REQUIRING THE INCLUSION OF WARNING STATEMENT FOR PRODUCTS CONTAINING SODIUM METABISULFITE AND OTHER DERIVATIVES OF THIS SODIUM SALT

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The Bureau of Food and Drugs has found the reports of adverse drug reactions (ADRs) relating to the administration of sodium metabisulfite-containing products substantial.

Wherefore and in the interest of consumer protection, the following appropriate warnings are hereby required in the labeling of preparations or drug products containing sodium metabisulfite.

1. On the immediate label of the product, the following statement shall be included: “Warning : contains (name of sulfite, e.g. sodium metabisulfite) which can cause anaphylaxis.”

2. The secondary label and package insert shall contain the following statement: “Warning: contains (name of sulfite, e.g. sodium metabisulfite), a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible person.”

Drug manufacturers, traders, importers and distributors carrying inventories of drug products whose label or labeling material themselves do not comply with the above requirement may be granted remedial labeling relief under the following terms or conditions:

a. Unto the immediate container shall be affixed a remedial stick-on label or a clarificatory leaflet containing the mandatory warning statement.

b. The secondary container shall likewise have a stick-on labeling with the warning statement outside the principal display panel.

Manufacturers, traders, importers and distributors are given until September 30, 1996 to submit the prototype labeling materials containing the warning statements. Distributors shall notify BFAD with the last batch number bearing the remedial labeling materials and the first batch number bearing the new labeling material, both containing the mandatory warning statement.

Manufacturers, traders, importers and distributors are hereby given until December 31, 1996 to comply with the remedial labeling relief or with the new labeling requirements. Products found in the market without the required warning statement after December 31, 1996 shall be deemed misbranded under R.A. 3720 as amended.

This Order shall _____

Adopted: 24 May 1996

(SGD.) QUINTIN L. KINTANAR, M.D. PH.D.
Director CESO I

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