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Attention Jenny Hazelton @ ANZFA

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Date March 24, 2003

Concerning FSANZ

Re Proposal P242 Foods for special Medical Purposes

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DATA BASE

ACKNOWLEDGED

Dear Jenny,

Thank you for the several time extensions granted to ANZEMA.

As you appreciate Novartis and the other industry members are not local producers and input has had to be sought from our offshore affiliates.

A brief description of the industry position will be forwarded to you today with additional information later in the week. Despite that each of (Novartis, Abbott, Nestle, Nutricia) us is still seeking specific detail on additives, and costings, that will be forwarded asap an expected before June.

Briefly the proposed composition limits will adversely affect most of our (Novartis) medical food products. If Australia proceeds with unique formulation requirements that do not allow product from both US and Europe we will be seriously adversely affected both in the product range that we can offer and in the restrictions imposed on our trading compared with European source suppliers (competitors). Proposed labelling requirements (specific and general) will also affect a number of our products, as it will bring into question, with our affiliates, the worth of Australia-specific label revision. We are hopeful that local literature is an acceptable alternative to label revision.

With respect to VLED whilst we are in a less inflexible position (compared with medical foods) we are concerned at restrictions that again evolve from one side of supply (EU) and may limit product innovation. Obesity is an acknowledged world problem and the company is very keen to excel in the development of global formulations as well as global innovative program strategies.

As a member of several industry bodies each of whom operate effective co-regulatory programs, with our pharmaceutical pedigree, we are opposed to the proposal to restrict advertising of either medical foods or VLED, and that is further explained in the upcoming submission. Which also offers some precedent for the interpretation of 'medical supervision'.

Novartis (and ANZEMA) also support the AFGC's submission.

Best regards,

Paul Bruhn