

Regulatory Evidence Reconciliation Pack

Independent Work Sample

Version 1.1 | Source review: 14 October 2026

Independent demonstration. No client engagement or endorsement is represented.

Executive summary

This pack demonstrates how PGSL links client-defined documentation requests to existing records, identifies uncertain document relationships, and prepares a traceable handover for internal review.

The public section cross-references two historical FDA letters concerning Zen Enterprises LLC. The separate fictional exercise uses six client-defined tasks and eight document-register entries, including seven supplied excerpts and one explicitly unprovided record.

Section	Result and boundary
Historical public records	Six attributed observations from two FDA letters. The same four products are identifiable in both. Closure is FDA's historical statement; internal records and current status remain unverified.
Fictional client exercise	One comparison matches. Five remain unresolved: version conflict, reference conflict, external dependency, partial support and a record not supplied. These are documentation statuses, not compliance findings.

Scope and input register

Public inputs: PUB-S01 and PUB-S02 only. **Simulated client inputs:** SIM-I01 to SIM-I06. **Simulated records:** SIM-D01 to SIM-D08. Sources and embedded excerpts are included later in this pack.

Client-controlled fields: task definition, owner, intended version, review date and report reference. All simulated dates are invented. No legal deadline has been calculated.

Primary deliverable: the accompanying XLSX contains filterable matrices, registers, status definitions and editable review fields. This PDF is a reader edition of the same sample.

PGSL had no role in the Zen Enterprises matter and reviewed no internal company records. The fictional exercise does not reconstruct that matter.

Historical public-record reconciliation

VERIFIED PUBLIC INFORMATION: attributed statements in dated FDA sources. Internal information remains Not Publicly Verifiable.

PUB-R01 Product population

The warning letter identifies Zen Sports Balm (73048-000), Zen Hemp Balm (73048-001), Zen Hand Sanitizer (73048-002) and Sycuan Casino Resort Hand Sanitizer (73048-003). The close-out identifies the same four products.

Source / locator: PUB-S01; PUB-S02. PUB-S01: opening paragraph. PUB-S02: first substantive paragraph.

Not Publicly Verifiable: Underlying listing submissions, version history and internal product roster were not reviewed.

PUB-R02 Manufacturer reference

FDA identified Dr. Sankunni's Ayurvedic Research Foundation Private Ltd. (DUNS 650517704) as the listed manufacturer and, citing a December 15, 2022 response, stated it was not involved in manufacturing the four drugs. The warning letter said the listing files had not been corrected at that time.

Source / locator: PUB-S01. Registration and Drug Listing Violations: paragraphs describing the establishment section and the December 15, 2022 response.

Not Publicly Verifiable: The underlying response and manufacturing records are not included in the reviewed sources.

PUB-R03 Earlier notices

The warning letter's footnote describes a December 4, 2023 listing-deficiency notice and a January 18, 2024 data-removal email.

Source / locator: PUB-S01. Footnote 1, first paragraph.

Not Publicly Verifiable: The notices themselves, delivery receipts, recipients' actions and internal owners were not reviewed.

PUB-R04 Response timing

The warning letter requests a written response within 15 working days of receipt, with steps taken and related documentation.

Source / locator: PUB-S01. Paragraph beginning Please notify FDA in writing.

Not Publicly Verifiable: Receipt date, actual response date, response package and evidence of timeliness are not established by the reviewed letters.

PUB-R05 Published close-out

FDA reported that end marketing dates were added to all four listings, described the products as discontinued, and closed the warning letter. The close-out references Warning Letter 2644.

Source / locator: PUB-S02; PUB-S01. PUB-S02: first substantive paragraph. PUB-S01: RE: WL 2644.

Not Publicly Verifiable: Submission files, exact end marketing dates, receipts and internal approvals were not reviewed.

PUB-R06 Limits of closure

FDA reserved future assessment and regulatory action and stated its expectation that previous errors be corrected if a product is reintroduced.

Source / locator: PUB-S02. Paragraphs after the first substantive paragraph, covering future activities, sustained compliance and future action.

Not Publicly Verifiable: Later commercial activity, current compliance, internal monitoring and reintroduction decisions are not evaluated here.

Simulated reconciliation 1-2

SIMULATED CLIENT INPUTS. All tasks, roles, providers, dates and records on this page are invented and unrelated to Zen Enterprises.

SIM-R01 / Matched

Client scope: Match the four-item handover roster to the client-defined population SIM-P-A, SIM-P-B, SIM-P-C and SIM-P-D.

