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## **GUIDELINE ON PROBIOTICS**

The Bureau of Food and Drugs would like to inform the public, clients and the BFAD personnel regarding the guideline on PROBIOTICS. A Probiotic, as defined by Gaarner and Scharfema in 1998, is "a dietary supplement based on living microorganisms which when administered in sufficient quantity, has a beneficial effect on the host organism, improving the equilibrium of the intestinal microflora". We would like to cite that the following are approved bacterial strains used as probiotics

- 1. Lactobacilli
- 2. Bifidobacteria
- 3. Nonpathogenic strains of Streptococcus
- 4. Saccharomyces boulardi
- 5. Bacillus causii

The use of bacterial strains not found in the above list shall be subject to (1) demonstration of evidence of safe use as food supplement and (2) analysis of the bacterial species found in formulation. Likewise, BFAD shall use as reference: WHO-FAO "Guidelines for the Evaluation of Probiotics in Food" (2002).

A. The BFAD also would like to inform everyone concerned that, for a Probiotic to be effective, the following properties should be demonstrated:

- a. beneficial effect on the host organism
- b. should be able to survive in the digestive tract
- c. should adhere to the mucosal epithelial cells
- d. should exhibit enhancement and protection of the intestinal ecology.
- e. should remain viable during periods of storage and use.

B. For the demonstration of the safety of a Probiotic, the following documents should be submitted

a. Determination of antibiotic resistance patterns

b. Assessment of certain metabolic activities (e.g., D-lactate production, bile salt deconjugation)

c. Assessment of side-effects during human studies

d. Epidemiological surveillance of adverse incidents in consumers (post-market)

e. If the strain under evaluation belongs to a species that is a known mammalian toxin producer, it must be tested for toxin production. One possible scheme for testing toxin production has been recommended by the EU Scientific Committee on Animal Nutrition (SCAN, 2000)