cations under both Indications and Clinical Discussion) are either not included in the list of U.S. Indications or could only possibly be included under the U.S. general indication of serious infections which, however, the U.S. qualifies with the phrase " for which less potentially dangerous drugs are ineffective or contraindicated", a very important restrictive general qualification Parke-Davis does not mention.

Another doctor friend described the Monograph as "loosely written" and suggested checking the Monograph's Indications and, I assume, implications for use with a specialist in infectious diseases. Until we obtain this expert opinion, our comments and comparison should be considered the personal reaction of laymen not well-informed on classification of diseases, for instance.

Another hematologist commenting on the hematological warnings in the Monograph said that what the Monograph states is true but it is so soft pedalled it will be relatively ineffective in restricting use compared to the U.S. label. Again the comment was made that it is not what is said but how it is said. so that there is not enough emphasis on adverse effects.

Still another doctor, (in infectious diseases) who did not comment on the whole Monograph, seemed to agree with sections in the Clinical Discussion dealing with the very serious diseases specifically listed in the U.S. label (which warranted initial use of chloramphenicol with concurrent testing) even though for some he stated that there were equally effective drugs. He criticized the Septicemia section as warranting more information and concluded that in some instances the information is general and disappointingly brief and would like to see the Company emphasize more strongly that chloramphenicol is not an agent that should be used for the treatment of colds or for fevers.

Another doctor in communicable diseases felt that the warnings and descriptions of adverse effects are clearly presented in the Monograph but agreed that a statement of warning on the containers sold overseas "would be humane".

Another difference between the Parke-Davis Monograph for other countries and the Parke-Davis U.S. label is in the manner of administration of Chloromycetin Succinate. The Monograph describes intramuscular use of Chloromycetin Succinate as "clinically effective although adim levels of free chloramphenicol are lower than when a comparable dose of chloramphenicol is given orally." In contrast, the U.S. banned intramuscular administration as ineffective, approving only intravenous parenteral administration.