in the English language: *Provided, however,* 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 language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required 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 representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

[41 FR 6908, Feb. 13, 1976]

### § 201.16 Drugs; Spanish-language version of certain required statements.

An increasing number of medications restricted to prescription use only are being labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language. Such labeling is authorized under § 201.15(c). Two required warnings, the wording of which is fixed by law in the English language, are presently being translated in various ways, from literal translation to loose interpretation. The statutory nature of these two statements requires that the translation must convey the meaning properly, in order to avoid confusion and dilution of the purposes of the warnings. The Commissioner of Food and Drugs hereby adopts the following Spanish-language versions as the accepted equivalents of the English wording of the following:

(a) Section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act requires the statement ''Caution: Federal law prohibits dispensing without prescription.'' The Spanish version of this shall be: ''Precaucion: La ley Federal prohibe su despacho sin prescripcion facultativa.''

(b) Section 502(d) of the Federal Food, Drug, and Cosmetic Act requires the statement ''Warning—May be habit forming'' on habit-forming drugs. The Spanish version of this shall be: ''Aviso—Puede formar habito o vicio.''

[41 FR 6908, Feb. 13, 1976]

### § 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 legible through such outer package. However, when single-dose containers are packed in individual cartons, the expiration date may properly appear on the individual carton instead of the immediate 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 complete 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 dietary foods (§ 105.3(e) of this chapter) define an infant as a child not more than 12 months old. Apart from this, the Food and Drug Administration has not established any definition of the term *infant.* Some question has arisen whether, for the purposes of drug labeling, 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 regulation, where the exact meaning of the term is significant, manufacturers should qualify any reference to ''infant'' 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 13998, Mar. 27, 1975, as amended at 42 FR 14091, Mar. 15, 1977; 44 FR 16006, Mar. 16, 1979]