which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502(c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: Provided, how-

ever, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant lan-

guage may be substituted for English.

(2) If the label contains any representa-

tion in a foreign language, all words, statements, and other information re-

quired by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any rep-

resentation in a foreign language, all words, statements, and other information re-

quired by or under authority of the act to appear on the label or label-

ing shall appear on the labeling in the foreign language.

[41 FR 6908, Feb. 13, 1976]

§ 201.16 Drugs; Spanish-language version of certain required state-

ments.

An increasing number of medications restricted to prescription use only are being labeled solely in Spanish for dis-

tribution in the Commonwealth of Puerto Rico where Spanish is the pre-

dominant language. Such labeling is authorized under §201.15(c). One re-

quired warning, the wording of which is fixed by law in the English language, could be translated in various ways, from literal translation to loose inter-

pretation. The statutory nature of this warning requires that the translation convey the meaning properly to avoid confusion and dilution of the purpose of the warning. Section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act requires, at a minimum, that the label bear the statement “Rx only.” The Spanish-language version of this must be “Solamente Rx”.

[67 FR 4906, Feb. 1, 2002]

§ 201.17 Drugs; location of expiration date.

When an expiration date of a drug is required, e.g., expiration dating of drug products required by §211.137 of this chapter, it shall appear on the immediate container and also the outer package, if any, unless it is easily leg-

ible through such outer package. How-

ever, when single-dose containers are packed in individual cartons, the expi-

ration date may properly appear on the individual carton instead of the imme-

diate product container.

[43 FR 45076, Sept. 29, 1978]

§ 201.18 Drugs; significance of control numbers.

The lot number on the label of a drug should be capable of yielding the com-

plete manufacturing history of the package. An incorrect lot number may be regarded as causing the article to be misbranded.

§ 201.19 Drugs; use of term “infant”.

The regulations affecting special die-

tary foods (§105.3(e) of this chapter) de-

fine an infant as a child not more than 12 months old. Apart from this, the Food and Drug Administration has not estab-

lished any definition of the term infant. Some question has arisen whether, for the purposes of drug label-

ing, an infant means a child up to 1 year of age or a child up to 2 years of age. Until the term is more precisely defined by legislation or formal regula-

tion, where the exact meaning of the term is significant, manufacturers should qualify any reference to “in-

fant” to indicate whether it refers to a child who is not more than 1 year of age, or a child not more than 2 years of age.

[40 FR 13968, Mar. 27, 1975, as amended at 42 FR 14091, Mar. 15, 1977; 44 FR 16006, Mar. 16, 1979]