LETTER TO THE EDITOR

“Nondecolorized” Qualifier Is a Misnomer for the Aloe Vera Whole Leaf Extract Test Material

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The IASC has stated that the qualifier “is important because omissions a vital test-material qualifier from the title and throughout the article.” The concern of the IASC is that the public will confuse the aloe vera whole leaf extract tested in this study with the “IASC industry standard aloe vera leaf products.”

The published article clearly and accurately describes the test material as a whole leaf extract obtained from the intact leaves of the Aloe barbadensis Miller (Aloe vera) plant. The aloe vera whole leaf extract test material was described as “yellow in color and retains the full complement of the \( \beta \)-linked high-molecular-weight polysaccharides of the inner aloe vera leaf gel and the \( \beta \)-linked C-glycoside anthrones of the outer aloe vera leaf latex.” As such, no qualifier was deemed necessary to describe this material; the material tested was indeed the aloe vera whole leaf extract and contained all of the aloe vera plant leaf components, namely aloe vera gel and aloe vera latex. No other ingredients were added to the material tested, and the contents of marker compounds (malic acid, aloin A, and aloe-emodin) in the aloe vera whole leaf extract test material were clearly noted in Table 2 of the publication.

The IASC has stated that the qualifier “is important because decolorized aloe vera leaf products containing less than 10 ppm aloin are the industry standard.” In their Letter to the Editor, the IASC stated that the difference between “decolorized aloe vera whole leaf extracts” (the industry standard) and the aloe vera whole leaf extract (the material tested) is that some of the components of the aloe vera whole leaf extract, primarily the anthrones and anthraquinones, have been removed in “decolorized aloe vera whole leaf extracts.” We understand the need for the IASC to use the qualifier “decolorized” to represent accurately the materials contained in the “industry standard” aloe vera leaf products because the “industry standard” does not contain all of the components of the aloe vera whole leaf extract. However, the material tested for this publication was the aloe vera whole leaf extract and to use the term “nondecolorized” is a misnomer, much the same as using the terms “nondefatted” milk for whole milk or “nondecaffeinated” coffee for regular coffee.

In their Letter to the Editor, the IASC erroneously stated that the “nondecolorized” qualifier has been included in all previous publications issued by the NTP on this research. This is not correct. The IASC is correct to point out that the title to the NTP Technical Report (TR) 577 was changed as the result of public comments; however, two routes of exposure were examined in studies of aloe vera that were conducted at the National Center for Toxicological Research (NCTR): dermal and oral. The aloe vera leaf extracts used in the dermal photocarcinogenesis study included aloe vera gel, aloe vera whole leaf, and decolorized aloe vera whole leaf. These were the terms used in the NCTR study reports (August 2007) and NTPTR 553 (September 2010). No public comments or objections to the terms used for the aloe vera plant extracts were raised by the IASC before, during, or after the public review meeting that was held by the NTP Board of Scientific Counselors’ Technical Reports Review Subcommittee in February 2008 for NTP TR 553.

The aloe vera leaf extracts used for the oral studies included aloe vera gel, aloe vera whole leaf, and decolorized aloe vera whole leaf. These were the terms used in the NCTR study reports (August 2010) and in the initial drafts of NTP TR 577 (January 2011). Public comments made by the IASC prior to the public review meeting for NTP TR 577 prompted the NTP staff to change the term aloe vera whole leaf to nondecolorized aloe vera whole leaf in the title and abstract of the review draft of NTP TR 577 (February 2011). The public review meeting for NTP TR 577 was held on April 5, 2011.

In our Toxicological Sciences publication we used the term aloe vera whole leaf, which for the reasons stated above we believe best describes the material tested.

The views expressed in this letter do not necessarily represent those of the U.S. Food and Drug Administration.