# README.txt

## FABRICATED NDA PACKAGE

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Company: Aureon Biotherapeutics, Inc. (fictional)
Product: Cardiavax (levorin) - fictional small-molecule cardiovascular agent
Purpose: Synthetic, fully fictional NDA submission created for testing AI document review agents.
DISCLAIMER: THIS PACKAGE IS COMPLETELY MADE-UP. Do NOT use for any real regulatory filing.

# appendix_fake_study_dataset_description.txt

## Appendix: Mock datasets (descriptions only)

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- FIC-301_SSD.csv (not included): subject-level dataset with demographics, BP readings, labs.
```

# labeling_prescribing_information.md

## Proposed USPI (Highlights - Fictional)

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Cardiavax (levorin) tablets, 25 mg

INDICATIONS AND USAGE
- Cardiavax is indicated for the treatment of symptomatic orthostatic hypotension in adults when no
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# module1_cover_letter.txt

## Cover Letter

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Cover Letter
Aureon Biotherapeutics, Inc.
123 Innovation Way
Biocity, XX 00000
Date: 2025-10-29

To: Division of New Drugs, FDA (fictional)
Re: New Drug Application (NDA) - Cardiavax (levorin) - NDA #FIC-2025-0001 (fabricated)

Dear Review Team,
Aureon Biotherapeutics submits this fictitious NDA for Cardiavax (levorin)... (see package)
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# module2_summaries.md

## Module 2: CTD Summaries (Fictional)

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2.1 Quality Overall Summary (QOS)
- Drug substance: Levorin (fictitious API). Proposed formulation: immediate-release tablets, 25 mg.
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# module3_cmc_summary.md

## Module 3: Chemistry, Manufacturing and Controls (CMC) - Summary (Fictional)

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Drug Substance (Levorin) - Manufacturer: Aureon API Works (fictional)
- Process overview: 6-step synthetic route; intermediate isolation at Step 4.

# module4_nonclinical_summary.md

## Module 4: Nonclinical Study Reports (Fictional)

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Studies included (summaries only):
- Single-dose toxicity (rat) — NOAEL: 50 mg/kg (fictitious)
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# module5_clinical_overview.md

## Module 5: Clinical Study Reports (Fictional)

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Pivotal Trials:
- FIC-301 (n=450): randomized 2:1 (active:placebo), 12-week double-blind.
```