of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (iii) is limited by an approved application under Section ~~505~~ 355 of the Federal Act or Section 189D of this subheading to use under the professional supervision of a practitioner licensed by law to administer such drug, shall be dispensed only upon a written prescription of a practitioner licensed by law to administer the drug, or upon an oral prescription of the practitioner which is reduced promptly to writing and filed by the pharmacist, or by refilling the written or oral prescription if the refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. If any prescription for the drug does not indicate the times it may be refilled, if any, the prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner. The act of dispensing a drug contrary to the provisions of this paragraph shall be an act which results in a drug being misbranded while held for sale.

(b) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of Section 189B, except paragraphs (1), (10)(b), (10)(c), (12), and (13) thereof, and the packaging requirements of subsections (8) and (9) thereof, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drugs dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of subsection (a) of this section.

(c) The Secretary may, by regulation, remove drugs subject to Section 189B (2) and Section 189D from the requirements of subsection (a) of this section when the requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued thereunder may also, by regulations issued by the Secretary, be removed from the requirements of subsection (a).

(d) A drug which is subject to subsection (a) of this section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription," or "Caution: State Law Prohibits Dispensing Without Prescription." A drug to which subsection (a) of this section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(e) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications of narcotic drugs or marihuana as defined in the applicable Federal and State laws relating to narcotic drugs and marihuana.