

# Warning Letter Response

Respond to an FDA warning letter within 15 working days, answering every violation and every item FDA asked for, with the data integrity remediation, management oversight and consultant FDA expects.

## WRITES

FDA warning  
letter response

## PRODUCT TYPE

FDA inspections

## GUIDANCE IT FOLLOWS

FDA Regulatory  
Procedures Manual  
Chapter 4 (4-1  
warning letters,  
close-out letters);  
FD&C Act 501(a)(2)  
(B); 21 CFR 210, 211;  
21 CFR 211.22 and  
211.34  
(consultants); 21  
CFR 820 (QMSR);  
FDA Data Integrity  
and Compliance  
with Drug CGMP  
Q&A (2018); FDA  
Import Alert 66-40;  
ICH Q9(R1), Q10

## TIME TO LEARN

About 20 minutes  
with the example

Open the tool at <https://app.cmcfy.com/app/warning-letter-response.html>. This guide is also online at <https://cmcfy.com/guides/warning-letter-response.html>

## 1. What this module does

You enter the letter, the date received and the date you will respond, one row per violation with its root cause, CAPA and retrospective review, and one row per item under "In response to this letter, provide" with your answer and attachment.

The tool counts the 15 working days, needs an answer to every violation and request, checks the three parts FDA asks for when data integrity is cited (comprehensive investigation, risk assessment, management strategy), needs management and quality unit oversight when violations repeat an earlier 483, and checks the consultant when the letter recommends one.

## What you get

- A Word or PDF file: the warning letter response with each violation, the requests answered, the data integrity remediation, management oversight and the commitment schedule.

## 2. Before you start

Have these ready. You can still start with the example data and replace it piece by piece.

- The warning letter.
- Investigation, CAPA and retrospective review reports.
- The consultant agreement and scope, if recommended.

**Your data stays on your computer.** The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. [Download offline](#) [copy](#) saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

## 3. Step by step with the example

Open the tool at [app.cmcfy.com/app/warning-letter-response.html](https://app.cmcfy.com/app/warning-letter-response.html). The example is loaded when the page opens, so every panel already has realistic data. Follow the steps to see how it works, then replace the example with your own data.

**1**

### Enter the letter

Give the firm, the letter reference and date, when it was received, who issued it and who signs. Tick whether a consultant is recommended and whether the firm is on import alert.

**Warning Letter Response** Projects All modules Training Security Runs entirely on this device Training guide

**PROJECTS** Keep this work in a project, with version history and your company logo on every report. Choose projects folder Keep in this browser

- Network requests since load: 0**  
Counted live by your browser. Your data never leaves this device.
- Works offline**  
Everything the tool needs is inside this page.
- Locked offline copy**  
Save a single file that opens from your own computer with all network access blocked.

**FDA warning letter response** Save project Open project Start blank Load example

Write the response to an FDA warning letter. The tool checks the 15 working day deadline, needs an answer to every violation and to every item FDA asks for, and checks the data integrity remediation, management oversight of repeat violations and the consultant FDA recommends. It writes the response letter and the commitment schedule.

Guidance: FDA Regulatory Procedures Manual Chapter 4 (4-1 warning letters, close-out letters); FD&C Act 501(a)(2)(B); 21 CFR 210, 211; 21 CFR 211.22 and 211.34 (consultants); 21 CFR 820 (QMSR); FDA Data Integrity and Compliance with Drug CGMP Q&A (2018); FDA Import Alert 66-40; ICH Q9(R1), Q10

**Guidances applied** 8 Your data and report are checked against these

**1 - WARNING LETTER**

Firm and site  
Acme Pharma, Raleigh NC

FEI number  
3001234567

Warning letter reference  
320-26-88 (CMS 712345)

Letter date  
07/14/2026

Date received  
07/15/2026

Date the response will be sent

**RESULT**

**Every violation and FDA request answered**

2 violations (1 repeat, 1 data integrity); 5 FDA requests, 3 provided now and 2 to follow.  
Due 2026-08-05; sent after 14 working days.

|                   |                     |                     |
|-------------------|---------------------|---------------------|
| <b>VIOLATIONS</b> | <b>FDA REQUESTS</b> | <b>RESPONSE DUE</b> |
| 2                 | 5                   | 2026-08-05          |
| <b>TO FOLLOW</b>  |                     |                     |
| 2                 |                     |                     |

## 2 Answer the violations

One row per numbered violation. Mark violations that repeat an earlier Form 483.

