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Navigating FDA Risks in Life Sciences M&A: A Practical Diligence Guide

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Counsel advising acquirers in pharmaceutical, biotechnology, and medical device transactions must assess a target's compliance with Food and Drug Administration (FDA) requirements in granular detail as a fundamental determinant of enterprise value, deal structure, and post-closing liability exposure. Hidden liabilities may erode transaction value, give rise to indemnification claims, or, in the most serious cases, prevent the lawful marketing of a core commercial asset altogether.

The FDA is the federal agency within the U.S. Department of Health and Human Services (HHS) responsible for regulating the safety, efficacy, and manufacture of drugs, biological products, and medical devices sold in the United States. Its authority is grounded in the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA) and extends to each operational dimension of a life sciences company. For deal counsel, this creates an obligation that goes beyond reviewing disclosed regulatory correspondence and demands systematic, expert-supported attention from deal inception through closing.

This Briefing provides M&A practitioners with a structured framework for conducting FDA regulatory diligence across the categories most likely to produce material transaction risk. Practitioners who utilize the frameworks offered herein will be equipped to recognize when FDA risk is present, ask the right questions of the right experts, and translate what those experts find into deal structures and transaction documents that protect their clients.

FDA's Scope and Authority: Foundation for Diligence

The FDA operates under a complex and overlapping statutory framework that has evolved over nearly a century. Understanding this statutory and enforcement architecture is essential for deal counsel to appreciate both the legal basis and enforcement regime applicable to a target's products and facilities. The FDA is organized into operating centers, each responsible for a distinct product

category, and counsel must account for the distinct regulatory frameworks and enforcement postures of each relevant center.

The FDA's jurisdiction extends to any drug, biologic, medical device, food, dietary supplement, tobacco product, or cosmetic introduced into interstate commerce in the United States. A threshold concept for deal counsel is the distinction between products that require premarket authorization (approval for new drugs, licensure for biologics, and clearance or approval for medical devices) and those that are regulated but may be lawfully marketed without individualized FDA authorization (overthe-counter products, dietary supplements, or cosmetics). The FDA also exercises jurisdiction over the manufacturing of regulated products regardless of where manufacturing occurs. In cross-border transactions involving foreign manufacturing operations, counsel must also assess the FDA compliance status of those facilities.

FDA's Enforcement Authority and Tools

The FDA's enforcement authority spans administrative, civil, and criminal mechanisms, and the agency has broad discretion in selecting the most appropriate tool for a given compliance failure. At the administrative level, the primary informal tools are Warning Letters and Untitled Letters. Warning Letters identify regulatory violations that may lead to enforcement action if not promptly corrected and request that recipients take voluntary corrective action, typically within 15 working days. Although they are not final agency action, they carry significant practical consequences because the FDA generally will not approve new drug applications, supplements, or related requests involving a facility subject to an unresolved Warning Letter until the violations have been corrected and verified through inspection or other means.

Public posting of Warning Letters on the FDA's website creates substantial commercial and reputational exposure. Untitled Letters address violations that do not meet the threshold of regulatory significance for a Warning Letter and typically do not include a warning about potential enforcement action or have the same approval-withholding consequences. In addition, FDA may issue import alerts, pursue administrative detention of violative products, request recalls, or take other enforcement steps.

On the civil and criminal side, the FDA's primary enforcement tools are injunctions and product seizures, pursued through the Department of Justice in federal district court. Consent decrees of permanent injunction can impose sweeping operational restrictions, require third-party oversight, and include stipulated financial penalties for future violations. Criminal enforcement under the FDCA (also known as the Park doctrine) is notable for the "responsible corporate officer" doctrine, under which corporate officers may be held strictly liable for violations committed by their organizations without

proof of personal knowledge or intent if they had authority to prevent or correct the violation and failed to do so.

FDA enforcement is inherently discretionary and typically escalates from inspectional observations (Form 483) to Warning Letters and ultimately to civil or criminal action, though the agency may bypass intermediate steps for serious or imminent public health risks. Key factors influencing enforcement prioritization include the severity of the violation, the entity's compliance history, evidence of fraud or concealment, and the potential for patient or consumer harm.

Key Diligence Considerations

FDA diligence in life sciences transactions demands more than a review of commercially available databases and public enforcement records. The most consequential findings, including undisclosed enforcement history, manufacturing compliance gaps, unencumbered regulatory authorizations, and various post-market obligations, typically reside in a target's internal records and require expert-supported review across every dimension of the company's regulatory footprint. The following sections address the key diligence areas counsel should evaluate in any pharmaceutical or medical device transaction.

Regulatory Approval History & Status

A threshold diligence question in any pharmaceutical or medical device transaction is whether the target's marketed products are lawfully on the market with valid, unencumbered FDA authorization as applicable for the product type. While seemingly fundamental, this question frequently presents complications in practice. Products may be sold under authorizations obtained through prior corporate predecessors, reflect formulations or designs that have drifted from approved specifications over time, or depend on manufacturing sites that are not properly listed in the applicable application or that are operating under inadequate quality conditions.

