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How to Navigate FDA's Non-Inspection Enforcement Actions

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Today's Topics

FDA Non-Inspection Enforcement Actions

1. **FDA actions not originating from inspections**
--other reasons why FDA may initiate Warning Letters and Actions:
 1. **Voluntary Records Requests,**
 2. **Unapproved Drugs & Devices,**
 3. **Advertising & Promotion ,**
 4. **OTC Drugs by monograph, import-export violations (customs referrals),**
 5. **Improper distributions**

Know your Rights

- FDA may use evidence of these violations to bring enforcement actions against companies. To avoid these potential actions, a business must understand the regulation and the law behind the regulation, know its rights, when to call legal counsel and have a detailed plan to avoid and deal with these alleged violations when they occur. When allegations arise, be sure to have proper thoughtful answers, reviewed by your legal team to respond and handle these inquiries or actions can result in a long , expensive process to resolve.**

A Few Basics

- Adulteration
- Misbranding
- Patient, doctor-- complaints

Adulterated Drugs (21 U.S.C § 351)

A Drug is considered adulterated if:

- contains any filthy or decomposed substance
 - (FDCA §501(a)(1), 21 U.S.C. §351(a)(1));
- prepared, packed or held under unsanitary conditions
 - (FDCA §501(a)(2)(A), 21 U.S.C. §351(a)(2)(A);
- methods or processes used are not in conformance with good manufacturing practices
 - (FDCA §501 (a)(2), 21 U.S.C. §351 (a)(2)(b), 21 CFR Part 210 & 211);

Adulterated Drugs (21 U.S.C § 351)

- container composed of poisonous or deleterious substance may cause contents to be injurious to health
 - (FDCA §501 (a)(3), 21 U.S.C. §351 (a)(3));
- contains an unsafe coloring additive
 - (§501 (a)(4), 21 U.S.C. §351 (a)(4));



Adulterated Drugs (21 U.S.C § 351)

- strength, quality or purity falls below compendia standards
 - (§501 (b), 21 U.S.C. §351 (b));
- strength or purity falls below what it purports to possess
 - (§501 (c), 21 U.S.C. §351 (c));
- mixed or packaged to reduce quality or strength
 - (§501 (d), 21 U.S.C. §351 (d)).

Misbranding (21 USC § 331)

A non-inspection Issue

- labeling is false or misleading
 - (FDCA §502 a), 21 U.S.C. §352(a));
- label fails to bear the name and place of business, an accurate statement of contents, weight, measure or numerical count
 - (FDCA §502(b), 21 U.S.C. §352(b));
- labeling required is not prominently displayed and understandable
 - (FDCA §502(c), 21 U.S.C. §352(c));

Misbranding (21 USC § 331)

- not packaged or labeled as prescribed in the official compendium
 - (FDCA §502(g), 21 U.S.C. §352(g))
- Reference to Registration or Registration Number denoting FDA's approval of firm or products.
 - 21 C.F.R. §207.39
- Manufacture in a Non-Registered Establishment
 - §502(o) 21 U.S.C. §352(o)
- Drugs Not Included in Drug List
 - §502(o); 21 U.S.C. §352(o); 21 U.S.C. §510

Misbranding (21 USC § 331)

- labeling does not contain the established name and names and quantities of active ingredients
 - (FDCA §502(e), 21 U.S.C. §352(e);
- labeling does not prominently display the established name at least half as large as the proprietary name
 - (FDCA §502(e)(1)(B), 21 U.S.C. §352(e)(1)(B));
- labeling doesn't bear adequate directions for use
 - (FDCA §502(f), 21 U.S.C. §352(f));

Misbranding

- Misbranding provisions can pertain to materials that are physically distant from the product or its container (ads making improper claims run in journals).
- Can occur even though the drug was not misbranded at the time of shipment.
- A drug can be misbranded if it was not manufactured in a registered facility (nothing to do with product container and related materials).



FDA Enforcement Authority

- Administrative:
 - warning/untitled letters
 - product recalls
 - civil penalties
 - debarment
 - withdrawals of product approvals



FDA Enforcement Authority (cont'd)

- Judicial:
 - civil penalties
 - seizures
 - injunctions
 - criminal prosecutions
 - disgorgement



Voluntary Records Requests

- Not be confused with Mandatory Records Request
- Mandatory must be answered or FDA will consider it an inspection refusal (not yet challenged if that will hold as it is NOT an inspection)
- Voluntary records request are called voluntary, but a refusal may have FDA show up for an inspection.

Unapproved drug claims/
Off-Label Marketing of
Pharmaceuticals/ Advertising
& promotion violations

FDCA Framework

- In order to introduce a “new drug” into interstate commerce, the manufacturer must demonstrate that it is both safe and effective for each intended use. 21 U.S.C. § 355 (a),(b).
- If approval to market is granted by FDA, approval is limited to specific approved and labeled therapeutic uses.



FDCA Framework (cont'd)

- The introduction into interstate commerce of an unapproved new drug violates FDCA. 21 U.S.C. § 331(d).
- Similarly, introduction of a new drug into interstate commerce intending that it be used for unapproved, unlabeled uses likewise violates 21 U.S.C. § 331(d).



Labeling

- “Labeling” includes promotional materials, including booklets, pamphlets, and literature that is textually related to the product
- According to 21 U.S.C. § 321 (k)(m), the term “labeling” encompasses all written, printed or graphic material:
 - “upon any [drug or device] or any of its containers or wrappers, or
 - accompanying such [drug or device]”

Misbranded Drugs

- A drug is misbranded if:
 - It contains a false or misleading label (21 U.S.C. § 352 (a)); or,
 - Its labeling bears inadequate directions for use (21 U.S.C. § (f); 21 C.F.R. §201.5).
- The introduction into interstate commerce of misbranded drugs violates FDCA. (21 U.S.C. § 331 (a)).



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Thank you

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