(12) If it is a color additive unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to the color additive prescribed under the provisions of the federal act.

(13) If, after its manufacturing or processing or packaging, the food was in a frozen state and if it is being offered for sale in an unfrozen state unless the labeling clearly and conspicuously states that the food should not be refrozen.

188F.

(a) Any added poisonous or deleterious substance, any food additive, and any color additive, shall with respect to any particular use or intended use, be deemed unsafe for the purpose of the application of clause (ii) of Section 188B (1) with respect to any food, Section 189A [(a)] with respect to any drug or device, or Section 190A [(1)] with respect to any cosmetic, unless there is in effect a regulation pursuant to Section 191B of this subheading or subsection (b) of this section limiting the permissible quantity of such substance with respect to the use, and the use or intended use of the substance conforms to the terms prescribed by the regulation. While the regulations relating to the substance are in effect, a food, drug, or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulations, be considered adulterated within the meaning of clause (i) of Section 188B (1), Section 189A (1); or Section 190A (1).

189C.

(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] *subsections* (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.

189D.

(g) This section shall not apply:

(1) To a drug sold in this State or introduced into interstate commerce at any time prior to the enactment of the federal act, if its labeling contained the same representations concerning the conditions of its use; or

(2) To any drug which is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the animal virus-serum-toxin act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.), as either of said acts have been or may be amended from time to time; or