



NORTH AMERICAN OLIVE OIL ASSOCIATION

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June 18, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2020-P-1423; Clarifying Certain Aspects of Citizen Petition

To Whom It May Concern:

The North American Olive Oil Association (NAOOA) hereby makes this submission to clarify and correct certain typographical errors in its above referenced Citizen Petition, submitted to FDA on May 22, 2020.

NAOOA has identified three clarifications in Appendix 1 ("Proposed Regulation re Citizen Petition from North American Olive Oil Association"), as indicated below in bold, italicized and underlined text:

1. On page 1, proposed § 167.5(b) ("Free acidity") states, "As determined by the method prescribed in COI/T.20/Doc. no. 34 Rev. 1 or ISO 660 1996, amended 2003 or AOCS Cd 3d-63(03)." The sentence should read, "As determined by the ***cold*** method prescribed in COI/T.20/Doc. no. 34 Rev. 1 or ISO 660:**2020** or AOCS Cd 3d-63(03)."
2. On page 8, Table 3's second footnote (denoted by "**") states in its first sentence, "When an authentic oil naturally has a delta-7-stigmastenol level $> 0.5\%$ and $\leq 0.8\%$: it is considered virgin or extra virgin olive oil if the stigmasterol level is $\leq 1.4\%$, campesterol level is $\leq 3.3\%$, the ratio app. beta-sitosterol (campesterol + delta-7-stigmastenol) is ≥ 25 , and delta-ECN42 is $\leq |0.10|$, and it is considered lampante virgin olive oil if campesterol level is $\leq 3.3\%$, stigmastadienes is ≤ 0.30 mg/kg and delta-ECN42 is $\leq |0.15|$." The sentence should contain a "/" symbol after beta-sitosterol and read, "When an authentic oil naturally has a delta-7-stigmastenol level

$> 0.5\%$ and $\leq 0.8\%$: it is considered virgin or extra virgin olive oil if the stigmasterol level is $\leq 1.4\%$, campesterol level is $\leq 3.3\%$, the ratio $\text{app. beta-sitosterol}/(\text{campesterol} + \text{delta-7-stigmastenol})$ is ≥ 25 , and delta-ECN42 is $\leq |0.10|$, and it is considered lampante virgin olive oil if campesterol level is $\leq 3.3\%$, stigmastadienes is $\leq 0.30 \text{ mg/kg}$ and delta-ECN42 is $\leq |0.15|$.”

3. On page 10, Table 11’s title is “ABSORBENCY IN ULTRA-VIOLET K270 AND DELTA-K (Δ).” Instead, it should read “ABSORBENCY IN ULTRA-VIOLET K270 (Δ) AND DELTA-K.”

If you have any questions, please do not hesitate to contact me.

Respectfully submitted,



Joseph R. Profaci
Executive Director
North American Olive Oil Association