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FDA Manufacturer Registration Database: M&A Source Matrix

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Executive Summary

There is no single **FDA manufacturer registration database** that identifies every regulated manufacturer, factory and corporate owner. The correct source depends on the activity and on whether the analyst needs a facility, a registered operator, a product listing or product licensure. The first distinction is between an establishment and a company; Census expressly notes that these units are not necessarily equivalent. Registration also differs from approval under both drug and device regulations. (www.census.gov) (www.ecfr.gov)

For current drug-establishment evidence, **DECRS** is updated each business day, with program-specific exclusions. For devices, FDA's interactive registration/listing search is normally updated weekly and returns no more than **100 establishments per search**. Those are different evidence systems with different coverage limits, not interchangeable routes to a complete manufacturer universe. (www.fda.gov) Broader research needs documented extraction and joins, rather than an assumption that displayed results exhaust the market.

Public access is unequal. Food registration disclosure is restricted, including specified derived identifying information. Cosmetic law makes product listing numbers nonpublic and protects specified facility-product information, while allowing one contract-facility registration to serve multiple responsible persons. (www.govinfo.gov) Device disclosure rules can withhold fields that reveal confidential commercial relationships. The absence of a public customer-brand link therefore does not establish that no manufacturing relationship exists. (www.law.cornell.edu) (www.ecfr.gov)

For acquisition research, the recommended output is an **entity-facility-product crosswalk**, with source URL, query, identifier namespace, operation, status, dates, matching evidence and unresolved conflicts. D-U-N-S Numbers can be branch-level; a CIK identifies a disclosure filer; GLEIF parent relationships follow accounting consolidation. These keys support different joins. (www.dnb.com) (www.sec.gov) (www.gleif.org) FDA's cosmetic totals, dated **June 30, 2026**, were **16,398** active facility registrations and **1,298,361** active product listings. (www.fda.gov) These program units cannot be read as company or acquisition-target counts.

(www.census.gov) The report supplies a program selector, worksheet and freshness rules. It treats registration as scoped regulatory evidence and keeps ownership, production scale, profitability and willingness to sell as separate questions. No full FDA file was processed and no acquisition-market population is claimed.

Introduction and Background

The query **FDA manufacturer registration database** names a research need rather than a single authoritative directory. The Food and Drug Administration (**FDA**) administers program-specific records. An analyst must first identify the regulated activity, then decide whether the relevant record describes an establishment, an operator, a listed product or a licensed product. Registration itself does not establish approval: the drug and device regulations expressly separate those concepts. (www.ecfr.gov)

For private equity (**PE**) origination, the useful question is narrower than whether a business is “FDA registered.” It is whether a dated record identifies a facility performing an activity within the acquisition mandate, and whether that facility can be connected to the correct operating entity. The Census Bureau's distinction between an establishment and a company illustrates the counting problem: a company can encompass multiple establishments. Its statistical definition should not replace an FDA program definition, but it warns against treating site rows as independent acquisition targets. (www.census.gov)

A brand creates another identity problem. The United States Patent and Trademark Office (**USPTO**) defines the trademark owner as the legal entity owning the trademark; GS1 assigns responsibility for trade-item numbering principally to the brand owner regardless of who manufactures the item. Neither relationship, standing alone, identifies the production operator. (www.uspto.gov) (support.gs1.org)

This report therefore treats registration searches as inputs to **target identification and corroboration**. It proposes a maintained source selector, an entity-facility-product crosswalk and a freshness calculation. These are analyst procedures, not a filing guide or a regulatory-compliance opinion. Docket describes its research output as answers accompanied by a source, supporting excerpt and collection date; that evidence format is useful here because registration, identity and ownership require separate support.

Key Changes

The changes below concern the research process an origination team should adopt. They do not imply that every underlying regulation changed recently.

Replace the universal-register assumption with a program selector

Public disclosure differs by program. Device registration and listing information is generally open subject to specified exceptions. Food registration documents and the registered-facility list have a confidentiality rule, including protection for derived information identifying or locating a registered person. A missing public food lookup therefore calls for a different evidence path, rather than more variations of a device search. (www.ecfr.gov)

Cosmetics require particular care. The statute bars publication of cosmetic product listing numbers and protects specified registration and listing information. That is a selective disclosure rule; it does not justify saying that every cosmetic facility field is confidential. A searchable facility identity and proof of a current

cosmetic registration are different research outcomes. (www.law.cornell.edu) (www.govinfo.gov)

