To the Editor:

Several articles in recent issues of *Clinical Chemistry* have made reference to the Dade Behring N High Sensitivity CRP (hs-CRP) assay and have indicated that it has been approved by the Food and Drug Administration (FDA) for cardiovascular risk prediction (1–3).

Although the use of hs-CRP assays in the assessment of cardiovascular risk is clearly gaining momentum, the FDA-cleared intended use for these tests is not cardiovascular risk prediction, but rather the quantitative determination of C-reactive protein (CRP) in serum and plasma. Measurements are useful in the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. The Summary and Explanation section of the FDA-cleared labeling for the Dade Behring hs-CRP assay states that the test may add to the predictive value of other markers used to assess the risk of cardiovascular and peripheral vascular disease (4). I am unaware of any CRP assay being cleared by the FDA for stand-alone use to predict risk of cardiovascular disease.

As a class II in vitro diagnostic medical device, the Dade Behring N High Sensitivity CRP assay referenced in these articles is not “approved” by the FDA per se, nor is premarket approval required. Instead, as with most in vitro diagnostic tests, marketing clearance for the N High Sensitivity CRP assay was obtained by way of the premarket notification process described in section 510(k) of the Food Drug and Cosmetic Act. This distinction is important to manufacturers inasmuch as FDA regulations state that, “any representation that creates the impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding” (5). To prevent publication of misleading information, I urge the *Clinical Chemistry* editorial staff to exercise specific caution in working with authors to appropriately identify the regulatory status of in vitro diagnostic medical devices.

**References**


**Comment on “High-Sensitivity C-Reactive Protein: Product Claims and the Food and Drug Administration”**

To the Editor:

Dr. Ayash’s letter is helpful in trying to clarify the regulatory terminology pertinent to Food and Drug Administration (FDA) marketing applications. It should be pointed out, however, that it is not, and should not be the responsibility of journal reviewers or editors to police the accuracy of claims statements from a regulatory standpoint. The FDA employs compliance officers who monitor advertised claims by manufacturers to ensure that they are consistent with the approved or cleared labeling for their products. Clinicians and researchers are not subject to the same claims restrictions as manufacturers.

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**RE: Europium Nanoparticles and Time-resolved Fluorescence for Ultrasensitive Detection of Prostate-specific Antigen**

To the Editor:

We were intrigued to read of the work reported by Harma et al. (1). Their report provides an excellent summary of the potential advantages and disadvantages of implementing an assay that uses small particles containing highly fluorescent rare earth complexes.

In the 1970s, we evaluated the use of reactive latex particles loaded with rare earth chelates. Europium chelates were of particular interest because of their characteristic strong red emission bands and the extended time course of emission following a pulse of excitation light. Although we ultimately chose to pursue assays using different labels, the work was documented in two US patents (2, 3), which may interest readers.