

Food and Drug Administration, HHS

§ 201.17

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, 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 prohíbe 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]

EFFECTIVE DATE NOTE: At 67 FR 4906, Feb. 1, 2002 §201.16 was revised, effective April 2, 2002. For the convenience of the user, the revised text is set forth as follows:

§ 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). One required warning, the wording of which is fixed by law in the English language, could be translated in various ways, from literal translation to loose interpretation. 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”.

§ 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]