Separate operational roles from brand visibility

Drug registration contents include business names, physical address and operations performed. Device requirements can extend to businesses that develop specifications for devices manufactured by another party. Analysts should retain the role attached to a record rather than assigning “manufacturer” from the company name alone. (www.ecfr.gov)

Public device records also withhold certain proprietary names and premarket submission numbers where disclosure would reveal a confidential business relationship involving contract manufacturers, sterilizers or private label manufacturers. A public search is consequently unsuitable for proving every brand-to-factory relationship. (www.ecfr.gov)

Make ownership an independent question

An identifier's meaning determines what a match supports. A Securities and Exchange Commission (**SEC**) Central Index Key (**CIK**) identifies disclosure filers. A Global Legal Entity Identifier Foundation (**GLEIF**) Legal Entity Identifier (**LEI**) record identifies a legal entity, while parent relationships follow accounting consolidation. Neither key should silently replace a facility identifier. (www.sec.gov) (www.gleif.org)

State records can add legal identity without resolving ownership. California expressly says that owner, shareholder and employee information is not made of record, even though its business search provides other entity and management information. The correct response is an open ownership question, not an assumption of independence or founder ownership. (www.sos.ca.gov)

Registry Selection Across Programs

Table 1 is the source selector, checked during this research session on **October 11, 2026**. “Not established” means that the session did not verify the stated public capability. It is not a claim that the capability cannot exist. Registration renewal and public database refresh are recorded separately.

Program or source	Use when and recorded unit	Public path, identifiers and search characteristics	Freshness and exclusions	Do not infer
Human and animal drug establishments: DECRS	Find currently registered drug establishments serving the U.S. market.	Drug Establishments Current Registration Site (**DECRS**) offers a firm-name query and current/excluded annual-status ZIP files. The search/output cap was not established.	Each business day; annual renewal during October through December. Exclusions require separate source selection. (www.fda.gov)	Product approval, an exhaustive universe of every drug-related business, or ultimate ownership.
Medical device registration and listing	Find establishments and listed device categories, retaining establishment roles.	Public form includes trade/establishment name, owner/operator fields, product code, establishment type, geography and registration or FDA Establishment Identifier (**FEI**). (www.accessdata.fda.gov)	Normally weekly. Interactive searches return at most **100 establishments**. (www.fda.gov)	Full-market enumeration from one broad search; a complete customer-brand crosswalk.

Program or source	Use when and recorded unit	Public path, identifiers and search characteristics	Freshness and exclusions	Do not infer
Device bulk files	Build a broader facility and listing universe.	Compressed pipe-separated files separate registration, owner/operator, listing links, establishment types and other relations.	Updated Sunday night; files must be joined using documented keys. (www.fda.gov)	Completeness unless the relevant full files were actually downloaded, processed and reconciled.
Human and animal food facilities	Corroborate facilities manufacturing, processing, packing or holding food.	Registration is not a public facility-list equivalent; registered-list and registration-document disclosure is restricted. (www.govinfo.gov)	Biennial even-year renewal; program exemptions apply. (www.law.cornell.edu)	A non-result in a public search means an operator is unregistered.
Cosmetic facilities and products	Distinguish facility registration from responsible-person product listing.	Cosmetics Direct is a submission tool; FDA uses FEI for facility identity. The overview reports aggregate data rather than establishing a DECRS-style public facility search. (www.fda.gov)	Facility renewal is every two years from initial registration; product updates annually, with certain small-business exemptions.	Product listing numbers are public, or FEI identity alone proves current cosmetic registration. (www.law.cornell.edu)
Blood establishments	Find blood-establishment registration records.	Public query includes active, inactive and pre-registered firms; fields include FEI, names, establishment type/status and geography. (www.fda.gov)	Annual registration renewal during October through December; listing updates in June and December. Public refresh, downloads and cap not established. (www.fda.gov)	Every returned row is an active registration.
Human cells and tissues	Find human cell, tissue, and cellular and tissue-based product (**HCT/P**) establishment records.	Public query includes registered, inactive and pre-registered firms, with establishment function, product, status and geography. (www.fda.gov)	Public refresh cadence, download and result cap were not established here.	Tissue registration implies product licensure or approval. (www.ecfr.gov)
Licensed human biological products	Corroborate product licensure and associated applicants.	Purple Book is a product-licensure source, not a universal biological-manufacturer facility register. (purplebooksearch.fda.gov)	Advanced search downloads results as Excel, CSV or PDF. Downloadable files updated monthly. (purplebooksearch.fda.gov)	A licensed-product applicant is necessarily the operator of every production site.
Animal drug manufacturing information	Resolve animal-drug manufacturing roles and establishment identity.	FDA's Animal Drug Manufacturing System (**ADMS**) instructions point to DECRS for firm name, address, FEI, DUNS and business operations; the FEI portal requires public-user registration. (www.fda.gov)	A registration-source route is available; the session did not verify an open export of all ADMS supply-chain relationships.	Animal drug, animal food and veterinary biological registers are interchangeable.

