

5 Per Cent Rule

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4. **Sales to Licensed Practitioners by Retail Pharmacies** In the preamble to the proposal (59 FR 11842 at 11858), the agency stated: FDA believes that permitting the sale of small quantities of prescription drugs by retail pharmacies to licensed practitioners for office use without the requirement of a State wholesale distributor's license satisfies a legitimate need and is consistent with the intent of the statute. Accordingly, the agency has included language in proposed § 203.3(y) that would exclude the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use from the definition of "wholesale distribution." In this context, sales of prescription drugs by a retail pharmacy to licensed practitioners for office use will be considered to be minimal if the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed 5 percent of the dollar volume of that retail pharmacy's annual prescription drug sales. 92. One comment supported the agency's decision to exclude minimal sales of prescription drugs by retail pharmacies from the definition of wholesale distribution and recommended that the 5 percent threshold be codified in the final regulation under § 203.3(y)(11). The agency believes that its position on what constitutes a minimal amount of prescription drugs for the purposes of revised § 203.3(cc)(10) was adequately explained in the preamble to the proposal and need not be codified. 93. Another comment recommended that the 5 percent threshold be increased to 20 percent and should be based on annual, not monthly or weekly, sales of a retail pharmacy. According to the comment, the 5 percent threshold would disadvantage small, independent pharmacies because a large percentage of their sales is derived from supplying local practitioners with prescription drugs. The comment also said that the 5 percent threshold could be reached easily by a pharmacy that supplies expensive drugs, such as chemotherapy medications, to practitioners. The distribution of prescription drugs to practitioners for office use constitutes wholesale distribution under section 503(e) of the act and proposed § 203.3(y) (i.e., distribution to other than a consumer or patient). The agency excluded the sale of minimal quantities of drugs by retail pharmacies to licensed practitioners for office use from the definition of wholesale distribution to meet the needs of licensed practitioners who may not purchase enough prescription drugs to go through a wholesale distributor and thus may not otherwise be able to easily obtain drugs for office use. Thus, the exemption was not created to confer a special benefit on retail pharmacies, but to meet the legitimate needs of licensed practitioners. The agency believes that the 20 percent threshold recommended by the comment is inconsistent with the purpose of the exemption and declines to follow the recommendation. The agency notes that a retail pharmacy is not precluded from making more than 5 percent of its annual sales to licensed practitioners. It must, however, obtain a State wholesale distributor license to do so.