

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13501

risk of cardiovascular mortality for tolbutamide and phenformin also applies to other sulfonylurea and biguanide drugs. Therefore, the labeling for oral hypoglycemic drugs shall describe properly the conditions for their use and include a warning concerning the possible increased risk of cardiovascular mortality associated with such use, as set forth in paragraphs (b) and (c) of this section.

(b) Labeling for oral hypoglycemic drugs of the sulfonylurea category shall be as follows:

DESCRIPTION

(Trade name, established name) is an oral blood-glucose-lowering drug of the sulfonylurea category. It is a white, crystalline compound, formulated as a tablet for oral administration. (Manufacturer to add structural formula and other appropriate information.)

ACTIONS

Administration of (drug) appears to lower the blood glucose initially by stimulating the release of insulin from the pancreas; the effect is thus dependent on functioning beta cells in the pancreatic islets. The mechanism by which (drug) lowers blood glucose during long term administration has not been clearly established. Many patients who at first demonstrate an adequate glucose-lowering effect with a sulfonylurea