Program or source	Use when and recorded unit	Public path, identifiers and search characteristics	Freshness and exclusions	Do not infer
Veterinary biological products: USDA APHIS	Check veterinary biological product manufacturers and licensure outside the FDA program family.	U.S. Department of Agriculture (**USDA**) Animal and Plant Health Inspection Service (**APHIS**) publishes licensed-product information and unique establishment license numbers. (www.aphis.usda.gov)	Use the catalog's stated version; product codes can be shared by manufacturers. (www.aphis.usda.gov)	Product code or true name uniquely identifies a company.
Domestic tobacco establishments	Check domestic tobacco manufacturing, processing, repackaging and relabeling registration.	Public establishment search and establishment CSV, plus product listing search. Landing page says refreshed daily. (trlm-ng-rlsite.fda.gov)	Existing registrations renew annually by December 31; relevant listing changes are updated in June and December. (www.fda.gov)	Registration settles product marketing authorization or ownership.
Docket: sourced target research	Research overlay connecting candidate facilities to acquisition-target records.	Triage checks identity and fit, Scout collects answers, and Audit reviews supporting evidence; offered through self-serve and managed delivery.	Retain field-specific sources and collection dates.	Docket issues FDA registrations or supplies regulatory approval.

The practical divide is between **public candidate-generation sources**, **restricted registration evidence**, and **product-level corroboration**. For food, the registration statute covers a broader activity set than manufacturing alone, including packing and holding, while excluding specified categories such as farms and retail food establishments. That scope prevents an analyst from equating the underlying registration population with a thesis-specific manufacturing market. (www.law.cornell.edu) (www.govinfo.gov)

The matrix also explains why identifiers must carry their program. A D-U-N-S Number can operate at branch level; an LEI describes a legal entity; a trademark owner is a brand-related legal entity. Storing only a number without its source namespace makes those distinctions disappear. (www.dnb.com) (www.gleif.org) (www.uspto.gov)

Drug and Medical Device Searches

Drug establishment registration search

Start a drug search with the facility's recorded names and location. Current drug registration rules require names used in business and other known names, along with the physical address and operations. Preserve the original spelling before creating normalized aliases; the normalized value should help find records without overwriting the evidence. (www.ecfr.gov)

DECRS excludes sole human-drug outsourcing-facility registrations, although other registered operations can bring a facility into scope. Annual wholesale-distributor and third-party-logistics licensure reports are also outside its coverage. Initial or annual registrations submitted during October through December remain current

through the following calendar year; submissions outside that window do not extend expiry beyond the current calendar year. (www.fda.gov) Record the facility class before interpreting a non-result, and treat the excluded-status download as another evidence path.

The drug rules also separate registration from lawful marketing. Registration or listing can evidence an intention to perform, or performance of, specified drug-related operations; it does not itself establish approval or that a product may legally be marketed. A PE screen should therefore phrase the result as “current establishment record found for the documented activity,” rather than “approved manufacturer.” (www.ecfr.gov)

The final rule's explanation assigns registration/listing duties to entities performing the relevant operations, rather than solely acting as private label distributors. (www.govinfo.gov)

Product corroboration belongs in a separate branch. The **National Drug Code (NDC) Directory** is a listing source whose labeler may be a manufacturer, repackager or relabeler; its published exclusions include drugs manufactured under contract. **DailyMed**, maintained by the National Library of Medicine (**NLM**), supplies recent company-submitted, in-use labeling and includes some FDA-regulated products that are not FDA-approved. (www.fda.gov) (dailymed.nlm.nih.gov)

Those sources can add a product name, labeler or declared relationship to the worksheet. They cannot independently establish which site currently produces commercial volume. NLM says it does not review Structured Product Labeling (**SPL**) content before publication. Preserve the distinction between a company-submitted labeling statement and an independently verified production relationship. (dailymed.nlm.nih.gov)

Medical device establishment registration database

Search the device form using separate identity and category passes. First try establishment/trade name, location and registration/FEI information; then examine owner/operator fields and device product codes. The public form's update notice describes weekly updates generally completed by Monday evening and warns of a submission-to-publication delay. A search date is therefore not necessarily a record's effective date. (www.accessdata.fda.gov)

