

CFR › Title 21 › Chapter I › Subchapter C › Part 250 › Subpart C › Section 250.201

21 CFR 250.201 - Preparations for the treatment of pernicious anemia.

§ 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 B¹² 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 B¹² with intrinsic factor concentrate, in place of parenteral vitamin B¹² 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 B¹² in the treatment of pernicious-anemia patients.

(7) Intrinsic factor and intrinsic factor concentrate serve no known useful therapeutic or nutritive purpose except to the extent that they do increase the gastrointestinal absorption of vitamin B¹² in patients with a deficiency or absence of intrinsic factor, which may eventually lead to pernicious anemia. This conclusion does not apply to diagnostic procedures using radioactive cyanocobalamin.

(8) Medical expertise is required for the diagnosis as well as the management of pernicious anemia.

(c) The Eleventh Edition of The National Formulary and its first Interim Revision include monographs for oral preparations of vitamin B¹² with intrinsic factor concentrate, establish a unit of vitamin B¹² with intrinsic factor concentrate, and provide for a National Formulary Anti-anemia Preparations Advisory Board to assign the potency of such preparations. This provides for the availability of such oral preparations, standardized within the meaning of the broad limits characteristic of the evaluation of such preparations.

(d) Any drug that is offered for or purports to contain intrinsic factor or intrinsic factor concentrate will be regarded as misbranded within the meaning of section 503(b) of the Federal Food, Drug, and Cosmetic Act unless it is labeled with the statement "Rx only."

(e) Any drug for oral ingestion intended, represented, or advertised for the prevention or treatment of pernicious anemia or which purports to contain any substance or mixture of substances described in paragraph (d) of this section (other than diagnostic drugs containing radioactive cyanocobalamin) will be regarded as misbranded under sections 502 (f)(2) and (j) of the act unless its labeling bears a statement to the effect that some patients afflicted with pernicious anemia may not respond to the orally ingested product and that there is no known way to predict which patients will respond or which patients may cease to respond to the orally ingested products. The labeling shall also bear a statement that periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended.

(f) Under section 409 of the Federal Food, Drug, and Cosmetic Act, intrinsic factor and intrinsic factor concentrate are regarded as food additives. No food additive regulation nor existing extension of the effective date of section 409 of the act authorizes these additives in foods, including foods for special dietary uses. Any food containing added intrinsic factor or intrinsic factor concentrate will be regarded as adulterated within the meaning of section 402(a)(2)(C) of the act.

(g) Regulatory action may be initiated with respect to any article shipped within the jurisdiction of the act contrary to the provisions of this policy statement after the 180th day following publication of this statement in the FEDERAL REGISTER.

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