Input: SIM-I01 / SIM-TASK-01

Owner: SIM Owner A - Records coordinator

Client review date: 2026-10-16 (fictional, not regulatory)

Report reference: SIM-REPORT-01 / section 1

Client-reported state: Client states the handover roster is ready for indexing.

Records: SIM-D01

Availability: Supplied in sample

Observation: The four identifiers in the supplied roster match the four-item population in the client task brief.

Next documentation action: Retain the roster reference in section 1. No further document query for this defined comparison.

Dependency: None identified in sample | **Question:** None

Boundary: Matching identifiers is not confirmation of compliance or the truth of an underlying operational assertion.

SIM-R02 / Version conflict

Client scope: Link the client-designated approved procedure SIM-PROC-07 version 3 to the report index.

Input: SIM-I02 / SIM-TASK-02

Owner: SIM Owner B - Document control

Client review date: 2026-10-19 (fictional, not regulatory)

Report reference: SIM-REPORT-01 / section 2

Client-reported state: Client task brief names version 3 as the intended supporting version.

Records: SIM-D02

Availability: Supplied in sample

Observation: Client asks for SIM-PROC-07 v3. Supplied header states v2 and superseded. The requested version is not present.

Next documentation action: Ask document control for the intended v3 or a corrected client reference. Preserve v2 as the received record.

Dependency: None identified in sample | **Question:** SIM-Q01

Boundary: Do not select or approve the governing procedure version on the client's behalf.

Simulated reconciliation 3-4

SIMULATED CLIENT INPUTS. All tasks, roles, providers, dates and records on this page are invented and unrelated to Zen Enterprises.

SIM-R03 / Reference conflict

Client scope: Tie the package reference in the response index to the receipt supplied by the submission service.

Input: SIM-I03 / SIM-TASK-03

Owner: SIM Owner C - Reporting coordinator

Client review date: 2026-10-19 (fictional, not regulatory)

Report reference: SIM-REPORT-01 / section 3

Client-reported state: Client states a receipt is available for the indexed package.

Records: SIM-D03; SIM-D04

Availability: Supplied in sample

Observation: Receipt SIM-RCPT-88 is referenced by both records, but the index names SIM-PKG-041 and the receipt names SIM-PKG-014.

Next documentation action: Request confirmation from the client and its service provider. Keep the package-to-receipt relationship unresolved.

Dependency: SIM-DEP02 | **Question:** SIM-Q02

Boundary: Receipt does not establish regulator acceptance. No inference of a typographical error.

SIM-R04 / External dependency

Client scope: Attach the archive export requested under SIM-REQ-22 to the handover record.

Input: SIM-I04 / SIM-TASK-04

Owner: SIM Owner A - Records coordinator

Client review date: 2026-10-20 (fictional, not regulatory)

Report reference: SIM-REPORT-01 / section 4

Client-reported state: Client states the external archive service acknowledged the request.

Records: SIM-D05

Availability: Mentioned, not supplied

Observation: Acknowledgment identifies SIM-REQ-22 but says the export is not attached and no delivery date is confirmed.

Next documentation action: Client coordinator to obtain the export and a delivery update from the archive service.

Dependency: SIM-DEP01 | **Question:** SIM-Q03

Boundary: Provider is fictional. No contact has been made and no service delivery has occurred.

Simulated reconciliation 5-6

SIMULATED CLIENT INPUTS. All tasks, roles, providers, dates and records on this page are invented and unrelated to Zen Enterprises.

SIM-R05 / Partial support

Client scope: Locate the approval name and date on the client-specified sign-off form SIM-APR-09.

Input: SIM-I05 / SIM-TASK-05

Owner: SIM Owner B - Document control

Client review date: 2026-10-20 (fictional, not regulatory)

Report reference: SIM-REPORT-01 / section 5

Client-reported state: Client supplied a sign-off form for the package.

Records: SIM-D06

Availability: Supplied in sample

Observation: Form SIM-APR-09 identifies the package and preparer. Approver name and approval date are blank.

Next documentation action: Ask whether a completed approval record exists. Keep the supplied unsigned form linked as received.

Dependency: None identified in sample | **Question:** SIM-Q04

Boundary: PGSL neither signs the form nor determines whether approval is legally required.

SIM-R06 / Not supplied

Client scope: Reconcile the client-defined four-item population to the supplied end-date extract and its referenced supplement.

Input: SIM-I06 / SIM-TASK-06

Owner: SIM Owner C - Reporting coordinator

Client review date: 2026-10-21 (fictional, not regulatory)

Report reference: SIM-REPORT-01 / section 6

Client-reported state: Client task brief expects coverage of SIM-P-A through SIM-P-D.

