

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).

(b) The Secretary, whenever public health or other considerations in the State so require, is authorized to adopt, amend, or repeal regulations whether or not in accordance with regulations promulgated under the Federal Act, prescribing therein tolerances for any added, poisonous or deleterious substances, for food additives, or for color additives, including, but not limited to, zero tolerances, and prescribing the conditions under which a food additive or a color additive may be safely used and exemptions where the food additive or color additive is to be used solely for investigational or experimental purposes, upon his own motion or upon the petition of any interested party requesting that the regulation be established. The petitioner shall establish by data submitted to the Secretary that a necessity exists for the regulation, and that its effect will not be detrimental to the public health. If the data furnished by the petitioner are not sufficient to allow the Secretary to determine whether the regulation should be promulgated, the Secretary may require additional data to be submitted and failure to comply with the request shall be sufficient grounds to deny the request. In adopting, amending or repealing regulations relating to the substances the Secretary shall consider among other relevant factors, the following which the petitioner, if any, shall furnish:

(1) The name and all pertinent information concerning the substance including where available, its chemical identity and composition, a statement of the conditions of the proposed use, including directions, recommendations and suggestions and including specimens of proposed labeling, all relevant data bearing on the physical or other technical effect and the quantity required to produce the effect.

(2) The probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of the substance.

(3) The probable consumption of the substance in the diet of man taking into account any chemically or pharmacologically related substance in the diet.

(4) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of the substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data.

(5) The availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the substance in or on an article, (ii) any substance formed in or on the article because of the use of the substance, and (iii) the pure substance and all intermediates and impurities and