

§ 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 "Caution: Federal law prohibits dispensing without prescription."

§ 250.106 Cobalt preparations intended for use by man.

(a) On January 17, 1967 (21 CFR 3.48; 32 FR 449), the Commissioner of Food and Drugs issued a revised statement of policy with respect to the status of cobalt-containing drug preparations intended for use by man, which revision was to be modified as needed following consideration of such drugs by a panel of hematologists. A panel consisting of authorities in the field of hematology met on March 8, 1967, with representatives of the Medical Advisory Board for the Food and Drug Administration to consider the status of cobalt-containing drugs and the following findings and recommendations were made:

(1) Cobalt salts are not suitable for over-the-counter sale to the public for the treatment of iron-deficiency anemia. They are associated with toxic effects and offer no advantage over iron alone.

(2) Potential toxic effects of these salts includes liver damage, claudication, myocardial damage, thyroid hyperplasia, hypothyroidism, dermatitis, nausea, and anorexia.

(3) Cobalt salts are not generally recognized as safe or effective therapy for any disease condition.

(b) On the basis of the available evidence and the findings and rec-

ommendations of the representatives of the Medical Advisory Board, the Commissioner of Food and Drugs finds and determines with respect to cobalt-containing drug preparations intended for use by man, except radioactive forms of cobalt and its salts and cobalamin and its derivatives, that:

(1) Such articles, because of their potential for causing toxic effects, are not suitable for over-the-counter use in iron-deficiency anemia; any such article that is labeled, represented, or advertised for over-the-counter use in the prevention or treatment of iron-deficiency anemia will be regarded as subject to regulatory proceedings.

(2) Such articles are not generally recognized by qualified experts as safe or effective therapeutic agents for iron-deficiency anemia or for any condition whether for over-the-counter sale or for prescription dispensing; any such article labeled, represented, or advertised for any condition will be regarded as subject to regulatory proceedings unless such recommendations are covered by a new-drug application approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and based on a showing of safety and effectiveness.

(3) Cobalt salts added to drugs in small amounts are not effective for any purpose and should be removed.

(c) A completed and signed "Investigational New Drug Application," set forth in part 312 of this chapter, must be submitted to cover clinical investigations to obtain evidence that such preparations are safe and effective for any purpose.

(d)(1) For such preparations for which new-drug approvals are in effect, supplemental new-drug applications may be submitted if changes consistent with this policy statement can be effected thereby. If the composition and labeling of an article are such that the cobalt is not significant in relation to the labeling claims, it will be permissible for the applicant to remove the cobalt salt from the formulation, delete all references to it in the labeling and resume marketing the reformulated drug, provided that a supplement is submitted within 30 days from the

date of publication of this policy statement in the FEDERAL REGISTER furnishing full information regarding such changes, including the date on which such changes are being effected.

(2) Applicants holding other approved new-drug applications for such preparations should submit, within 30 days, a written statement waiving opportunity for a hearing preliminary to withdrawing approval of the application unless the applicant wishes to avail himself of the opportunity for a hearing.

(e) Regulatory proceedings may be initiated with respect to any drug within the jurisdiction of the act that is contrary to the provisions of:

(1) Paragraph (b) of this section and shipped after the date of publication of this policy statement in the FEDERAL REGISTER.

(2) Paragraphs (c) and (d) of this section and shipped after 30 days from the date of publication of this policy statement in the FEDERAL REGISTER.

[40 FR 14033, Mar. 27, 1975, as amended at 55 FR 11577, Mar. 29, 1990]

EFFECTIVE DATE NOTE: At 62 FR 12084, Mar. 14, 1997, §250.106 was removed, effective Apr. 14, 1997.

§ 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.

(b) Potassium permanganate is a strong oxidizing agent, a highly caustic, tissue-destroying chemical, and a poison. There are no circumstances under which crystals and tablets of potassium permanganate constitute safe dosage forms for use in self-medication. It is the consensus of informed medical opinion that the only dosage forms of potassium permanganate known to be safe for use in self-medication are aqueous solutions containing not more than 0.04 percent potassium permanganate. Such solutions are safe for use in self-medication only by external application to the skin.

(c) In view of the very real potentiality for harmful effect, and the actual injuries caused by the misuse of potassium permanganate, the Food and Drug Administration believes that in order adequately to protect the public health:

(1) Potassium permanganate and potassium permanganate tablets intended for human use are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and should be restricted to prescription sale. Such drugs will be regarded as misbranded if at any time prior to dispensing the label fails to bear the legend, "Caution: Federal law prohibits dispensing without prescription."

(2) Potassium permanganate labeled for use as a prescription component in human drugs under the exemption provided in §201.120 of this chapter or labeled for manufacturing use under the exemption provided in §201.122 of this chapter will be regarded as misbranded unless the label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

(3) These drugs will be regarded as misbranded when intended for veterinary use unless the label bears the legend, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian"; *Provided, however*, That this shall not apply to a drug labeled and marketed for veterinary use if such drug contains not more than 50 percent of potassium permanganate and includes other ingredients which make it unsuitable for human use and unlikely that the article would be used in an attempt to induce abortion.

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