To Whom it may concern,

Under 21 CFR 170.30(c) and 170.3(f),, Zaffronel® saffron extract is generally recognized as "GRAS", an acronym for the phrase Generally Recognized As Safe.

Our safety claim is based on past experience of common use of several years history of consumption by a significant number of consumers.

FDA GRAS status is only issued to Food items not nutraceuticals

Upon receiving several requests from our customers regarding GRAS Status for Saffron extract or Zaffronel®, we contacted FDA inquiring about the procedure that we need to follow to obtain such certificate. We were informed that there is no such a certificate for the Nutraceutical Industry & that Gras is issued for conventional food only.

Please see copy of email below:

"There is no such document as a "GRAS certificate." We get such requests all of the time, but there is no such document. Also, GRAS applies to the use of an ingredient in conventional foods only, not dietary supplements.

Regards,

Susan Carlson, Ph.D.
Supervisory Consumer Safety Officer
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Food Additive Safety
Division of Biotechnology and GRAS Notice Review"

Mary Hasrouni

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