

(1) AS TO ANY FACTORY, WAREHOUSE, CONSULTING LABORATORY, OR OTHER ESTABLISHMENT IN WHICH ANY PRESCRIPTION DRUG IS MANUFACTURED, PROCESSED, PACKED, OR HELD, AN EXTENDED INSPECTION UNDER THIS SECTION SHALL INCLUDE EVERYTHING IN THE ESTABLISHMENT THAT MAY HAVE A BEARING ON WHETHER THE ESTABLISHMENT HAS VIOLATED A PROVISION OF THIS SUBTITLE REGARDING PRESCRIPTION DRUGS, INCLUDING THE RECORDS, PROCESSES, CONTROLS, AND FACILITIES.

(2) THE AUTHORITY UNDER THIS SUBSECTION TO CONDUCT EXTENDED INSPECTIONS OF THE RECORDS OF AN ESTABLISHMENT THAT RELATE TO PRESCRIPTION DRUGS DOES NOT INCLUDE THE AUTHORITY TO INSPECT RECORDS OF THE ESTABLISHMENT THAT RELATE TO:

- (I) FINANCIAL INFORMATION;
- (II) SALE INFORMATION, OTHER THAN SHIPMENT INFORMATION;
- (III) PRICING INFORMATION;
- (IV) PERSONNEL INFORMATION, OTHER THAN INFORMATION AS TO THE QUALIFICATIONS OF TECHNICAL AND PROFESSIONAL PERSONNEL WHO PERFORM FUNCTIONS SUBJECT TO THIS SUBTITLE; OR
- (V) RESEARCH INFORMATION, OTHER THAN INFORMATION THAT:

1. RELATES TO A NEW DRUG OR AN ANTIBIOTIC DRUG AND IS SUBJECT TO REQUIREMENTS FOR REPORTING AND INSPECTION THAT ARE IMPOSED BY RULES AND REGULATIONS ADOPTED UNDER § 355(I) OR (J) OR § 357 (D) OR (G) OF THE FEDERAL ACT; OR

2. RELATES TO ANY OTHER DRUG AND WOULD BE SUBJECT TO REPORTING OR INSPECTION UNDER RULES AND REGULATIONS ADOPTED UNDER § 355 (J) OF THE FEDERAL ACT.

(3) AUTHORITY TO CONDUCT EXTENDED INSPECTIONS UNDER THIS SUBSECTION DOES NOT APPLY TO:

(I) ANY PHARMACY THAT COMPLIES WITH THE LAWS OF THIS STATE THAT REGULATE PRACTICING PHARMACY OR MEDICINE AND THAT DOES NOT, THROUGH A SUBSIDIARY OR OTHERWISE, MANUFACTURE, PREPARE, PROPAGATE, COMPOUND, OR PROCESS ANY DRUG FOR SALE, OTHER THAN IN THE REGULAR COURSE OF ITS BUSINESS OF DISPENSING OR SELLING DRUGS AT RETAIL;

(II) ANY HEALTH PRACTITIONER WHO IS AUTHORIZED BY LAW TO PRESCRIBE OR ADMINISTER DRUGS AND WHO MANUFACTURES, PREPARES, PROPAGATES, COMPOUNDS, OR PROCESSES A DRUG SOLELY FOR USE IN THE COURSE OF THE PRACTITIONER'S PROFESSIONAL PRACTICE;