

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.

(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 statement “Rx only.”

(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, “Rx only.”

(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.

(4) Any preparation of potassium permanganate intended for over-the-

counter sale for human use internally or by application to any mucous membranes or for use in the vagina will be regarded as misbranded under the provisions of section 502(f) (1) and (2) and section 502(j) of the act.

(5) Any other preparation of potassium permanganate intended for over-the-counter sale for human use will be regarded as misbranded under section 502(f) (1) and (2) and section 502(j) of the act unless, among other things, all of the following conditions are met:

(i) It is an aqueous solution containing not more than 0.04 percent potassium permanganate.

(ii) The label and labeling bear, in juxtaposition with adequate directions for use, clear warning statements designated as "Warning," and to the effect: "Warning—For external use on the skin only. Severe injury may result from use internally or as a douche. Avoid contact with mucous membranes."

(d) The labeling or dispensing of any potassium permanganate preparations intended for drug use within the jurisdiction of the Federal Food, Drug, and Cosmetic Act contrary to this statement after 60 days from the date of its publication in the FEDERAL REGISTER may be made the subject of regulatory proceedings.

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

### Subpart C—Requirements for Drugs and Foods

#### § 250.201 Preparations for the treatment of pernicious anemia.

(a) The ninth announcement of the Anti-anemia Preparations Advisory Board of the United States Pharmacopeia is concerned with the status of the treatment of pernicious anemia. It clearly presents the following facts:

(1) The Sixteenth Revision of the Pharmacopeia of the United States, which became official on October 1, 1960, does not include preparations intended for the treatment of pernicious anemia by oral administration.

(2) The U.S.P. unit for anti-anemia preparations no longer has any significance.

(3) The U.S.P. Anti-anemia Preparations Advisory Board was disbanded.

(b) On the basis of the scientific evidence and conclusions summarized in the statement of the U.S.P. Anti-anemia Preparations Advisory Board as well as pertinent information from other sources, the Commissioner of Food and Drugs finds it is the consensus of well informed medical opinion that:

(1) The parenteral administration of cyanocobalamin or vitamin B<sub>12</sub> is generally recognized as a fully effective treatment of pernicious anemia. Parenteral cyanocobalamin preparations have not been and are not authorized for use except by or on the prescription of a duly licensed medical practitioner.

(2) Some patients afflicted with pernicious anemia do not respond to orally ingested products. There is no known way to predict which patients will fail to respond or will cease to respond to the treatment of pernicious anemia with orally ingested preparations.

(3) The substitution of a possibly inadequate treatment, such as the ingestion of oral preparations of vitamin B<sub>12</sub> with intrinsic factor concentrate, in place of parenteral vitamin B<sub>12</sub> products for a disease condition as serious as pernicious anemia cannot be regarded as safe in all cases.

(4) The development of the classical symptoms of pernicious anemia that would cause a person to seek medical attention may in some cases be delayed by oral ingestion of intrinsic factor. Pernicious anemia is a disease that is associated, among other things, with a higher than normal incidence of cancer of the stomach and that for the safety of the patient, requires continuous expert medical supervision.

(5) With inadequate treatment there may be markedly deleterious effects on the nervous system. It is well established that whereas the development of anemia is completely reversible with adequate treatment, the involvement of the nervous system may not be completely reversible and thus may result in permanent damage.

(6) Some hematologists prescribe oral preparations of vitamin B<sub>12</sub> in the treatment of pernicious-anemia patients.

(7) Intrinsic factor and intrinsic factor concentrate serve no known useful