Vitamin A Oral Liquid Preparation

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Reason for Revision: Compliance

In accordance with the Rules and Procedures of the 2010–2015 Council of Experts, the Dietary Supplements Expert Committee has revised the Vitamin A Oral Liquid Preparation monograph. Based on the new stability data submitted for the Vitamin A Oral Liquid Preparation products, the Dietary Supplements Expert Committee proposed to reduce the lower limit of vitamin A in the Vitamin A Oral Liquid Preparation monograph from NLT 95.0 % to NLT 90.0 % of the label claim.

High-potency Vitamin A Oral Liquid Preparation products (containing 100,000 – 200,000 IU) are used in the third world countries to prevent diseases arising from vitamin A deficiency, which often results in the death of children as a result of common childhood infections in vitamin-deficient children. Many organizations like UNICEF, WHO, and MI (Micronutrient Initiative), which distribute high-potency vitamin A products to third world countries, accept only those products that meet the USP monographs requirements over the shelf life of the products.

However, manufacturers, which collaborate with WHO and UNICEF and produce high potency vitamin A products, cannot comply with current lower limit (NLT 95% of label claim) of monograph requirements for the content of vitamin A through the products’ shelf life. In June 2012 USP received a request from the high potency vitamin A products manufacturer, in collaboration with UNICEF and MI, to revise a lower limit of vitamin A in the Vitamin A Oral Liquid Preparation monograph from NLT 95.0 % to 90.0 % of the label claim. The request was supported by data from the stability studies.

Dietary Supplements Expert Committee has carefully evaluated submitted data including potential safety issues from possibly degraded products and agreed to reduce the lower limit of vitamin A in the Vitamin A Oral Liquid Preparation monograph from NLT 95.0 % to 90.0 % of label claim.

Taking into consideration the intended use of high potency vitamin A products in preventing vitamin A deficiency/xerophthalmia and potentially preventing blindness in third world countries, its use is considered a high priority within public health. Therefore, a shortage of high-potency vitamin A products in the market due to current monograph requirement for lower limit of NLT 95% labeled content would be untenable. As such, the Dietary Supplement Expert Committee proposed to use an accelerated revision process to revise the Definition of Vitamin A Oral Liquid Preparation as follows: “Vitamin A Oral Liquid Preparation is an emulsion, suspension, or solution that contains retinyl acetate or retinyl palmitate in an amount equivalent to NLT 90.0% and NMT 120.0% of the labeled amount of vitamin A, as retinol (C20H30O).”

The Vitamin A Oral Liquid Preparation Revision Bulletin supersedes the currently official monograph. The Revision Bulletin will be incorporated in USP 37–NF 32.

Should you have any questions, please contact Natalia Davydova (301-816-8328 or nd@usp.org).

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