European Food Safety Authority

Unit on Dietetic products, Nutrition and Allergies

Parma, 5 July 2010
Ref. JK/lf (2010) **out-4975374**

Mr. Basil Mathioudakis
European Commission
Head of Unit
DG Health & Consumers
Directorate E4
Rue de la Loi 200
1049 Brussels

Subject: **Response to comments with regard to an EFSA opinion on the scientific substantiation of a health claim related to Eye q™ and working memory pursuant to Article 14 of Regulation (EC) No 1924/2006 (EFSA-Q-2009-00485; Claim serial No 0247-UK).**

Dear Mr. Mathioudakis,

Thank you for informing EFSA about the comments the European Commission received from the applicant (Vifor Pharma (Potters)) related to the EFSA opinion on Eye q™ and working memory pursuant (EFSA-Q-2009-00485)

I have discussed these comments with the chair of the NDA panel and the chair of the NDA standing working group on health claims and EFSA wishes to clarify the issues raised by the applicant:

1. Plausible biological mechanism
With regards to the conclusion of the Panel that the evidence provided did not establish a biologically plausible mechanism by which the combination of DHA, EPA, and GLA in Eye q™ could exert the claimed effect in the target population, the applicant states in the comments that a plausible mechanism would be by incorporation of PUFA in cerebral membranes and by modulation of pro- and anti-inflammatory cytokine production. However, the evidence provided in support of an association of such effects with working memory is weak and was not convincing for the Panel.

In addition the applicant states that establishment of a plausible biological mechanism should not be a requirement for substantiation of the claim. EFSA did not indicate that establishment of a plausible biological mechanism is a requirement for substantiation of the claim. However, evidence for biological plausibility could be supportive and is taken into account when weighing the evidence for substantiation.

2. Dose response relationship
With regards to the observation of the Panel that there were no data indicating a dose-

response relationship between Eye q^{TM} consumption and working memory outcomes in healthy children, the applicant indicates in the comments that establishment of a dose-response relationship should not be a requirement for substantiation of the claim. EFSA did not indicate that establishment of a dose-response relationship is a requirement for substantiation of the claim. However, evidence for a dose-response relationship could be supportive and is taken into account when weighing the evidence for substantiation.

3. Additional data corroborating the RCT

With regards to the observation of the Panel that there were no other data presented on this combination of fatty acids in the target population in order to corroborate the findings of the one study undertaken in healthy children, the applicant indicates that the application did provide corroborating data. The reference provided in the comments and the application is for a press release and refers to an effect of Eye qTM on academic achievement (but not working memory) in healthy school children between the age of 11 - 14 years and 16 years. The Panel considered that no scientific conclusions can be drawn from such a reference for the substantiation of the claimed effect.

The applicant also indicates that further data should have been considered supportive of the claim (Richardson and Montgomery, 2005; Sinn and Bryan, 2007). The study of Richardson and Montgomery (2005) was conducted on children with developmental coordination disorder while the study of Sinn and Bryan (2007) was conducted in children with attention deficit/hyperactivity disorder (ADHD). The applicant proposes that findings of these studies could be extrapolated to children in the general population. However, the rationale provided in support of such extrapolation is weak and was not convincing for the Panel. In addition the study of Sinn and Bryan (2007) investigated the effect of Eye qTM on cognitive and behavioural problems but not on working memory.

4. General considerations

The applicant has suggested that EFSA's requirements for the claim are higher than for other applications, e.g. ALA and brain development in children. However, the latter claim is for a function of ALA (also for DHA) for which there is consensus among scientific experts as to its substantiation and EFSA has therefore used authoritative scientific sources to support substantiation. However, for the claim proposed by the applicant related to working memory there is not consensus among scientific experts as to its substantiation and EFSA therefore relies on the primary studies to assess whether the claim is substantiated.

The applicant has suggested that EFSA should have considered adopting a favourable opinion on the claim with appropriate modulation of the proposed wording (e.g. related to verbal working memory). However, the Panel considered that the evidence provided is insufficient to establish a cause and effect relationship between the intake of Eye q TM and the improvement of working memory (including verbal working memory).

5. Conclusion

In conclusion, having taken into account the comments raised by the applicant we wish to reiterate the overall conclusion of the Panel, i.e. that the information provided is insufficient to establish a cause and effect relationship between the consumption of Eye q™ and the improvement of working memory (including verbal working memory).

Yours sincerely,

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References

Richardson AJ and Montgomery P, 2005. The Oxford-Durham study: a randomized, controlled trial of dietary supplementation with fatty acids in children with developmental coordination disorder. Pediatrics, 115, 1360-1366.

Sinn N and Bryan J, 2007. Effect of supplementation with polyunsaturated fatty acids and micronutrients on learning and behaviour problems associated with child ADHD. Journal of Developmental and Behavioral Pediatrics, 28, 82-91.

Cc: Christophe Didion, Sabine Osaer, Christina Antoniou, Noel Griffin, Francesco Felice Carlucci