## 3 Answer what FDA asked for

One row per item FDA asks you to provide, linked to its violation number. Give the date for anything that will follow.

## 4 Read the result

The headline gives the outcome, for example "Every violation and FDA request answered".

| VIOLATIONS |           |        |                |            |       |               |
|------------|-----------|--------|----------------|------------|-------|---------------|
| ITEM       | 21 CFR    | REPEAT | DATA INTEGRITY | ROOT CAUSE | CAPA  | RETROSPECTIVE |
| 1          | 211.192   | repeat | -              | given      | given | given         |
| 2          | 211.68(b) | -      | yes            | given      | given | given         |

Violations and FDA requests.

5 Resolve alerts and download

A late response, an unanswered request, no retrospective review, a missing data integrity part and repeats without management oversight are critical. Then preview and download.

Preview and review before download

Review

Checked on this device: gaps in the data, gaps in the report against ICH and regional expectations, and differences from the protocol.

No open gaps

No open gaps: the data, the report and the protocol (if given) match every rule checked, or you accepted the rest. Read the preview before you sign.

Compare with the protocol

Load or paste the approved protocol. Every requirement and acceptance criterion in it is looked for in the report.

Paste the protocol text here, or load the file.

Load protocol fileCompare

AI review against guidance

AI reads the report, the protocol and the data against the ICH, FDA or EMA requirements for these sections, and lists gaps with the guideline it applies, protocol and data mismatches, and how to fix them. You see exactly what is sent before anything leaves this device. Results and pass/fail are not changed.

Run AI review

Response to FDA warning letter

Acme Pharma, Raleigh NC · 320-26-88 (CMS 712345)

|                |                                          |
|----------------|------------------------------------------|
| To             | CDER Office of Manufacturing Quality     |
| From           | Acme Pharma, Raleigh NC                  |
| FEI number     | 3001234567                               |
| Warning letter | 320-26-88 (CMS 712345), dated 2026-07-14 |
| Received       | 2026-07-15                               |
| Date           | 2026-08-04                               |

Introduction

Acme Pharma, Raleigh NC (FEI 3001234567) responds to warning letter 320-26-88 (CMS 712345) dated 2026-07-14 from CDER Office of Manufacturing Quality, received on 2026-07-15. Executive management takes full responsibility for the violations and for their correction. Qualified CGMP consultant engaged on 2026-07-27 for a full CGMP and data integrity audit of the site, reporting to executive management. This response answers each of the 2 violations and each of the 5 items FDA asked for. 2 items follow on the dates given, and we will send monthly updates until every action is complete.

Responses to the violations

Violation 1

Your quality unit failed to ensure that unexplained discrepancies and OOS results were thoroughly investigated (21 CFR 211.192). This repeats an observation from an earlier inspection.

|                                  |                                                                                                                            |
|----------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Root cause                       | OOS procedure allowed invalidation without a confirmed assignable cause; quality unit oversight of investigations was weak |
| Corrective and preventive action | SOP-QC-021 revised: QA approval of every invalidation; investigation training with competency assessment                   |
| Retrospective review             | Review of all OOS and deviation investigations since 2024 for every product                                                |

Download Word (.docx)

Download PDF

4. Field reference

Every input in the tool, panel by panel. Tables accept rows pasted straight from Excel, comma-separated text, or a loaded file; check the columns after loading a file. Fields marked “when it applies” appear only for the choices that need them.

1 · Warning letter

| FIELD                    | WHAT TO ENTER |
|--------------------------|---------------|
| Firm and site            | Type it in.   |
| FEI number               | Type it in.   |
| Warning letter reference | Type it in.   |
| Letter date              | Type it in.   |
| Date received            | Type it in.   |

| FIELD                                                   | WHAT TO ENTER                                                                                                                 |
|---------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Date the response will be sent                          | Type it in.                                                                                                                   |
| Issued by                                               | Type it in.                                                                                                                   |
| Signed by (executive management)                        | Type it in.                                                                                                                   |
| The letter recommends a qualified CGMP consultant       | Tick the box if it applies.                                                                                                   |
| Consultant engaged and scope <b>when it applies</b>     | Type it in.                                                                                                                   |
| The firm is on import alert (for example 66-40)         | Tick the box if it applies.                                                                                                   |
| Executive management and quality unit oversight actions | FDA reads repeat violations as a failure of management oversight; say what executive management now does. Type or paste text. |