Records: SIM-D07; SIM-D08

Availability: Partly supplied

Observation: Extract supplies dates for three of four client-defined items. The fourth points to SIM-SUPP-D, which is not supplied.

Next documentation action: Request SIM-SUPP-D or another client-approved reference for SIM-P-D. Do not infer its end date.

Dependency: None identified in sample | **Question:** SIM-Q05

Boundary: Not supplied is a bounded package observation, not a conclusion that the underlying record does not exist.

Simulated record excerpts 1-4

SIMULATED CLIENT INPUTS. These embedded excerpts are the actual inputs reviewed in the fictional exercise. They are not real company records.

SIM-D01 Handover roster

Reference: SIM-ROSTER-01 | **Version:** 1 | **Date:** 2026-10-10

Availability: Supplied in sample

SIMULATED RECORD. Roster reference: SIM-ROSTER-01. Version: 1. Items in scope: SIM-P-A; SIM-P-B; SIM-P-C; SIM-P-D. Prepared by: SIM Owner A. Purpose: identify the four records for a documentation handover. No real products or companies are represented.

Limit: A roster does not establish regulatory or technical adequacy.

SIM-D02 Procedure control header

Reference: SIM-PROC-07 | **Version:** 2 | **Date:** 2026-10-09

Availability: Supplied in sample

SIMULATED RECORD. Procedure: SIM-PROC-07. Version: 2. Title: Report attachment indexing. Document-control status: superseded. Header only. The client task brief separately requests version 3; version 3 is not supplied in this exercise.

Limit: The procedure body and the requested version 3 are not provided; no evaluation of procedure adequacy.

SIM-D03 Response index entry

Reference: SIM-INDEX-05 | **Version:** 1 | **Date:** 2026-10-11

Availability: Supplied in sample

SIMULATED RECORD. Index: SIM-INDEX-05, version 1. Report location: SIM-REPORT-01 / section 3. Package reference: SIM-PKG-041. Linked receipt reference: SIM-RCPT-88. This index records an intended document link, not an external acceptance decision.

Limit: Index linkage must be checked against the receipt's own package field.

SIM-D04 Submission service receipt

Reference: SIM-RCPT-88 | **Version:** 1 | **Date:** 2026-10-11

Availability: Supplied in sample

SIMULATED RECORD. Service: SIM Submission Service B, a fictional provider. Receipt reference: SIM-RCPT-88. Package reference: SIM-PKG-014. Service event: file transfer received on 2026-10-11. No statement of regulator receipt, acceptance or adequacy.

Limit: Receipt and index name different packages. Neither reference has been silently corrected.

Simulated record excerpts 5-8

SIMULATED CLIENT INPUTS. These embedded excerpts are the actual inputs reviewed in the fictional exercise. They are not real company records.

SIM-D05 Archive request acknowledgment

Reference: SIM-REQ-22 | **Version:** 1 | **Date:** 2026-10-12

Availability: Supplied in sample

SIMULATED RECORD. Provider: SIM Archive Service A, a fictional provider. Request: SIM-REQ-22. Requested item: four-item archive export. Message: request received; export not attached; delivery date not confirmed. Client coordinator: SIM Owner A.

Limit: Acknowledgment supports the existence of the simulated request only; it does not establish delivery.

SIM-D06 Approval form

Reference: SIM-APR-09 | **Version:** 1 | **Date:** 2026-10-12

Availability: Supplied in sample

SIMULATED RECORD. Form: SIM-APR-09. Package: SIM-PKG-041. Prepared by: SIM Owner B. Prepared date: 2026-10-12. Approver name: [blank]. Approval date: [blank]. The blank fields are intentionally retained as part of the exercise.

Limit: Prepared status is not approval. No signature authenticity assessment is performed.

SIM-D07 End-date extract

Reference: SIM-EXTRACT-03 | **Version:** 1 | **Date:** 2026-10-13

Availability: Supplied in sample

SIMULATED RECORD. Extract: SIM-EXTRACT-03. SIM-P-A: 2026-09-30. SIM-P-B: 2026-09-30. SIM-P-C: 2026-09-30. SIM-P-D: see supplement SIM-SUPP-D. These are invented record values, not legal deadlines or actual marketing data.

Limit: The extract contains dated entries for three items and a supplement reference for the fourth.

SIM-D08 Referenced supplement

Reference: SIM-SUPP-D | **Version:** Unknown | **Date:** Not provided

Availability: Not supplied in sample

NO RECORD CONTENT SUPPLIED. SIM-D07 references SIM-SUPP-D, but this exercise contains no supplement. No date, approval, version or contents are inferred.

Limit: Not supplied refers only to this fictional input package. It is not a claim about any real company's records.

