

Appendix II. Additional FDA Submissions



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

May 7, 1968

Dear Doctor:

Serious and often fatal blood dyscrasias are known to occur following the administration of chloramphenicol. Prominent warning to this effect has been part of the approved labeling for this drug since 1952, and this information has been disseminated in the medical and lay press, including editorials in the Journal of the American Medical Association.

Because the amount of chloramphenicol distributed exceeds that to be expected if the drug were prescribed only for its valid indications, the Food and Drug Administration believes that chloramphenicol is often prescribed for conditions for which it is not indicated, including trivial conditions such as acne, the common cold, and simple infections. Fatal reactions have been associated with use in these conditions.

To enlist your aid in ending the over-prescribing of this drug, the Food and Drug Administration asks that you carefully study the following "box warning" the substance of which has been and will continue to be part of the recently revised labeling of this drug:

WARNING

Serious and fatal blood dyscrasias (aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia) are known to occur after the administration of chloramphenicol. In addition, there have been reports of aplastic anemia attributed to chloramphenicol which later terminated in leukemia. Blood dyscrasias have occurred after both short term and prolonged therapy with this drug. Chloramphenicol must not be used when less potentially dangerous agents will be effective, as described in the "Indications" section. It must not be used in the treatment of trivial infections or where it is not indicated, as in colds, influenza, infec-

tions of the throat; or as a prophylactic agent to prevent bacterial infections.

Precautions: It is essential that adequate blood studies be made during treatment with the drug. While blood studies may detect early peripheral blood changes, such as leukopenia, reticulocytopenia, or granulocytopenia, before they become irreversible, such studies cannot be relied on to detect bone marrow depression prior to development of aplastic anemia. To facilitate appropriate studies and observation during therapy, it is desirable that patients be hospitalized.