On July 18, 2016, Federal Register notice 46578 was issued announcing that FDA has amended the food additive regulations to permit the use of vitamin D₃ as a nutrient supplement in milk at levels higher than those currently permitted in 21 CFR 172.380 and referenced in the Standard of Identity (SOI) for “milk” in 21 CFR 131.110(b)(2).

Under the law, FDA may approve the use of a food additive only after conducting a scientific safety review of information to ensure that the use of the ingredients added to foods are safe for the general population. In this case, the FDA evaluated the projected human dietary exposure to vitamin D from foods and dietary supplements, safety data, and other relevant information and found the higher fortification levels of vitamin D₃ for milk and milk products to be safe.

**NOTE:** Vitamin D without a subscript represents either vitamin D₂ or vitamin D₃ or both.

This approval, which amends existing 21 CFR 172.380, will allow manufacturers to fortify milk with Vitamin D₃ at a level not to exceed 84 international units (IU) per 100 g (800 IU/quart) and that meets the requirements for foods named by use of a nutrient content claim and a standardized term in accordance with 21 CFR 130.110. The minimum allowable limit for a fortified milk remains unchanged at 42 IU per 100 g (400 IU/quart) as cited in 21 CFR 131.110(b)(2).

Manufacturers may begin using the new amount on July 18, 2016

The new 800 IU/quart level conflicts with the text contained in Appendix O-Vitamin Fortification of Fluid Milk Products of the PMO that states “** 100% - 150% of label claims = 400 – 600 IU per quart for vitamin D and …”

FDA has been informed by industry that some manufacturers will be updating their labels in the marketplace to comply with new regulations for nutrition facts information.
before the 2017 National Conference on Interstate Milk Shipments (NCIMS) conference. One of the provisions of the new nutrition labeling regulations was that the recommended amount of vitamin D be increased from 400 IU to 800 IU per day. As a result some milk processor may voluntarily choose to increase vitamin D fortification of milk to this higher level. FDA plans to submit a Proposal to the 2017 NCIMS conference to address the conflict cited above.

In the interim, FDA recommends Regulatory Agencies to exercise regulatory discretion during routine regulatory inspections. FDA will also instruct Milk Sanitation Rating Officers (SROs) and FDA Regional Milk Specialists (RMSs) to extend similar discretion during ratings and check ratings, respectively, by not debiting milk plants related to the vitamin D fortification requirements currently cited in Appendix O of the PMO.

For purposes of determining compliance relative to the required annual vitamin assays for milk fortified with vitamin D as cited in Section 6-The Examination of Milk and/or Milk Products of the PMO the standardized milk products listed in 21 CFR, 131.110 Milk, 131.111 Acidified Milk, 131.112 Cultured Milk, 131.127 Nonfat Dry Milk Fortified with Vitamin A and D (vitamin addition not optional), 131.200 Yogurt, 131.203 Lowfat Yogurt, and 131.206 Nonfat Yogurt to which vitamin D₃ has been added for fortification purposes, the assay results should indicate that the minimum of 400 IU/quart has been met and that the maximum of 800 IU/quart has not been exceeded.

**NOTE:** Refer to M-a-98, latest revision, for the specific milk and/or milk products that have FDA validated and NCIMS accepted vitamin assay test methods.

An electronic version of this memorandum is available for distribution to Regional Milk Specialists, Milk Regulatory/Rating Agencies, Laboratory Evaluation Officers and Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to representatives of the dairy industry and other interested parties and will be available on the FDA Web Site at [http://www.fda.gov](http://www.fda.gov) at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to robert.hennes@fda.hhs.gov.

Robert F. Hennes, RS, MPH  
CAPT U.S. Public Health Service  
Milk and Milk Products Branch