

بِسْمِ اللّٰهِ الرَّحْمٰنِ الرَّحِیْمِ



Maldivian Medical Association

LETTER TO MALDIVES FOOD AND DRUG AUTHORITY: MMA CONCERNED ABOUT ELKEN DISTRIBUTORS MARKETING TACTICS.

OFFICIAL LETTER



Maldivian Medical Association

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letters issued by USFDA against persons marketing spirulina, ‘aerobic oxygen’ and ‘bovine colostrum’ with medical claims similar to those being freely proclaimed by marketing agents in Maldives.

We have also been made aware of certain skin preparations of Elken being promoted unchecked by the same marketing machinery. Since the very basic premise for unregulated import and distribution of most Elken products was the label of nutritional supplements we fail to see how skin preparations can also be bracketed as a nutritional supplement, any claims notwithstanding. Thus we urge you to include the skin preparations in the regulated drug list with immediate effect.

It has also been brought to our notice that promotional material for Elken spirulina contains a claim that it is an ideal substitute for breast milk. This claim has to be taken with utmost seriousness and immediate steps taken to check the product’s content and advisability to be used as a breast milk substitute. It is also recommended that a product with such a proposed use be regulated as other breast milk substitutes.

We strongly urge you, given the body of evidence present in the form of promotional material, the methods used to market it (please find attached disease and pathophysiology specific health claims found on one promotional DVD) as well as the feed back from the patients, to declare these products as drugs and appropriately regulate it. This association is in agreement with the ruling by US FDA in this respect that “The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product.” This is irrespective of the claim made while importing that it is only a nutritional supplement.

We also recommend that any such product your authority is satisfied to allow to be marketed here as only a nutritional supplement without any claim of an effect on disease processes either in promotional material or by their dealers be required to carry a prominent disclaimer with the packaging saying that “This product is not intended to diagnose, treat, cure, or prevent any disease” in Dhivehi. It will not be unknown to you that this very disclaimer was inserted in packaging of a Spirulina Pacifica product marketed in United States at the insistence of US FDA in 2000. It is with this view that we recommend that for the sake of public and patient safety the MFDA make its stand on this issue public. We cannot overstress the importance of timely action in this regard and take note that while MFDA collects the necessary evidence conforming to scientific standards there are definite steps which are of immediate necessity to protect the vulnerable public from exploitation by business enterprises.

We also note with great concern the fact that some medical personnel including health workers and nurses have been reported to us to be involved in selling and



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marketing of these products. Though there is no conflict of interest here, the fact that the marketing involves unfounded medical claims, we feel it is unethical that medical persons get involved in this business thereby lending credence to the said claims. Some employees of MFDA have also been reported to be involved in marketing this product, though we are unable to confirm these reports. Since these products are marketed at ground level invariably with claims of medicinal effects (ie: as a drug) there is considerable conflict of interest if employees of the regulatory body stand to profit from any such business. Thus we urge you to seriously look into this matter.

Our association is greatly disturbed by these recent developments of mushrooming of commercial products being sold with health claims which go totally unchecked and for which there seems to be no accountability. This has resulted in health hazards to many a patient. We would like to draw your attention to the case of 60 year old male patient who landed in the emergency department of Indira Gandhi Memorial Hospital, (IGMH) on 31st December 2007 in a state of diabetic ketoacidosis after stopping insulin and starting on Elken Spirulina sold to him by an authorized dealer with the claim to have the power of curing diabetes. This incident, which resulted in a condition carrying a mortality rate of as high as 5% even with best medical care, has been cited to depict the extent of health risk such products pose when its distribution and marketing is not regulated.

We hope that necessary steps will be speedily taken by your esteemed authority and assure you of our commitment to patient safety.

Yours Sincerely,

Dr Ibrahim Shiham, MD
Vice President

Dr Aseel Jaleel, MD
Scientific Secretary

Date: 1st March 2008



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Attached Documents:

1. Claims in Elken promotional DVD
2. Claims by 'patients' endorsed by Elken in promotional DVD
3. FDA Warning against false claims regarding spirulina
4. FDA Warning against false claims regarding "aerobic Oxygen"
5. FDA Warning against false claims regarding "Colostrum"

Copy:

Minister of Health

Deputy Minister of Health

Director General Health Services

Department of Public Health

Department of Medical Services

President, Maldivian Medical Council

President, Maldivian Nursing Council

President, Maldives Board of Health Science

Minister of Trade and Industries

Minister of Legal Reform, Information and Arts

Resident Representative, World Health Organization