

**§§ 250.103–250.104**

the management of angina pectoris in some patients:

Amyl nitrite.  
Erythryl tetranitrate.  
Mannitol hexanitrate.  
Nitroglycerin.  
Potassium nitrite.  
Sodium nitrite.

(2) Additionally, new-drug applications have been approved for products containing:

Inositol hexanitrate.  
Isosorbide dinitrate.  
Octyl nitrite.  
Pentaerythritol tetranitrate.  
Triethanolamine trinitrate biphosphate  
(trolnitrate phosphate).

(b) The Food and Drug Administration also finds that there is neither substantial evidence of effectiveness nor a general recognition by qualified experts that such drugs are effective for any of the other purposes for which some such drugs are promoted to the medical profession in labeling and advertising. In particular, neither clinical investigations nor clinical experience justify any representations that such drugs are effective in the management of hypertension; in the management of coronary insufficiency or coronary artery disease, except for their anginal manifestations; or in the management of the post coronary state, except angina pectoris present after coronary occlusion and myocardial infarction.

(c) Any preparation containing such drugs that is labeled or advertised for any use other than management of angina pectoris, or that is represented to be efficacious for any other purpose by reason of its containing such drug, will be regarded by the Food and Drug Administration as misbranded and subject to regulatory proceedings, unless such recommendations are covered by the approval of a new-drug application based on a showing of safety and effectiveness.

(d) Any such drug in long-acting dosage form is regarded as a new drug that requires an approved new-drug application before marketing.

(e) Any of the drugs listed in paragraph (a)(2) of this section is regarded as a new drug that requires an approved new-drug application. Articles for which new-drug approvals are now

**21 CFR Ch. I (4–1–03 Edition)**

in effect should be covered by supplemental new-drug applications as necessary to provide for labeling revisions consistent with this policy statement.

**§§ 250.103–250.104 [Reserved]**

**§ 250.105 Gelsemium-containing preparations regarded as prescription drugs.**

It is the consensus of informed medical opinion that the margin of safety between the therapeutic and toxic concentration of gelsemium is narrow and it is difficult to predict the point at which the dose will be toxic. Very small doses may cause toxic symptoms. It is therefore the view of the Food and Drug Administration that gelsemium is not a proper ingredient in any product that is to be sold without prescription. Accordingly, any drug containing gelsemium will be regarded as misbranded under section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act if its label fails to bear in a prominent and conspicuous fashion the statement “Rx only.”

[40 FR 14033, Mar. 27, 1975, as amended at 67 FR 4906, Feb. 1, 2002]

**§§ 250.106–250.107 [Reserved]**

**§ 250.108 Potassium permanganate preparations as prescription drugs.**

(a) There have been a number of reports in the medical literature of serious injuries to women resulting from the misuse of potassium permanganate in an effort to induce abortion. Reports from physicians who have treated such cases show that the injuries are commonly caused by introducing tablets or crystals of potassium permanganate into the vagina. Experience with these cases shows that such use of potassium permanganate is not effective in producing abortion, but that instead the drug produces serious and painful injury to the walls of the vagina, causing ulcers, massive hemorrhage, and infection. Such dangerous and useless employment of potassium permanganate is apparently encouraged among the misinformed by the mistaken idea that the vaginal bleeding caused by the corrosive action of the drug indicates a termination of pregnancy, which it does not.