DOSSIER ASSEMBLY AND REVIEW · TRAINING GUIDE

NDA & BLA Submission

Plan a 505(b)(1) or 505(b)(2) NDA, or a 351(a) or 351(k) BLA: the content the application type needs, the refuse-to-file risks and the review timeline to the PDUFA or BsUFA goal date.

WRITES	PRODUCT TYPE	GUIDANCE IT FOLLOWS	TIME TO LEARN
`Module 1` `Plan`	Small molecule and biologics	21 CFR 314.50, 314.54, 314.101; 21 CFR 601.2; PHS Act 351(a) and 351(k); FD&C Act 505(b), 505B (PREA), 736 and 744H (user fees), 745A(a); PDUFA VII and BsUFA III commitment letters; FDA Refuse to File: NDA and BLA Submissions to CDER (2017); FDA Study Data Technical Conformance Guide; ICH M4	About 20 minutes with the example

Open the tool at https://app.cmcfy.com/app/nda-bla-submission.html. This guide is also online at https://cmcfy.com/guides/nda-bla-submission.html

1. What this module does

You choose the application type, whether it is a new molecular entity or original BLA, priority or standard review and orphan status, and give the status and eCTD location of each item.

The tool lists the items the application type needs (patent information and exclusivity for NDAs, patent certification and a scientific bridge for 505(b)(2), establishment information for BLAs, biosimilarity data for 351(k)), flags refuse-to-file risks and dates the filing date, day-74 letter and goal date.

What you get

- Two Word or PDF files: cover letter; submission content and review timeline.

2. Before you start

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

- The pre-NDA or pre-BLA meeting minutes.
- The agreed iPSP, or the orphan designation.
- The planned submission date.

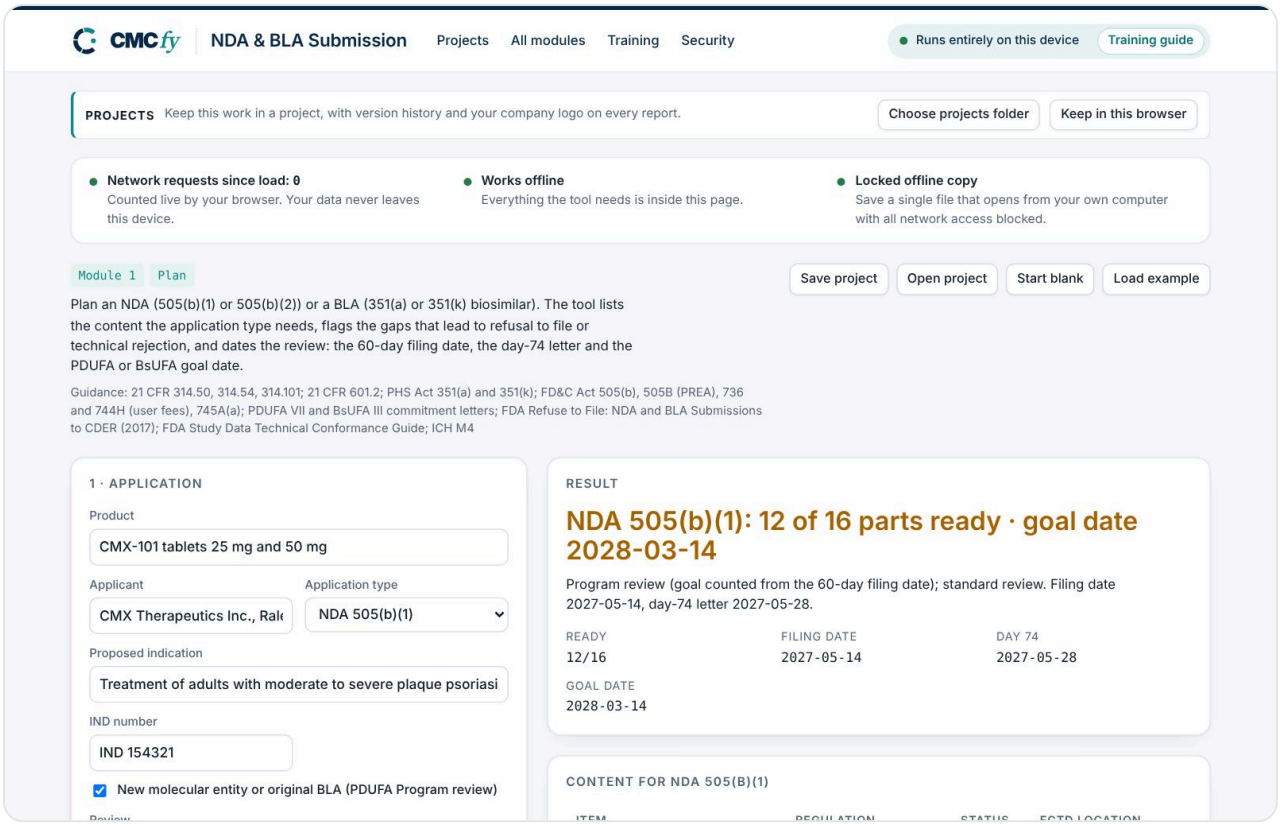
> **Your data stays on your computer.** The bar under the title counts every network request the page makes; it stays at 0 because your data never leaves your computer. `Download offline copy` saves a single file that opens from your own computer with all network access blocked, for air-gapped PCs.