## 2 · Violations cited

One row per numbered violation in the letter.

| FIELD      | WHAT TO ENTER                                                                                                                                                                                                                                                                               |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Violations | A table. Columns: Item   Violation (as cited)   21 CFR   Repeat of an earlier 483 (yes/no)   Root cause   CAPA   Retrospective review   Due   Status (complete/in progress). Paste rows from Excel, type comma-separated rows, or press <b>Load file</b> (Excel, CSV, Word, PDF or a scan). |

## 3 · What FDA asked for

One row per item under "In response to this letter, provide".

| FIELD        | WHAT TO ENTER                                                                                                                                                                                                                                                                                                                                                                         |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FDA requests | Copy each "In response to this letter, provide" bullet as one row; the Item column is the violation number it sits under. A table.<br>Columns: Request   Item   What FDA asks for   Our response   Attachment   Status (provided/to follow)   Date to follow. Paste rows from Excel, type comma-separated rows, or press <a href="#">Load file</a> (Excel, CSV, Word, PDF or a scan). |

## 5. Checks and alerts

Calculations and pass/fail outcomes always come from fixed rules, never from AI. The tool checks:

- 15 working day deadline.
- Every violation and every FDA request answered.
- Data integrity remediation, management oversight and consultant.

### How to resolve alerts

- **Critical** alerts block the download and must be fixed in the data. A failing result can instead be linked to an investigation: type the investigation reference and outcome and press [Record](#).
- **Major** alerts block the download until you fix them or type a justification and press [Accept justification](#).
- **Minor** alerts do not block anything. They are listed in the documents so the reviewer sees them.
- Some alerts have an [Apply fix](#) button that makes the change for you. [Reopen](#) undoes a justification.

### Narratives

This module writes: Opening; Management oversight; Closing. Each narrative is written by fixed rules from your data. You can edit it in the box. [Rewrite with AI](#) (where your plan includes AI) rewrites it in regulatory style; every number in the text is checked against your data, and a number that does not match is flagged under the box and blocks the download until you correct it. [Reset to rule-based text](#) brings back the original.

## 6. Preview, gap review and download

1. Press [Preview](#) next to a section, or [Preview and download all](#). The document opens in a preview window, exactly as the Word file will read.
2. The left side lists the review, run on your device: **gaps in the data** (missing values, open alerts), **gaps in the report** (missing content the guidance expects, placeholders such as [site] or TBD left

in the text) and, if you load the approved protocol under **Compare with the protocol**, **differences from the protocol** (requirements, criteria, batches or time points it plans that the report does not show).

3. Click a finding to jump to the place in the preview. Fix it in the tool, then preview again.
4. Optional **AI review**: a second read for contradictions, claims without data and vague wording. The report text is sent to Claude only when you press it, and only where your plan includes AI. Check every AI finding; AI can be wrong.
5. Press **Download Word (.docx)** or **Download PDF**. With several documents open, **All as Word (.zip)** and **All as PDF (.zip)** download the set. The download buttons stay disabled while a blocking alert is open; the preview still works.

## Documents this module produces

| SECTION | DOCUMENT                       |
|---------|--------------------------------|
| Report  | Response to FDA warning letter |

Use **Save project** to keep your work as a file on your computer, and **Open project** to continue later. **Start blank** clears every field; **Load example** brings the example back. Nothing is stored on CMCfy servers.

## 7. US and EU submissions

US only: FDA warning letters (Regulatory Procedures Manual Chapter 4).

## 8. Working with other modules

- Track every commitment to close-out in the Remediation Tracker.

## 9. Common pitfalls

- Answering the violations but not the specific items FDA listed.
- Data integrity remediation without the extent of the problem and its effect on product.

## 10. Practice exercises

Each exercise starts from the example (press **Load example** to reset). We run these on every update of this guide, so the result you see should match.

1. **Leave a request unanswered**

Delete the answer to request B.

**EXPECTED RESULT**

The unanswered request is critical.

2. **Respond late**

Change the send date to 2026-08-12.

**EXPECTED RESULT**

Late response is critical.

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Guide updated 28 October 2026 for the current version of the tool. CMCfy drafts are for review by a qualified person before use in a submission.