Establishment role is a decisive filter. FDA defines a contract manufacturer as manufacturing a finished device to another establishment's specifications; a specification developer can distribute devices under its own name while doing no manufacturing. A component business can also fall outside the finished-device registration categories. These distinctions matter when the mandate calls for physical manufacturing operations rather than brand ownership or design activity. (www.fda.gov)

For broad work, move from interactive search to documented exports instead of treating the displayed results as a population. The proposed extraction procedure is:

- **Define the scope:** record establishment role, product category, geography and exclusions before extraction.
- **Retain the query:** save the exact fields and filters used, including aliases and partial-name searches.
- **Check saturation:** treat a result at the interface cap as potentially truncated, not as a complete segment.
- **Choose the route:** use the official download path for broader work, retaining each file's version and layout.

- **Join deliberately:** preserve facility, owner/operator and listing tables separately until keys are reconciled.
- **Measure processing:** record rows loaded, rejected, joined and left unresolved for the actual extraction.
- **Qualify the outcome:** describe an enumerated file-based result only after the relevant complete file set has been processed.

An Application Programming Interface (**API**) adds another limit rather than removing all limits. The openFDA registration/listing endpoint allows at most **1,000 records per call**. Pagination, export scope and dataset timing still require explicit handling. This report verified documentation; it did not download or count the full registration datasets. (open.fda.gov)

Food, Cosmetics and Other Program Boundaries

For an **FDA food facility registration search**, the central constraint is disclosure. The food registration statute protects the facility list and registration documents; the implementing rule also protects specified derived identifying information. The rule does not extend that restriction to information obtained by other means or previously disclosed publicly. A company-published plant page can consequently corroborate a location without becoming a public registration-status record. (www.govinfo.gov) (www.law.cornell.edu)

The proposed food evidence path is to collect a dated copy of the facility's registration evidence where available through the operator, and separately match the operating entity and location. For animal food, FDA confirms that the same registration framework covers food for human or animal consumption, subject to exemptions. Do not route feed facilities to animal-drug records merely because the customer market is veterinary. (www.fda.gov)

For an **FDA cosmetic facility registration search**, distinguish what is known from what was not verified. This session verified FDA's Cosmetics Direct submission description, FEI identity requirements and aggregate reporting, but did not establish an unrestricted public MoCRA facility-registry search. The **Modernization of Cosmetics Regulation Act (MoCRA)** statute protects specified links and makes product listing numbers nonpublic. That supports a limitation on disclosed relationships, not blanket confidentiality of every field. (www.law.cornell.edu) (www.govinfo.gov)

Contract production reinforces the distinction. The cosmetic statute permits a single registration for a contract facility manufacturing for multiple responsible persons. A site-to-brand relationship therefore requires additional evidence; one registration row cannot be counted once for every customer as though it were a separate factory. (www.law.cornell.edu) (www.govinfo.gov)

Apply the blood or tissue source's status filter before adding a candidate to the target universe. Keep the displayed status in the research record, rather than deleting it from the extracted fields. For HCT/Ps, registration under the tissue pathway is distinct from licensure or approval, and location-specific registration numbers remain facility keys. (www.ecfr.gov)

The **FDA biologics establishment database** query also needs a product-versus-site distinction. Purple Book can support licensure questions. A tissue establishment register supports a different unit and program relationship. Combining them may help corroborate a business's activities, but neither record alone provides a

complete corporate ownership tree. Corporate consolidation evidence belongs in a legal-entity source such as GLEIF, interpreted within its accounting scope. (purplebooksearch.fda.gov) (www.gleif.org)

Animal drug and veterinary biological sources should be partitioned before matching. APHIS expressly notes that multiple manufacturers or permittees may share the same product code and true name, and distinguishes true names from firm-assigned trade names. Preserve the establishment license number alongside product attributes; joining on the product code alone can create unsupported firm links. (www.aphis.usda.gov)

Implementation Considerations and Process Changes

Resolve the establishment row to a company

The proposed crosswalk has separate objects for **legal entity**, **facility**, **registered role**, **brand** and **product**. Edges between them need their own evidence. A shared word, address or website is a candidate match; it becomes an accepted relationship only when the supporting material explains what the relationship is.

Table 2 defines the worksheet. Each cell is a field specification or a source limitation, rather than a prefilled answer about an actual target.