3. Step by step with the example

Open the tool at app.cmcfy.com/app/nda-bla-submission.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 Describe the application

Choose the application type and review, and give the indication, IND number and planned submission date.

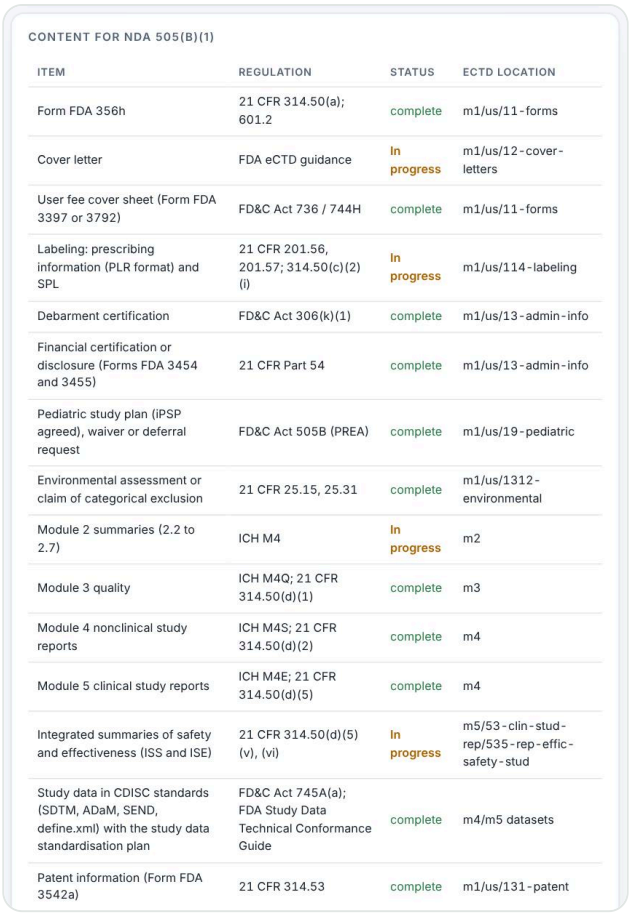


2 Track the content

One row per item with its status and eCTD location.

3 Read the result

The headline gives the readiness and the goal date: "NDA 505(b)(1): 12 of 16 parts ready · goal date 2028-03-14".



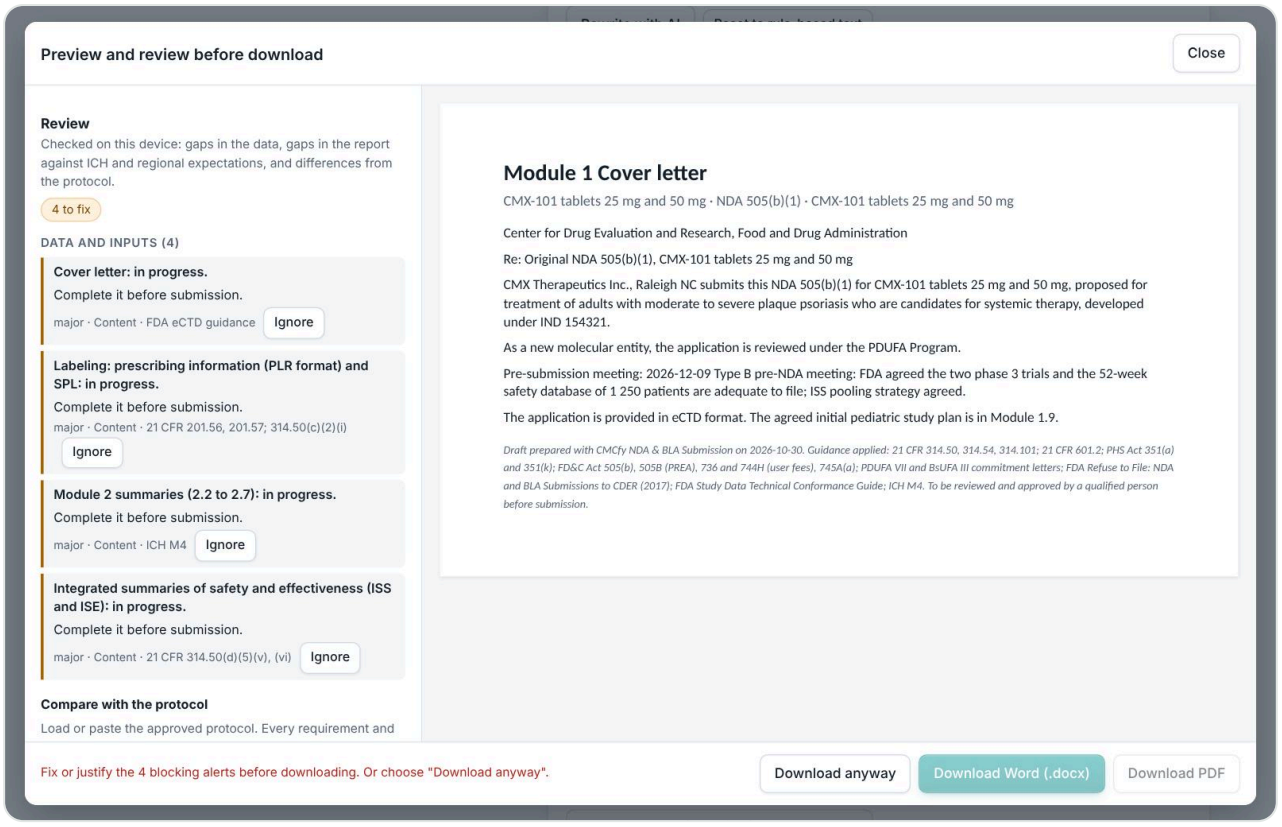
CONTENT FOR NDA 505(B)(1)

