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**Re: Comment on Proposed New USP-NF General Chapter on Heavy Metals
-- Concern Over Limit for Lead Contamination in Drugs and Supplements**

Dear Dr. Zaidi:

We at ConsumerLab.com are concerned by the USP's proposed allowance of lead contamination in supplements and medications at a level of 10 mcg (micrograms) per daily serving, as referenced in the Proposed New USP-NF General Chapter on Heavy Metals.¹ This allowance would permit excessive lead in health products and create an unnecessary health risk. We applaud USP's proposed adoption of more specific testing techniques and specific limits for each heavy metal, but see no justification for permitting such a high amount of lead: Significantly lower levels have been well documented as achievable by industry and are already established as a viable standard in California, as noted below.

We suggest a lead limit of 0.5 mcg per daily serving of a dietary supplement or medication. An allowance of an additional 1.0 mcg per daily serving should be considered for supplements containing a large amount of calcium or whole (non-extracted) herbs where lower levels are not feasible. Supplements exceeding this level should carry a lead warning on their labels and, if exceeding 3 mcg, should be not be permitted on the market.

BACKGROUND:

Lead poses a danger

U.S. FDA scientists have determined that the *total* daily ingestion of lead from *all sources* should not exceed 6 mcg for children.² Some risk exists with any level of lead exposure, as has been pointed out by FDA toxicologist Michael Bolger, Ph.D. To permit up to 10 mg per day from a *single* supplement or medication would clearly be dangerous. In fact, the average lead exposure from *all* the food a person eats each day is already 1.3 mcg to 2.5 mcg. To permit several more micrograms of lead from a single supplement or medication would pose a danger further multiplied by the number of supplements and medications used by an individual.

Much lower levels of lead are already achievable

Although USP derives its standard-setting authority from the federal government, the proposed allowance of 10 mcg is contradictory to the U.S. FDA's policy "of reducing lead levels in the food supply to reduce consumers' lead exposure to the lowest level that can be practicably obtained."³ Marketed supplements have been shown to generally contain less than 1 mcg of lead per daily serving:

- A recent report by FDA scientists on tests of 324 multivitamins for woman and children showed the average lead content per daily serving to be just 0.576 mcg, and three-quarters of these products had under 1 mcg of lead.⁴ Only five products (1.5% of products tested) exceeded 4 mcg of lead per day.
- The vast majority (over 90%) of the more than one thousand supplements that ConsumerLab.com has tested for lead between 1999 and 2008 have contained no more than 0.5 mcg of lead per daily serving. The small percentage of products that exceed this level have typically contained herbs (most commonly “whole herb” rather than “extract”) or substantial amounts of minerals and, generally, were contaminated with 1 mcg to 4 mcg of lead per day. In nearly all cases of contamination, we have been able to identify comparable products with less than 0.5 mcg of lead, helping consumers avoid unnecessary lead exposure.

The lead limit used applied by ConsumerLab.com is based on the limit under Proposition 65 in the State of California, the only state with an established a limit. This limit is 0.5 mcg per daily serving of a supplement, and 1.5 mcg for products that include 1,000 milligrams or more of calcium. California established that limit based on what is achievable, as there is no reason to unnecessarily expose individuals to lead.

The proposed USP allowance of 10 mcg of lead in supplements is more lax than the FDA’s guidance on *candy* frequently consumed by small children. In November 2006, the FDA lowered the maximum lead level for such candy to 0.1 ppm (0.1 mcg per gram).³ A typical daily serving of a medicine or supplement weighs approximately one to two grams. If the limit for candy were applied to supplements or medicines, such products would be expected to contain no more than 0.1 mcg to 0.2 mcg of lead.

Permitting a high amount of lead may encourage more contamination:

The recently enacted GMPs (Good Manufacturing Practices) for dietary supplements fail to specify a limit on lead contamination, permitting manufacturers to set their own limits. The proposed USP limit is likely to become a reference for dietary supplement manufacturers as they set their internal limits. Until now, many manufacturers have focused on meeting the California limit of 0.5 mcg of lead in their products. Should the USP allow 10 mcg of lead per day in a single supplement or medication, it may encourage more widespread contamination as manufacturers feel less need to keep lead out of their products and may use ingredients of lower purity if they are of lower cost.

CONCLUSION

Ten micrograms of lead in a supplement or medicine is *not* an amount that ConsumerLab.com would accept in its independent testing, nor is it a standard that any group should adopt, particularly the USP. We respectfully suggest that the USP choose a much safer limit – one similar to that of the State of California.

Regarding the proposed change in test methodology, we support the revision to use modern instrumentation rather than out-of-date, non-specific techniques defined in the current *USP–NF* General Chapter *Heavy Metals* <231>.

Sincerely,

Tod Cooperman, MD, President, ConsumerLab.com

William Obermeyer, PhD, Vice President for Research, ConsumerLab.com

REFERENCES:

¹ Proposed New “USP General Chapter on Inorganic Impurities: Heavy Metals – Table 1,” USP Ad Hoc Advisory Panel on Inorganic Impurities and Heavy Metals. Accessed 11/20/2008 from <http://www.usp.org/pdf/EN/USPNF/2008-04-10InorganicImpuritiesStim.pdf>

² Dangers of Lead Still Linger. FDA Consumer Magazine, Jan-Feb 1998. Accessed 11/20/2008 at http://www.fda.gov/FDAC/features/1998/198_lead.html

³ Lead in Candy Likely To Be Consumed Frequently by Small Children: Recommended Maximum Level and Enforcement Policy, November 2006, FDA Center for Food Safety and Applied Nutrition. Accessed 11/20/2008 at <http://www.cfsan.fda.gov/~dms/pbguid3.html>

⁴ Survey Data on Lead in Women’s and Children’s Vitamins, August 2008, FDA Center for Food Safety and Applied Nutrition. Accessed 11/20/2008 from <http://www.cfsan.fda.gov/~dms/pbvitami.html>