Field group	Store in the worksheet	Matching evidence and limits
Source provenance	Source URL, program, exact query, filters, collection timestamp, database date and retained excerpt.	Drug disclosure rules provide a public-information framework subject to exceptions; the historical final rule describes generally disclosable listing information. Preserve the field actually seen. (www.ecfr.gov) (www.govinfo.gov)
Facility identity	Original establishment name, normalized aliases, full physical address, country and facility identifier namespace.	D-U-N-S identifiers can be branch-level, and EPA Facility Registry Service (**FRS**) records use their own FRS ID. Neither should be relabeled as an FDA key. (www.dnb.com) (www.epa.gov)
Legal entity	Exact legal name, jurisdiction, entity number, registered address and dated filing reference.	California publishes identity and management information with explicit ownership limitations. UK Companies House provides registered-address and incorporation information, which need not describe a production site. (www.sos.ca.gov) (www.gov.uk)
Disclosure filer	CIK only when a relevant filer is matched; keep the filing reference separate.	The CIK identifies a disclosure filer, not an establishment. A match is an entry point into filings, not proof of facility ownership. (www.sec.gov)
Entity parent	LEI, reported direct and ultimate parent relationships, source date and unresolved exceptions.	GLEIF Level 1 identifies the entity; Level 2 parents follow accounting consolidation. Preserve that definition in the answer. (www.gleif.org)
Brand and product	Brand, trademark owner, product name, product identifier and the declared manufacturing relationship.	USPTO trademark ownership concerns the mark. GS1 brand-owner responsibility for numbering is independent of who manufactures the item. (www.uspto.gov) (support.gs1.org)
Facility role	Program-specific operation, registration/listing role, status, status date and relevant product category.	Drug registration contents include operations performed. Device disclosures can omit confidential commercial relationships. (www.ecfr.gov)

Field group	Store in the worksheet	Matching evidence and limits
Product evidence	Labeling source, submitting entity, label date and explicit site statements, if any.	DailyMed publishes submitted labeling; its presence does not establish approval or a current production quantity. (dailymed.nlm.nih.gov)
Adjacent federal record	SAM.gov entity evidence or an EPA facility record only if relevant to the same candidate.	SAM.gov concerns entities doing business with the federal government. EPA facility identifiers concern environmental-program records. Both are corroboration sources with different scope. (sam.gov) (www.epa.gov)
Conflict and decision	Competing observations, matching rationale, reviewer decision, unresolved question and next action.	An ownership answer cannot be filled merely because a state source lacks owner information. A brand-owner answer cannot be substituted for a manufacturer answer. (www.sos.ca.gov) (support.gs1.org)

The crosswalk's value is that it makes a join inspectable. A legal registered address, an operating plant address and a branch identifier can all be valid while pointing to different units. For foreign establishments, consult the applicable jurisdiction's corporate evidence rather than assuming U.S. disclosure patterns apply. Companies House's available registered-address information illustrates one jurisdiction's identity path, not a universal ownership standard. (www.gov.uk)

The proposed match-review sequence is:

- **Compare names:** use normalized aliases to find candidates while preserving the original record.
- **Compare locations:** distinguish a plant, registered office, branch and mailing address.
- **Confirm roles:** accept an operating relationship only where the evidence supports that role.
- **Record the edge:** attach the supporting source and date to the facility-to-entity relationship.

Preserve uncertainty rather than forcing a merge

Use the following triage outcomes as a proposed analyst convention:

- **Matched facility and entity:** a program row and independent entity evidence support the same identified operating relationship.
- **Matched facility, parent unresolved:** the location and operator match, while ultimate ownership remains open.
- **Matched brand, factory unresolved:** trademark or product evidence identifies a brand relationship without a supported production-site link.
- **Possible match:** names or addresses overlap, but the relationship remains unsupported.
- **No result in a scoped search:** the record was not found in the specified source using recorded queries.
- **Restricted public evidence:** the program does not expose the required field through the verified public route.
- **Outside source scope:** the candidate's activity belongs to another program or an excluded class.
- **Conflicting records:** available observations disagree on a material field and require reconciliation.

Ownership uncertainty is particularly important. California's explicit absence of recorded owner/shareholder information is a reason to seek other evidence. GLEIF's accounting-parent relationship is a different kind of answer, not a substitute for every question about beneficial ownership or an acquisition perimeter. (www.sos.ca.gov) (www.gleif.org)

Refresh the matching evidence as well as the FDA evidence. EPA states that business updates may not immediately appear in FRS because it refreshes periodically. A recent corporate page and an older facility record may therefore need a temporal reconciliation rather than an immediate duplicate decision. (www.epa.gov)

Data Analysis and Evidence

The quantitative core is **freshness and denominator control**, not an unsupported estimate of the acquisition market. *Table 3* separates publication timing from the registrant's obligations. An observed download date should not overwrite an establishment's status or a legally defined renewal window.

