creating a new e-mail message which includes the same information that is in a previously submitted manual override request*
- E-mail messages with no subject line or with subject lines which are not related to the message in the content of the e-mail message*
- Illegible images of carton/container labels*

Manual Overrides are Difficult and Time Consuming, Final



It's best to avoid the need for an override in the first place!

Check your data before submitting!

Ingredients and strengths

No typos in the proprietary and non-proprietary names

Correct NDC

Contact Us!

- eDRLS Helpdesk: edrls@fda.hhs.gov
- CDER Direct Helpdesk: CDERdirect@fda.hhs.gov
- SPL Office: SPL@fda.hhs.gov
- Thank you

