§ 330.2 Pregnancy-nursing warning.

A pregnancy-nursing warning for OTC drugs is set forth under §201.63 of this chapter.

§ 330.3 Imprinting of solid oral dosage form drug products.

A requirement to imprint an identification code on solid oral dosage form drug products is set forth under part 206 of this chapter.

§ 330.5 Drug categories.

Monographs promulgated pursuant to the provisions of this part shall be established in this part 330 and following parts and shall cover the following designated categories:

(a) Antacids.
(b) Laxatives.
(c) Antidiarrheal products.
(d) Emetics.
(e) Antiemetics.
(f) Antiperspirants.
(g) Sunburn prevention and treatment products.
(h) Vitamin-mineral products.
(i) Antiinfectives.
(j) Bronchodilator and antiasthmatic products.
(k) Hemorrhoidal products.
(l) Hematinics.
(m) Antifever products.
(n) Analgesics.
(o) Sedatives and sleep aids.
(p) Stimulants.
(q) Antidiabetics.
(r) Allergy treatment products.
(s) Sunburn prevention and treatment products.
(t) Antihistamines.
(u) Anticoagulants.
(v) Antihypertensive products.
(w) Ophthalmic products.
(x) Miscellaneous dermatologic products.
(y) Dentifrices and dental products such as analgesics, antiseptics, etc.
(z) Miscellaneous (all other OTC drugs not falling within one of the above therapeutic categories).

Subpart B—Administrative Procedures

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

For purposes of classifying over-the-counter (OTC) drugs as drugs generally recognized among qualified experts as safe and effective for use and as not