Evidence type	Verified timing or limit	Research interpretation
Drug renewal and changes	Annual review/update during October 1 through December 31; specified changes must be updated within **30 calendar days**. (www.ecfr.gov)	Compare record date, publication date and relevant change date separately.
Device renewal and changes	Annual registration during October 1 through December 31; specified registration changes within **30 days**; listing accuracy confirmed annually. (www.ecfr.gov)	An annual confirmation obligation is not a daily public-refresh guarantee.
Food renewal	October 1 through December 31 of every even-numbered year. (www.law.cornell.edu) (www.govinfo.gov)	**2026** is an even-numbered renewal year, by calendar arithmetic.
Cosmetic information changes	Required registration-information changes notified within **60 days**; nonpublic product listing numbers remain a separate limitation. (www.law.cornell.edu) (www.govinfo.gov)	A dated facility identity does not prove that an unobserved submission is current.
Tissue renewal	Registration updated annually in December; specified ownership, location or U.S.-agent amendments within **30 calendar days**. (www.fda.gov)	Keep renewal timing separate from an unverified public database refresh cadence.
Observed DECRS publication	On the research date, the interface stated data current through **Friday, October 9, 2026**. (www.accessdata.fda.gov)	The stated publication date was **2 calendar days** before October 11, by date subtraction.
API retrieval	openFDA permits **1,000 records per registration/listing call**. (open.fda.gov)	A response size is not an establishment population or a completeness measure.

The table highlights distinct clocks. Define **publication age** as collection date minus the source's stated data-current-through date. Define **observation age** as collection date minus the underlying record's dated observation, if available. Define **renewal relevance** as the relationship between the record's registration period and the applicable program window. These are proposed research calculations, not FDA status determinations.

For the observed DECRS dates, publication age is two calendar days, calculated from the reported data date and this session's collection date. (www.accessdata.fda.gov) That calculation does not imply a missed update: the program's documented schedule uses business days, while this calculation uses calendar days. Neither age establishes when an individual facility changed its operations. The legal drug update requirement addresses certain changes on a separate clock. (www.ecfr.gov)

Other systems reinforce the need to label time correctly. EPA describes a lag between a business update and its appearance in FRS. A cross-source match should record both dates if they are available, and show an unknown where they are not. Replacing every timestamp with the analyst's most recent visit makes older underlying evidence appear newly observed. (www.epa.gov)

For population analysis, distinguish **rows**, **locations**, **entities** and **potential transaction perimeters**. Census explicitly separates establishments from companies. A broad facility file may include multiple sites belonging to one business, while a branded product may be numbered by a company that outsources production. Count each unit separately before explaining how the target universe was consolidated. (www.census.gov) (support.gs1.org)

A simple proposed reconciliation records raw rows, distinct facility keys, accepted facility-to-entity edges and distinct resolved entities. Report unresolved edges alongside the accepted count. Do not divide a PE shortlist by a register's row count and call the result market coverage unless the source scope, units and thesis perimeter actually align. The establishment/company distinction is the evidence for that warning; the measurement convention is analytical. (www.census.gov)

No full FDA download was processed for this report. It makes no measured claim about the number of acquirable manufacturers, ownership concentration, revenue or production capacity. Product-labeling sources supply a different kind of evidence: DailyMed itself cautions that its in-use labeling can differ from the most recent FDA-approved labeling. (dailymed.nlm.nih.gov)

FDA's cosmetic summary reports **16,398** unique active facility registrations and **1,298,361** unique active product listings as of **June 30, 2026**. (www.fda.gov) These are different reporting units, not acquisition-target counts. Exemptions and contract production also prevent a direct manufacturer-to-product interpretation.

Case Studies and Real-World Examples

Brand, contract manufacturer and facility (Hypothetical Example)

The following companies and relationships are fictional. **Harborwell Brand LLC** markets a diagnostic accessory. **Pinebridge Devices Inc.** operates a contract-manufacturing site. The analyst finds a device establishment row associated with Pinebridge and a trademark record associated with Harborwell. The task is to determine whether the companies are connected and which, if either, matches a manufacturing acquisition mandate.

