Republic of the Philippines
Department of Health
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City
Alabang, Muntinlupa City

26 October 2004

Bureau Circular
No. 16 s. 2004

SUBJECT : Guidelines on PROBIOTICS

The Bureau of Food and Drugs would like to inform the public, clients and the BFAD personnel regarding guidelines 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. Sacchromyces 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 the 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)
    f. If the strain under evaluation belongs to a species with known hemolytic potential, determination of hemolytic activity is required.

BFAD recognizes and approves the following Probiotic claims as food supplements:

- enhancement of intestinal ecology
- helping improve lactose malabsorption
- improving digestion
- aid to the enhancement of natural resistance to intestinal infections.

Such claims may be reflected on the labels and can be used for advertisement and product promotion.

When a Probiotic makes a claim of altering disease or as an immunomodulator, the said product shall be classified as drug. Such above-cited claims denote therapeutic advantage which only a drug product can make. The therapeutic claim should be based on sound scientific evidence based on studies on human subjects.

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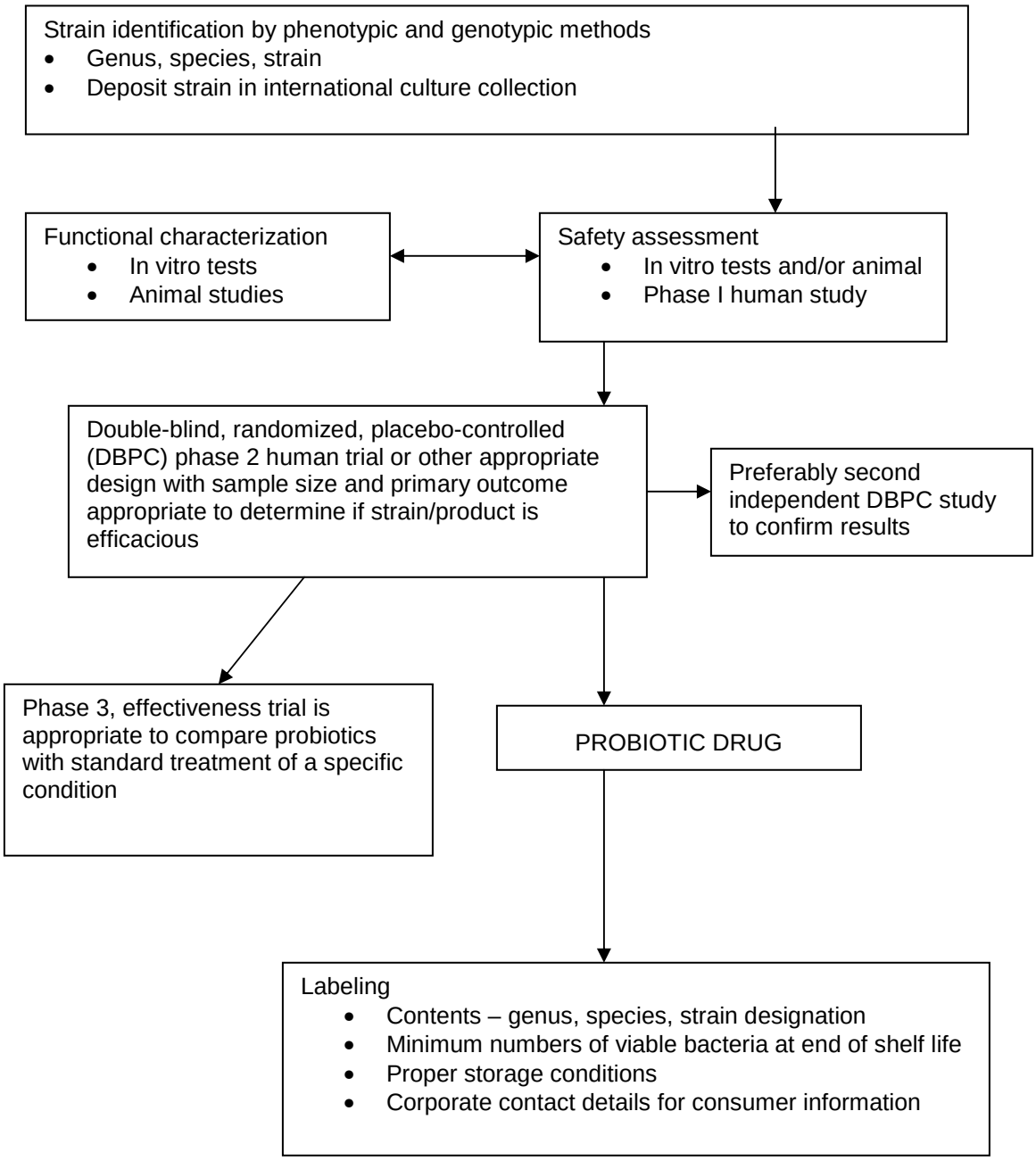
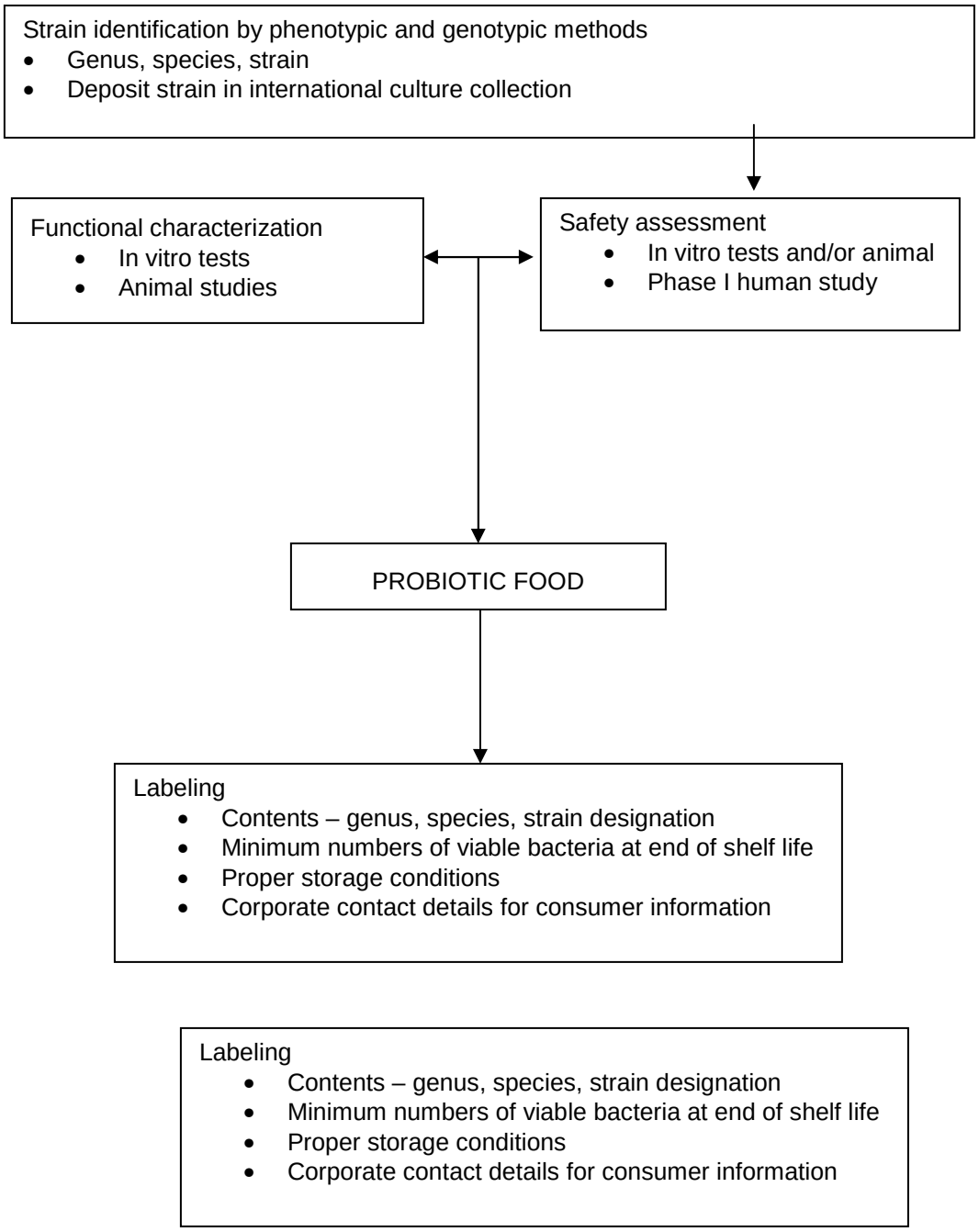
Director

GUIDELINES FOR THE EVALUATION OF PROBIOTIC DRUG USE



GUIDELINES FOR THE EVALUATION OF PROBIOTIC FOOD USE



Labeling
- Contents – genus, species, strain designation
- Minimum numbers of viable bacteria at end of shelf life
- Proper storage conditions
- Corporate contact details for consumer information