Counsel should map all commercial products to their regulatory pathway and confirm that each authorization is current, accurate, and transferable to the acquirer. Document requests may include the following:

- Submissions and approval letters (NDA, ANDA, BLA, IND, IDE, 510(k), PMA, and De Novo submissions and approval letters), including all amendments, supplements, annual reports, letters to file, FDA meeting minutes, and correspondence with FDA's relevant review divisions.
- Complete regulatory history for each authorized product, including complete response letters (CRLs), refuse-to-file (RTF) letters, refuse-to-accept (RTA) letters, requests for additional information, deficiency letters, and all resubmission records.

- Manufacturing site authorizations, including all facilities listed in approved applications, site change supplements, and prior approval supplements (PAS) for any manufacturing changes.
- Current approved labeling, labeling history (including major safety or indication changes), and any pending labeling changes or FDA correspondence regarding labeling disputes, Instructions for Use, user manuals, and product-specific promotional claims.
- Import alerts and detention records.
- DrugMaster File (DMF) listings for any third-party materials or API suppliers whose DMFs are referenced in the target's approved applications, including authorization letters from DMF holders; and for devices, all master files and technical files.

Warning Letters & Enforcement Actions

FDA enforcement actions are among the highest-consequence diligence findings in any life sciences transaction. A consent decree can impose third-party supervision of manufacturing operations, production caps, and significant remediation costs that transfer to the acquirer. It may also restrict product distribution, require recurring third-party certifications or audits, and delay approval or launch timelines for affected products or facilities. Warning Letters, while not themselves final agency action, signal systemic compliance deficiencies in the FDA's view and frequently precede formal enforcement, product holds, or regulatory delay if remediation is not appropriately completed.

Enforcement exposure is not always disclosed in a target's financial statements or public filings at the level of granularity needed for deal purposes. The FDA's publicly accessible databases (Enforcement Reports, Warning Letter database, Inspection Classification database) provide a useful starting point but are not exhaustive. Counsel should request the complete internal documentation files and quality documentation and cross-reference them against the FDA public records to identify any discrepancies.

Examples of key document requests include:

- All FDA Form 483s and Establishment Inspection Reports (EIR) issued to any company-operated, contract manufacturing, testing, packaging, or distribution facility (if accessible), together with corrective action and preventive action (CAPA) plans, including status reports showing whether corrective actions were fully implemented and verified for effectiveness.
- All Warning Letters received, including company responses, current FDA status, and any formal closeout correspondence or acknowledgment letters, as well as any internal remediation plans or consultant assessments prepared in response.
- Consent decrees, consent agreements, injunctions, seizure orders, debarment orders, and any other formal enforcement instruments to which the company or its principals are subject,

including all reporting obligations, third-party expert requirements, and current status under any such order or agreement. Complete recall history, including all voluntary recalls, market withdrawals, and field corrections, FDA recall classification (Class I, II, or III) determinations, together with internal decision memoranda, health hazard assessments, and root cause analyses as applicable, supporting each action.

- Any criminal investigations, grand jury subpoenas, or DOJ Civil Investigative Demands relating to FDA-regulated activities, promotional practices, or reimbursement conduct.
- OPDP (Office of Prescription Drug Promotion) Untitled Letters and Warning Letters relating to promotional materials or activities, together with related promotional review committee materials, substantiation files, and final approved claims.
- Internal audit reports, management review materials, and quality committee presentations, documentation of significant manufacturing deviations, or data integrity concerns.

The existence of a prior Warning Letter or Form 483 observation is not itself disqualifying; the quality and robustness of the remediation is key. Counsel should assess whether CAPA plans submitted in response to FDA findings were systemic (addressing root causes) or merely tactical (addressing the specific observation without addressing underlying quality system deficiencies). FDA inspections often revisit prior observations on repeat inspections, and a pattern of repeat findings can be a red flag that should be closely reviewed. Repeat observations, especially across multiple inspections or sites, may indicate that management has treated issues as isolated events rather than enterprise-wide quality failures.

For transactions involving facilities under a consent decree, counsel should engage a qualified quality systems consultant to review the current state of compliance and the decree's remaining term and exit criteria. The cost of ongoing compliance, including third-party expert fees, remediation expenditures, and potential production disruptions, should be quantified and incorporated into deal economics. That review should also evaluate whether projected remediation timelines are realistic, whether capital expenditures have been fully scoped, and whether the consent decree could affect post-closing integration, supply continuity, or any applicable product launch planning.

Clinical Trials & Pipeline Regulatory Risk

Many life sciences transactions are driven by pipeline value rather than current commercial revenues. Counsel must assess whether a target's pipeline assets rest on defensible product regulatory pathways and development plans aligned with FDA requirements. For example, an asset trading at a substantial multiple has dramatically different value depending on whether a key pivotal trial was designed with FDA alignment, conducted in compliance with good clinical practice (GCP) requirements, and supported by a constructive FDA relationship across all applicable FDA

submission interactions. Undisclosed clinical holds, disputed primary endpoints, or GCP compliance deficiencies can render a pipeline asset commercially worthless regardless of the underlying science.