ITEM	REGULATION	STATUS	ECTD LOCATION
Form FDA 356h	21 CFR 314.50(a); 601.2	complete	m1/us/11-forms
Cover letter	FDA eCTD guidance	In progress	m1/us/12-cover-letters
User fee cover sheet (Form FDA 3397 or 3792)	FD&C Act 736 / 744H	complete	m1/us/11-forms
Labeling: prescribing information (PLR format) and SPL	21 CFR 201.56, 201.57; 314.50(c)(2)(i)	In progress	m1/us/114-labeling
Debarment certification	FD&C Act 306(k)(1)	complete	m1/us/13-admin-info
Financial certification or disclosure (Forms FDA 3454 and 3455)	21 CFR Part 54	complete	m1/us/13-admin-info
Pediatric study plan (iPSP agreed), waiver or deferral request	FD&C Act 505B (PREA)	complete	m1/us/19-pediatric
Environmental assessment or claim of categorical exclusion	21 CFR 25.15, 25.31	complete	m1/us/1312-environmental
Module 2 summaries (2.2 to 2.7)	ICH M4	In progress	m2
Module 3 quality	ICH M4Q; 21 CFR 314.50(d)(1)	complete	m3
Module 4 nonclinical study reports	ICH M4S; 21 CFR 314.50(d)(2)	complete	m4
Module 5 clinical study reports	ICH M4E; 21 CFR 314.50(d)(5)	complete	m4
Integrated summaries of safety and effectiveness (ISS and ISE)	21 CFR 314.50(d)(5)(v), (vi)	In progress	m5/53-clin-stud-rep/535-rep-effic-safety-stud
Study data in CDISC standards (SDTM, ADaM, SEND, define.xml) with the study data standardisation plan	FD&C Act 745A(a); FDA Study Data Technical Conformance Guide	complete	m4/m5 datasets
Patent information (Form FDA 3542a)	21 CFR 314.53	complete	m1/us/131-patent

Content and review timeline.

4 Resolve alerts and download

A missing form, labeling, ISS/ISE, standardised study data or pediatric plan is a refuse-to-file risk. Then preview and download.



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 · Application

FIELD	WHAT TO ENTER
Product	Type it in.
Applicant	Type it in.
Application type	Choose one: NDA 505(b)(1); NDA 505(b)(2); BLA 351(a); BLA 351(k) biosimilar.
Proposed indication	Type it in.
IND number	Type it in.

FIELD	WHAT TO ENTER
New molecular entity or original BLA (PDUFA Program review) when it applies	Tick the box if it applies.
Review when it applies	Choose one: Standard; Priority (designation requested).
Orphan designation for this indication	Tick the box if it applies.
Listed drug or reference product relied upon when it applies	Type it in.
Planned submission date	Type it in.
Pre-NDA or pre-BLA meeting (date and key agreements)	Type it in.

2 · Content

Status: complete, in progress, not started or not applicable. Add the eCTD location.

FIELD	WHAT TO ENTER
Items	Name the item as in the list (for example "Form FDA 356h", "Patent information") so the tool can match it. A table. Columns: Item | Status | eCTD location. Paste rows from Excel, type comma-separated rows, or press `Load file` (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:

- Content by application type.
- Refuse-to-file and technical rejection risks.
- Filing date, day-74 letter and goal date.

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: Cover letter. 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.

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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
Module 1	Cover letter

SECTION	DOCUMENT
`Plan`	Submission content and review timeline

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 NDA (21 CFR 314) and BLA (21 CFR 601, PHS Act 351).

8. Working with other modules

- Plan and check the eCTD sequence in eCTD Dossier Planner; write Module 2.3 in QOS Composer & Dossier Assembler and Module 1 CMC items in Regional Information (3.2.R and Module 1).

9. Common pitfalls

- A 505(b)(2) without a patent certification for each listed drug relied upon.
- Study data not in CDISC standards, which leads to technical rejection.

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. **Switch to a 505(b)(2)**

   Change the application type to NDA 505(b)(2).

   EXPECTED RESULT

   The headline shows refuse-to-file risks: no patent certification and no listed drug relied upon.

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.