

191C.

(a) For purposes of enforcement of this subheading, the Secretary or any of his authorized agents, are authorized upon presenting appropriate credentials to the owner, operator or agent in charge to enter at reasonable times any factory, warehouse or establishment in which food, drugs, devices or cosmetics are manufactured, processed, packed or held for introduction into commerce or after such introduction or to enter any vehicle being used to transport or hold the food, drugs, devices or cosmetics in commerce; and to inspect at reasonable times and within reasonable limits and in a reasonable manner the factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein, and to obtain samples necessary to the enforcement of this subheading. In the case of any factory, warehouse, establishment or consulting laboratory in which prescription drugs 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 which are adulterated or misbranded within the meaning of this subheading or which are prohibited from being manufactured, introduced into commerce or sold or offered for sale by reason of any provision of this subheading, have been or are being manufactured, processed, packed, transported or held in any such place or otherwise bearing on violation of this subheading. No inspection authorized for prescription drugs by the preceding sentence shall extend to (i) financial data, (ii) sales data other than shipment data, (iii) pricing data, (iv) personnel data (other than data as to the qualifications of technical and professional personnel performing functions subject to this subheading, and (v) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to Section ~~501 (i)~~ 505 ~~or (j)~~ ~~or~~ 355 (I) OR (J) OR Section ~~507~~ 357 (d) or (g) of the Federal Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to Section 505 (j) of the Federal Act). The inspection shall be commenced and completed with reasonable promptness. The provision of the second sentence of this subsection shall not apply to:

(1) pharmacies which maintain establishments in conformance with Maryland laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs 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 for sale other than in the regular course of their business of dispensing or selling drugs at retail;

(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound or process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound or process drugs solely for use in research, teaching or chemical analysis and not for sale;