SUPWM HEALTHCARE MERCHANT READINESS

Pharmaceutical Manufacturer Readiness Checklist

A structured evidence guide for drug manufacturers, repackers, relabelers, private-label arrangements, and their payment and digital-commerce partners.

USE THIS GUIDE TO	**PREPARE AN EVIDENCE PACKET**
DESIGNED FOR	**Pharmaceutical manufacturers and portfolio reviewers**
VERSION	**1.0 | August 2026**

Important: This is an educational preparation guide, not a certification standard, legal opinion, regulatory determination, or promise of approval by SUPWM, a regulator, card network, payment provider, or advertising platform. Requirements vary by jurisdiction and business model. Confirm obligations with qualified counsel and the appropriate authorities.

Evidence preparation checklist

Mark each item when the evidence is current, internally consistent, and ready for secure review. Use N/A only after documenting why the item does not apply.

Business identity and ownership

Build a complete record of the organization and the people who control it.

- [ ] Current legal entity formation documents, registration number, DBA names, ownership chart, and principal contact details.
- [ ] Beneficial owners, controlling persons, officers, directors, medical leadership, and material disciplinary or enforcement history.
- [ ] Every active, parked, redirecting, campaign, patient-portal, checkout, and affiliated domain used by the business.
- [ ] Physical operating locations, service areas, fulfillment locations, and jurisdictions in which customers or patients are accepted.

Partners, affiliates, and the care pathway

Document every material third party involved in marketing, clinical care, prescribing, dispensing, fulfillment, technology, or payments.

- [ ] Executed agreements and current contact details for pharmacies, provider groups, laboratories, manufacturers, distributors, and fulfillment partners.
- [ ] A patient or customer journey map showing referrals, clinical decisions, prescriptions, payment, fulfillment, and support handoffs.
- [ ] Evidence that partner licenses and registrations are current and appropriate for the activities performed.
- [ ] All co-owned businesses, promotional partners, lead generators, agencies, affiliates, and domains they operate on your behalf.

Website, disclosures, and customer experience

Prepare the exact online experience a reviewer or monitoring system should evaluate.

- [ ] Public pages, logged-in areas, product catalogs, intake flows, checkout, payment pages, and post-purchase communications are accessible for authorized review.
- [ ] Legal business name, contact information, service area, pricing or material cost disclosures, refund/cancellation terms, and fulfillment expectations are clear.
- [ ] Privacy notice, terms of use, consent language, data practices, and security disclosures reflect actual operations.
- [ ] A test account and documented navigation path are available for restricted or member-only areas when authorized review is required.

Marketing and claims evidence

Create a claim inventory before an external reviewer or payment partner finds inconsistencies.

- [ ] Inventory all express and implied health, safety, performance, outcome, comparative, testimonial, and before-and-after claims.
- [ ] Attach the substantiation, approvals, labeling, limitations, and required disclosures supporting each material claim.
- [ ] Review websites, social accounts, paid ads, email, influencers, affiliates, scripts, and sales materials for consistent claims.
- [ ] Document an approval and monitoring process for new claims, promotions, products, and third-party marketing.

Establishment registration and product listing

Reconcile the organization, every manufacturing establishment, and each commercially distributed product.

- [ ] Current FDA establishment registration information and corresponding foreign establishment, U.S. agent, and importer details where applicable.
- [ ] Current drug listing records, NDC information, labels, Structured Product Labeling records, and change history for marketed products.
- [ ] A role matrix distinguishing manufacturer, contract manufacturer, repacker, relabeler, API supplier, private-label distributor, and specification owner.
- [ ] Evidence that registration and listing data are reviewed and updated on the required cadence; do not represent registration or listing as FDA approval.

Quality systems and CGMP evidence

Prepare records that show the facilities, methods, and controls used to maintain product quality.

- [ ] Quality manual, organizational responsibilities, document controls, training, deviation, CAPA, change-control, and supplier-qualification procedures.
- [ ] Batch records, laboratory controls, stability program, specifications, release procedures, complaints, returned goods, and reserve samples as applicable.
- [ ] Inspection history, Form FDA 483 observations, warning letters, import alerts, consent decrees, corrective actions, and effectiveness checks.
- [ ] Contract manufacturing quality agreements and oversight records defining responsibilities for testing, release, reporting, and record retention.

Product status, labeling, and promotion

Ensure each digital claim is consistent with the product's lawful status and approved or otherwise permitted labeling.

- [ ] Product inventory identifying approval, authorization, monograph, compounding, investigational, export-only, or other regulatory status.
- [ ] Current labels, prescribing information, risk information, required warnings, promotional review records, and distribution limitations.
- [ ] Evidence supporting product-quality, safety, performance, comparative, and manufacturing claims made online or through sales partners.
- [ ] Controls for websites, brand sites, social media, scientific exchange, distributors, affiliates, and third-party promotional content.

Supply chain, complaints, and market action

Map custody and accountability from incoming material through distribution and postmarket response.

- [ ] Qualified supplier and customer records, serialization or traceability evidence where applicable, warehousing, transport, and distribution controls.
- [ ] Complaint intake, adverse-event escalation, field alert, recall, shortage, counterfeit, diversion, and returns procedures as applicable.
- [ ] Recall history, root-cause documentation, notification records, reconciliation, and effectiveness checks.
- [ ] Business continuity and quality risk controls for critical materials, sites, laboratories, and contract partners.

Suggested review packet index

Keep the packet organized and versioned. Do not send credentials, protected health information, personal data, or sensitive records by ordinary email.

- [ ] 01 - Legal entity, ownership, DBAs, locations, and domain inventory
- [ ] 02 - Licenses, registrations, expiration dates, and verification evidence
- [ ] 03 - Products, services, jurisdictions, and business-model narrative
- [ ] 04 - Partner and affiliate roster, agreements, and oversight evidence
- [ ] 05 - Website journey, restricted-area access plan, terms, and disclosures
- [ ] 06 - Marketing claim inventory, substantiation, approvals, and monitoring
- [ ] 07 - Privacy, security, complaints, incidents, and corrective-action records
- [ ] 08 - Ongoing monitoring owner, cadence, escalation, and evidence retention

Reference starting points

These links are starting points only. Use the rules, guidance, and authorities applicable to the specific business and jurisdictions under review.

FDA Electronic Drug Registration and Listing System
https://www.fda.gov/drug-registration-and-listing

FDA CGMP Regulations
https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations

FDA Pharmaceutical Inspections and Compliance
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/pharmaceutical-inspections-and-compliance

FTC Health Products Compliance Guidance
https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance

Ready to discuss an evidence-first merchant review?

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