



Soni & Associates Inc

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RE: Generally Recognized As Safe (GRAS) status of standardized Fenugreek Seed Extract containing Glycosides.

To whom it may concern:

Indus Biotech Private Limited, India (Indus Biotech), requested Soni & Associates, Inc., USA to convene an independent panel of recognized experts to determine the Generally Recognized As Safe (GRAS) status of standardized Fenugreek Seed Extract containing glycosides as a food ingredient. The Expert Panelists consisting of John A. Thomas, Ph.D., FACT, DATS; Robert L. Martin, Ph.D.; and Madhusudan G. Soni, Ph.D., FACN, FATS, was assembled.

Based on a critical evaluation of the publicly available data and in accordance with section 201 (s) of the Federal Food, Drug and Cosmetic Act of the United States, the Expert Panel members have individually and collectively concluded that Fenugreek Seed Extract containing glycosides, meeting the specifications cited in the GRAS dossier, and when used at maximum use levels of 100 mg *per* serving (reference amounts customarily consumed, 21 CFR 101.12) in foods such as cereal bars (energy bars, granola bars, nutritional bars) and fats and oils (includes table fats; cooking fats; vegetable oils; salad dressings; nondairy cream substitutes; and tartar sauce and other sauces that mainly fat or oil), when not otherwise precluded by a Standard of Identity as described in the GRAS dossier and resulting in an estimated maximum daily intake of 527 mg/person/day is safe.

The Expert Panel considered that the available qualitative and quantitative scientific evidence, including human and animal data, to be sufficient to establish safety of standardized Fenugreek Seed Extract containing glycosides at the intended use levels. The safety assessment to ascertain GRAS status for standardized Fenugreek Seed Extract containing glycosides for the specified food uses meets FDA criteria for reasonable certainty of no harm by considering both the technical and common knowledge elements.

It is also the opinion of the Expert Panelists that other qualified and competent scientist reviewing the same publicly available toxicological and safety information would reach the same conclusion. Therefore, the Panelists have also concluded that standardized Fenugreek Seed Extract containing glycosides, when used as described in the GRAS dossier, is GRAS based on scientific procedures.

Sincerely

Madhusudan G. Soni, *PhD*,
Fellow American College of Nutrition
Fellow Academy of Toxicological Sciences