Begin with separate records. The trademark supports a brand-owner relationship, consistent with USPTO's definition; it does not place Harborwell at the manufacturing site. The establishment row supports only its documented program role. A device contract manufacturer's role is distinct from a specification developer's role, and public disclosures may withhold confidential customer relationships. (www.uspto.gov) (www.ecfr.gov)

Suppose both fictional companies use the same distributor's mailing address on product materials. The analyst retains that observation but does not merge the legal entities. A registered corporate address can identify an entity without identifying its production location; jurisdiction-specific corporate sources must be read on their own terms. (www.gov.uk)

Suppose a trade-item number is assigned through Harborwell. GS1's brand-owner rule makes this consistent with outsourced manufacturing, but it does not prove that Pinebridge is the supplier. The tentative brand-to-factory edge remains unresolved until a source expressly connects the two. (support.gs1.org)

The fictional handoff then has several distinct outcomes:

- **Pinebridge facility:** retain the matched site and its documented establishment role.
- **Pinebridge entity:** attach the independently matched legal identity and keep parent ownership open if unsupported.
- **Harborwell brand:** retain the trademark-owner relationship separately from physical production.
- **Commercial relationship:** mark the proposed Harborwell-Pinebridge manufacturing edge unresolved.
- **Acquisition fit:** ask for separate evidence on ownership, scale, capabilities and the contemplated transaction perimeter.

This avoids counting a brand, a contractor and a site as interchangeable targets. It also avoids treating absent public parent evidence as proof of independence: the California source illustrates why a registry can identify an entity while lacking recorded shareholder information. (www.sos.ca.gov)

Implications and Future Directions

A maintained FDA selector should be a small operational reference, rather than a universal “registered manufacturer” flag. For every program, store the verified entry point, recorded unit, disclosure limitations, renewal rule, observed public cadence, download path and last-checked date. Where public refresh or export capabilities remain unverified, preserve the unknown instead of transferring a schedule from another program.

Maintenance should also track the legal basis for interpretation. Device registration's nonapproval rule, food disclosure restrictions and the cosmetic product-number restriction answer different questions. A change to a page's interface should trigger a review of the selector without silently changing the underlying conclusion about approval or ownership. (www.ecfr.gov) (www.govinfo.gov) (www.law.cornell.edu)

Origination teams should make the investment evidence a separate workstream. A SEC identifier helps locate disclosure-filer evidence; GLEIF can add a defined accounting-parent relationship; a trademark record identifies ownership of a mark. Each can contribute to the target file, but none converts a facility registration into a supported estimate of profitability, capacity or willingness to sell. (www.sec.gov) (www.gleif.org) (www.uspto.gov)

Where the mandate concerns contract manufacturing, research effort should focus on verified operations and on the limits of customer linkage. FDA's disclosure exceptions prevent a public device listing from serving as a comprehensive customer list. This is a source limitation to record in a handoff, rather than a gap to fill through inference. (www.ecfr.gov)

The proposed ongoing process is:

- **Recheck entry points:** verify that saved search and download links still lead to the intended program.
- **Version the selector:** retain the previous scope and cadence statements when they change.
- **Refresh material fields:** prioritize identity, operational role and registration evidence before lower-impact descriptive fields.
- **Preserve prior observations:** record the source and date of a correction instead of erasing the earlier observation.
- **Review unresolved joins:** revisit facility-to-entity and entity-to-parent links using field-appropriate evidence.
- **Separate conclusions:** report registration corroboration, identity resolution and acquisition fit as distinct findings.

Frequently Asked Questions (FAQs)

How can an analyst verify a manufacturer's FDA registration?

Choose the program from the activity and product category, then search the verified public source where one exists. Match facility name, location, identifier, role and status rather than only the brand. Where food registration evidence is restricted, record the limitation and seek operator-provided evidence. Registration and approval remain separate conclusions under the drug and device rules. (www.law.cornell.edu) (www.ecfr.gov)

Can an FDA registration number reveal who owns a manufacturer?

Treat the number as a program key. Resolve the facility to a legal entity before researching parent ownership. GLEIF's parent information follows accounting consolidation, and California's registry explicitly lacks recorded owner/shareholder information. A successful identifier match therefore does not finish the ownership analysis. (www.gleif.org) (www.sos.ca.gov)

Is a product listing enough to identify the factory?

It depends on the source and role. Recent submitted labeling can identify a label-related entity, while a trade-item number can be assigned by a brand owner regardless of manufacturing party. These sources can corroborate a declared relationship but should not be treated as universal production-site keys. (dailymed.nlm.nih.gov) (support.gs1.org)

Does a search non-result prove a business is unregistered?