Dependencies and open questions

SIMULATED CLIENT INPUTS ONLY. No external provider has been contacted. Questions are intentionally unanswered in this sample.

Third-party dependency register

SIM-DEP01 / SIM-R04 - SIM Archive Service A (fictional)

Four-item archive export for SIM-REQ-22

Basis: SIM-D05. **State:** Acknowledged; export not supplied.

Owner: SIM Owner A. **Client review date:** 2026-10-20.

Client-requested review date only. Provider delivery date unconfirmed. PGSL has not contacted this fictional provider.

SIM-DEP02 / SIM-R03 - SIM Submission Service B (fictional)

Confirm the package associated with receipt SIM-RCPT-88

Basis: SIM-D03; SIM-D04. **State:** Clarification needed; not requested in this exercise.

Owner: SIM Owner C. **Client review date:** 2026-10-19.

Client-requested review date only. No regulator or provider communication is represented.

Open information / documentation questions

SIM-Q01 / SIM-R02 / SIM Owner B

Can you provide SIM-PROC-07 v3, or confirm that the client task reference should change?

To resolve: Client supplies intended version or approves a corrected reference; retain original version trail.

SIM-Q02 / SIM-R03 / SIM Owner C

Which package does SIM-RCPT-88 belong to: SIM-PKG-041 or SIM-PKG-014?

To resolve: Client/provider confirmation and consistent package reference; preserve both original records.

SIM-Q03 / SIM-R04 / SIM Owner A

Can the archive service provide the export for SIM-REQ-22 and confirm its delivery date?

To resolve: Requested export received and indexed to the client-defined four-item scope.

SIM-Q04 / SIM-R05 / SIM Owner B

Is there a completed approval record for SIM-APR-09?

To resolve: Client supplies the intended completed record or explicitly revises the documentation request.

SIM-Q05 / SIM-R06 / SIM Owner C

Can you provide SIM-SUPP-D or an alternative client-approved reference for SIM-P-D?

To resolve: Fourth item's date is supported by a supplied record linked to the correct item.

How to use the registers

Keep the original received records. Ask the client to resolve the specific reference or supply the requested document. Record the answer and replacement reference before changing the matrix status. A documentation match is not a regulatory sign-off.

Sources, definitions and limits

Official source / document reference register

PUB-S01 - Warning Letter, 2024-04-18

FDA, Zen Enterprises LLC, MARCS-CMS 678407.

[Open official FDA document](#). Reviewed 2026-10-14. Document date confirmed; original webpage publication date not displayed in reviewed page.

PUB-S02 - Close-Out Letter, 2024-09-11

FDA, Zen Enterprises LLC, MARCS-CMS 678407.

[Open official FDA document](#). Reviewed 2026-10-14. Document date confirmed; original webpage publication date not displayed in reviewed page.

Status definitions

Public-source verified	The attributed statement can be located in a reviewed official source. This is not independent validation of the underlying activity.
Matched	The supplied fictional records agree on the specific fields compared. No open question for that defined comparison.
Version conflict	The supplied version differs from the version designated in the fictional client task.
Reference conflict	Supplied records disagree on an identifier needed to establish the document link.
External dependency	A requested supporting item awaits a fictional third party; an acknowledgment alone is not delivery.
Partial support	A supplied record addresses part of the client-defined request, but specified fields remain unsupported.
Not supplied	The expected supporting item is absent from the explicitly bounded fictional input package. It may exist elsewhere.
Not Publicly Verifiable	The reviewed public sources do not establish the internal fact. This is an evidence-boundary label, not a finding of missing company evidence.

Limitations and exclusions

No engagement, affiliation, endorsement or client relationship with Zen Enterprises LLC is represented. PGSI had no role in its FDA matter.

Public facts concern two dated FDA letters only. The sample is not a current-status investigation or a complete reconstruction of the matter.

All SIM identifiers, roles, providers, dates, task statements and record contents are invented. They do not describe Zen Enterprises or any actual client.

In a paid engagement, the client identifies the obligations, owners, deadlines, intended document versions and reporting references before reconciliation. PGSI does not derive or interpret them.

No legal or regulatory advice, representation, regulator submissions, technical remediation, product-safety judgment, medical or engineering opinion, audit opinion or compliance certification.

Document presence and field agreement do not establish authenticity, adequacy, effectiveness, regulatory acceptance or compliance. Specialist decisions remain with the client and its qualified advisers.

Request a similar bounded engagement

Use pgssystemslab.com/contact/ to describe one documentation problem, the available records and the output you need. Scoping can be handled by email. Do not include confidential files in the initial inquiry.