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FDA INSPECTION AUTHORITY – KNOW THE LAW

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In light of the memos released by Attorney General Jeff Sessions and Associate Attorney General Rachel Brand in recent months indicating that FDA guidance documents are non-binding and that noncompliance with guidance documents may not be used as a basis for proving violations of applicable law in Affirmative Civil Enforcement (ACE) cases, it is more important than ever for owners and pharmacists-in-charge of 503A pharmacies to understand the statutory limitations on the FDA's inspection authority. They should be aware that, although FDA inspectors frequently cite guidance documents, federal statutes—not FDA guidance documents—govern the FDA's inspection authority.

State boards of pharmacy have historically regulated 503A pharmacies, whereas the FDA has traditionally regulated drug manufacturers. The following is an excerpt from 21 U.S.C. § 374(a), which sets forth the permissible scope of the FDA's inspection authority. It is noteworthy that, although the FDA has broad authority to inspect records and processes at manufacturers and 503B outsourcing facilities, its inspection authority is much more limited as to 503A pharmacies that qualify for the exemption under § 374(a)(2)(A). Specifically, when inspecting an exempt 503A pharmacy, the FDA may only inspect the premises and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

A 503A pharmacy that qualifies for the exemption under § 374(a)(2)(A) should alert the FDA inspectors at the beginning of the inspection that it is an exempt 503A pharmacy to ensure that the inspectors properly limit their inspection to those areas permitted by federal statute.

21 U.S.C. § 374. Inspection
(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions.

(1) For purposes of enforcement of this Act [21 USCS §§ 301 et seq.], officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized

> **(A)** to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and
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> **(B)** to inspect, at reasonable times and within reasonable limits and in a reasonable manner, **such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.**

In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) [21 USCS § 350c(a)] applies, subject to the limitations established in section 414(d) [21 USCS § 350c(d)].

In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act [21 USCS §§ 301 et seq.], or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of

any provision of this Act [21 USCS §§ 301 et seq.], have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act [21 USCS §§ 301 et seq.].

No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act [21 USCS §§ 301 et seq.]), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX [21 USCS § 355(i) or (k), 360i, 360j(g), or 387 et seq.] and data relating to other drugs, devices, or tobacco products which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) [21 USCS § 355(j)]).

A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(2) The provisions of the third sentence of paragraph (1) [underlined above] shall not apply to--

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; . . .

*Note: The formatting above has been altered from the original statute for clarity purposes and certain text has been underlined or bolded for emphasis.

Bendin Sumrall & Ladner's Pharmaceutical Regulation Practice Group welcomes your questions and comments. Please contact any of the following attorneys:

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