INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

18th May 2013

Director
FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
FDA Bhawan; Near Bal Bhavan
Kotla Road
New Delhi – 110 002

Subject: FSSAI Advisory: No. P 15025/01/2013-PA/FSSAI – Dated 11th May 2013

Dear Sir,

In the abovementioned advisory the subject of "Guidelines to be followed for product approval" has been taken up. As per the advisory the food products are being categorized as per the following.

Class 1 (a): Food products wherein the safety of its ingredients are known and are permitted by regulatory bodies **and** does not contain plants and botanicals or substances from animal origin. Product Approval (PA) to be granted.

Class 1 (b): Food products wherein the safety of its ingredients are known and are permitted by regulatory bodies **and does** contain plants and botanicals or substances from animal origin. No Objection Certificate (NOC) / PA to be given, or NOC initially and PA after assessment of safety documents.

Class 1 (c): Food products under category 1 (b) to be referred to Scientific Panels for assessment of safety of its ingredients if insufficient. PA to be granted / denied based on risk assessment.

Class 1 (d): Food products for which safety of ingredients and conditions of use is as published by FSSAI, or whose ingredients are standardized or permitted under FSSR 2011 will not require further safety assessment except for authorization of the ingredients contained therein. PA to be granted.

Pragati 30/5/13

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The alarming is issue is the point no 3 which states that: "**The use of minerals/ vitamins/ proteins/ metals/amino acids/ their compounds should not exceed the Recommended Daily Allowance for Indians.** In this regard, FBO shall follow the guidelines issued by Indian Council of Medical Research (ICMR) / National Institute of Nutrition (NIN) / World Health Organisation (WHO) / Food and Agriculture Organisation (FAO)."

In this aspect we would like to state that such a clause will adversely impact the consumer health and their management of ill-health with nutraceuticals. This is because vitamins and minerals and such are not merely only to prevent / correct deficiency; these could have additional roles to play. For example, free radicals can be combated with antioxidants and we have 3 vitamin & 3 enzyme antioxidants bestowed naturally. In such typical case, which makes the concern of the industry amply clear – vitamin E RDA is not released by NIN / ICMR, the other organizations like WHO and FAO do **not** state RDAs *specifically* for Indians. If the Food and Nutrition Board (FNB) RDAs are to be considered, then it is 15 mg / day for vitamin E. The antioxidant requirement of this vitamin is, however, 400 IU / day if it is required to ably tackle free radicals.

Only one of the many studies published is being provided as an abstract to emphasize the point made:

Ren Fail. 2011;33(2):118-23. doi: 10.3109/0886022X.2010.541579.

Comparative effects of silymarin and vitamin E supplementation on oxidative stress markers, and hemoglobin levels among patients on hemodialysis.

Roozbeh J, Shahriyari B, Akmali M, Vessal G, Pakfetrat M, Raees Jalali GA, Afshariani R, Hasheminasab M, Ghahramani N.

Abstract

BACKGROUND:

The incidence of accelerated atherosclerosis among patients on hemodialysis is very high and oxidative stress (OS) is a potentially major contributor to their morbidity and mortality.

OBJECTIVE:

To evaluate the effects of Silymarin and/or vitamin E on OS markers and hemoglobin levels in patients on hemodialysis.

METHODS:

Eighty patients on hemodialysis were randomized into four groups: Group 1 received silymarin 140 mg 3 times daily; **Group 2 received vitamin E 400 IU/day;** Group 3 received silymarin 140 mg 3 times daily and vitamin E 400 IU/day; and Group 4 was the control. Samples were obtained at baseline and on day 21 for measurement of malondialdehyde (MDA), red blood cell (RBC) glutathione peroxidase (GPX), and hemoglobin.

RESULTS:

Combination of silymarin and vitamin E led to a reduction in the MDA levels (7.84 ± 1.84 vs. 9.20 ± 2.74 nmol/mL; $p = 0.008$). There was a significant increase in RBC GPX levels in all treatment groups compared with controls after 3 weeks. This was more pronounced in the group receiving combination compared with the group receiving vitamin E or the control group (5.78 ± 3.51, 4.22 ± 1.63, and 3.16 ± 1.89 IU/grHb, respectively; $p < 0.001$). There was also a significant increase in mean hemoglobin of all treatment groups compared with the control.

CONCLUSIONS:

Oral supplementation with silymarin and **vitamin E leads to reduction in MDA**, increase in RBC GPX, and increase in hemoglobin levels in patients with end-stage renal disease. Studies with larger sample sizes and longer follow-up are required to investigate the effect of silymarin on cardiovascular outcomes and erythropoietin requirement.

Besides, vitamins (and minerals) as antioxidants, there are other uses for the same. Again WHO specifies 20 mg/day zinc for diarrhea even though the RDA as per FAO is 3-14 mg/day (http://whqlibdoc.who.int/publications/2004/9241546123.pdf).

It must be emphasized here that nutraceutical supplements are natural products which are intended to prevent or as an aid to manage ill-health *and not merely to meet nutritional requirement.*

We look forward to your immediate *corrective* action in this regard. We hope you could send a rejoinder that the point 3 of advisory dated 11th May 2013 (Ref No: No. P 15025/01/2013-PA/FSSAI) the suggested corrections are as stated herein.

> "The use of minerals/ vitamins/ proteins/ metals/amino acids/ their compounds '**in food products**' should not exceed the Recommended Daily Allowance for Indians '**in food products solely meant for replenishing deficiencies alone**'. In this regard, FBO shall follow the guidelines issued by Indian Council of Medical Research (ICMR) / National Institute of Nutrition (NIN) / World Health Organisation (WHO) / Food and Agriculture Organisation (FAO)."

Also, it is important to note that still there are no definite timelines mentioned for PA/NOC release from FSSAI and any product denied NOC/PA should be clarified with proper reason. Additionally for such established and existing product in the market, if NOC/PA is denied, minimum 1 year should be provided to the FBOs/Marketer to reformulate and be aligned as per FSSAI regulations as applicable - considering that the transition time will involve formulation development, stability study, and above all, the inventory of such Products/Materials with manufacturers and in distribution pipeline. Kindly note that all the established/existing products in the market are being manufactured and marketed under valid erstwhile authorized licenses which also came under purview of Government of India.

We would appreciate that our valid concerns as above are immediately clarified by release of extended advisory on high priority so the there are no disturbances and uncertainties in the Food Industry and to clarify the matter for all the FBOs /Marketers/ Promoters/ Importers who would be affected despite no fault of theirs.

Looking forward to your co-operation and positive response based on wider understanding of this sensitive issue to ensure that consumers gain and are not deprived of real benefits with nutraceutical supplements.

Thanking you

DR R K SANGHAVI
Chairman, Nutraceutical Subcommittee
IDMA

Mr MANISH DOSHI
President
IDMA