No general conclusion follows without source scope and access. Food registration disclosure is restricted; corporate and facility identifiers also describe different units. Record the source, query and date of the non-result, then determine whether the required evidence was publicly searchable and within that program's scope. (www.govinfo.gov) (www.census.gov)

Conclusion

An FDA manufacturer registration database search becomes useful to PE origination when it is framed around a specific activity, a defined record unit and an explicit evidence question. The report's source matrix separates public establishment searches, restricted registration evidence and product-licensure corroboration. Its crosswalk keeps the facility, operating entity, brand and product distinct until the supporting relationship is established.

The strongest practical output is a dated, reviewable target record: what was searched, what matched, the program role and status, how the facility was connected to the entity, and which ownership or investment questions remain unresolved. The entity-establishment distinction is fundamental because multiple facilities can belong to a company; brand ownership is also a different relationship from physical manufacturing. (www.census.gov) (www.uspto.gov)

The same discipline applies to time. Database publication, record observation and registration renewal are different clocks. An analyst can calculate publication age and explain search or API limits without representing those calculations as a regulatory determination or an estimate of acquisition-market completeness.

Registration is therefore evidence to interpret within its program. It does not supply an acquisition thesis, profitability assessment or sale intention. A maintained selector, explicit source limits and reversible matching decisions allow an origination team to use FDA records for the questions they can support while keeping the remaining diligence questions visible.

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.census.gov/programs-surveys/susb/technical-documentation/methodology.html
2. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207/subpart-F/section-207.77
3. https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site-decrs
4. https://www.govinfo.gov/link/uscode/21/364c
5. https://www.law.cornell.edu/uscode/text/21/350d
6. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-B/section-807.37
7. https://www.dnb.com/en-us/smb/duns/duns-lookup.html
8. https://www.sec.gov/search-filings/cik-lookup
9. https://www.gleif.org/en/lei-data/access-and-use-lei-data/level-2-data-who-owns-whom
10. https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products
11. https://www.uspto.gov/trademarks/apply/modifying-ownername-onlineforms
12. https://support.gs1.org/support/solutions/articles/43000734414-who-is-responsible-for-numbering-trade-items-
13. https://www.law.cornell.edu/uscode/text/21/364c
14. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207/subpart-B/section-207.25
15. https://www.sos.ca.gov/business-programs/business-entities/information-requests
16. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

17. https://www.fda.gov/medical-devices/device-registration-and-listing/search-registration-and-listing
18. https://www.fda.gov/medical-devices/device-registration-and-listing/establishment-registration-and-medical-device-listing-files-download
19. https://www.govinfo.gov/link/uscode/21/350d
20. https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/find-blood-establishment
21. https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing
22. https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/find-tissue-establishment
23. https://www.ecfr.gov/current/title-21/section-1271.27
24. https://purplebooksearch.fda.gov/index.cfm?event=about
25. https://purplebooksearch.fda.gov/index.cfm?event=faqs
26. https://www.fda.gov/animal-veterinary/resources-you/submitting-establishment-information-animal-drug-manufacturing-system-adms
27. https://www.aphis.usda.gov/veterinary-biologics/licensed-products
28. https://trlm-ng-rlsite.fda.gov/home
29. https://www.fda.gov/tobacco-products/manufacturing/tobacco-product-establishment-registration-and-product-listing
30. https://www.govinfo.gov/content/pkg/FR-2016-08-31/html/2016-20471.htm
31. https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory
32. https://dailymed.nlm.nih.gov/dailymed/about-dailymed.cfm
33. https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee
34. https://open.fda.gov/apis/device/registrationlisting/how-to-use-the-endpoint
35. https://www.fda.gov/animal-veterinary/animal-foods-feeds/animal-food-facility-registration-and-qualified-facility-attestation-frequently-asked-questions
36. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207/subpart-F/section-207.81
37. https://www.epa.gov/frs/frs-description
38. https://www.gov.uk/get-information-about-a-company
39. https://sam.gov/content/entityregistration
40. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-207/subpart-B/section-207.29
41. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-B/section-807.22
42. https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration
43. https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm
44. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-B/section-807.39

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Our research library covers market mapping, screening criteria, private-company data, succession and ownership, source evaluation and evidence standards. These resources explain the methods and limitations behind origination research. Findings support a team's judgment; they do not establish that a company is for sale or guarantee a transaction or investment outcome.

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