Counsel evaluating pipeline-driven transactions should request and review all applicable product submissions, such as active and inactive IND applications; clinical hold correspondence; special protocol assessment (SPA) agreements; breakthrough therapy, fast track, priority review, and accelerated approval designation letters; FDA meeting minutes; and briefing packages. Requests should also encompass key protocol versions and amendments, statistical analysis plans (SAPs), data monitoring committee (DMC) minutes, and summaries of major protocol deviations or FDA inspection findings at clinical sites.

Special regulatory designations, such as fast track or priority review, can dramatically accelerate timelines and attract premium valuations, but these pathways are frequently misunderstood. Each designation (fast track, breakthrough therapy, accelerated approval, and priority review) has distinct eligibility criteria, benefits, and post-approval obligations that must be understood in context rather than treated as interchangeable indicators of regulatory favor. Counsel should specifically request any FDA correspondence relating to these designations, which may indicate skepticism or questions about trial endpoints, patient populations, or control arms, or reflect a shift in FDA's regulatory expectations. Where FDA feedback reflects reservations or conditions around approvability, those caveats should be incorporated directly into valuation, milestone structuring, and risk allocation.

Manufacturing Compliance

Chemistry, Manufacturing, and Controls (CMC) compliance is typically the most operationally complex area of FDA diligence and is consistently underweighted by deal teams. Manufacturing deficiencies are a common source of product compliance issues, and FDA enforcement action and are among the most operationally disruptive post-closing liabilities. Product supply disruptions caused by manufacturing compliance failures can trigger product shortages, create commercial breaches with distribution partners, and in extreme cases result in facility shutdowns that interrupt supply of marketed products.

The Current Good Manufacturing Practice (cGMP) framework imposes detailed obligations on virtually every aspect of pharmaceutical and device manufacturing, including process validation, equipment qualification, laboratory controls, change management, deviation investigation, and batch release. Deficiencies in any of these areas can result in Form 483 observations or, when systemic, in Warning Letters. CMC compliance should be evaluated not only through the lens of public enforcement records but also through internal audit reports, and quality management system metrics.

Examples of key document requests include:

- Site master files and facility-level quality system documentation.
- Complete cGMP inspection history for each site, including all FDA Form 483 observations, EIRs, and FDA action indicated classification determinations.
- Validated manufacturing process and change control records for all material commercial products, including any process validation failures or ongoing validation activities.
- Product quality review annual reports for all commercial products, including trending data, product complaint data, and complaint trend analysis.
- Drug shortage notifications or anticipatory shortage reports filed with FDA, and any FDA correspondence in response.

Post-Market Obligations

FDA approval is not the end of a product's regulatory lifecycle or risk profile. Many approved products carry substantial ongoing obligations that are legally binding on whoever holds the approved application. Those obligations generally remain tied to the approved application and, as a practical matter, become the acquirer's responsibility upon closing. Failure to appreciate the scope, cost, and compliance complexity of post-market obligations may result in post-closing disputes. Risk Evaluation and Mitigation Strategies (REMS) and post-marketing commitments and requirements (PMCs/PMRs) are of particular focus, but counsel should also consider related pharmacovigilance, safety reporting, and other post-approval operational burdens.

PMRs and PMCs require separate attention because they are often not fully evaluated in transaction processes. PMRs are studies or clinical trials that the FDA requires under statute or regulation, whereas PMCs are studies or trials the sponsor has agreed to conduct but that are not themselves legally required by statute or regulation. Both can require substantial spending, multi-year operational support, and recurring status reporting to the FDA.

Counsel should request a product-by-product schedule of all open and closed PMRs and PMCs, current status designations, target milestones, annual status reports, correspondence with the FDA, and internal budget assumptions for completion. The diligence team should evaluate whether any open obligations could create enforcement risk, require additional clinical work, or materially affect integration planning and valuation.

Structuring & Managing Open Risk

Effective FDA diligence requires a multidisciplinary team working in a coordinated, systematic manner from the outset of the diligence process. Deal counsel should assemble teams prepared to go beyond commercially available regulatory databases. The FDA's publicly available tools are valuable as starting points and for screening, but internal records are where the most significant findings typically

reside. Public databases may identify signals, but they rarely capture the full status of remediation, internal escalation, budgeted compliance costs, or disputes with the FDA over timing, scope, or adequacy of corrective action. Counsel should push for comprehensive access to these materials and treat gaps in regulatory document production with appropriate skepticism.

Similarly, standard health care representations are often insufficient for complex FDA-regulated businesses. Counsel should negotiate targeted representations addressing the validity, completeness, and accuracy of regulatory authorizations and required statuses, as well as the absence of undisclosed enforcement actions.

FDA regulatory diligence requires systematic, expert-supported attention from deal inception through closing. Practitioners who build FDA diligence into the deal process; staff it with the right regulatory, quality, and clinical expertise; scope it to the target's full regulatory footprint; and translate findings into targeted representations, indemnities, covenants, purchase price adjustments, or other structural protections are best positioned to reduce the risk of expensive and avoidable post-closing surprises.

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