Pathways to Market for Food Ingredients

Algae Biomass Summit
October 25, 2016
Plenty of Algae-Derived Ingredients

- Agars, Carrageenans, Alginates – long history of use
- DHA from algae
- Algal oil
  - (Schizochytrium sp. (2/12/2004)
  - Micro-algal oil (Ulkenia sp. (4/1/2005)
  - 87% oleic acid (Prototheca moriformis strain S2532 (2/6/2015)
- Algae flour/powder
  - Chlorella protothecoides strain S106 flor with 40-70-% lipid (6/7/2013)
Algae Derived Ingredients; FDA-Regulated Uses

- Food or feed additive
- Generally recognized as safe for its intended use ("GRAS")
- Color additive
- Dietary ingredient (for use in dietary supplement)
Any substance that is reasonably expected to become a component of food is a food additive.

Unless the substance, under the intended conditions of use, is generally recognized as safe by experts, based on publicly available data and information.
Food Additive/GRAS Comparison

Food additive
- FDA must issue regulation to authorize use
- Additive must be safe under its intended conditions of use
- “Safe” means reasonable certainty of no harm
- Data can be unpublished
- Process to issue food additive regulation can be lengthy

GRAS
- Intended use of a substance can be determined to be GRAS by private person
- Same safety standard as for food additive, but general recognition also needed
- Data in public domain
- GRAS has become primary means for new ingredients/uses to get to market
FDA runs a voluntary GRAS notification process
Submitters get a “no objection” letter
GRAS self-determination is a unique process
GRAS under attack from NGOs (Pew, CSPI, NRDC, others)
Color Additives

- Color equivalent to food additives
- Color additive regulation – foods, drugs, cosmetics, and medical devices (FD&C or D&C)
- No GRAS for color additives; premarket review is mandatory
Spirulina Blue CAP

- Rule to authorize use – August 13, 2013 (effective September 13, 2013)
- Amendment to expand use (proposed on October 22, 2014; approved August 21, 2015)
- All things considered, FDA handled expeditiously
Algae Supplements

- Phytochemicals (chlorophyll)
- EPA/DHA
- Iodine & Marine Minerals
“Old” – sold prior to enactment of DSHEA
  – FDA burden to show that ingredient presents a significant or unreasonable risk of injury or illness

“New” – Not marketed as dietary supplements in the United States before October 15, 1994
  – Pre-market notification must be submitted to FDA at least 75 days before the NDI is placed into commerce; notification must provide evidence that NDI is reasonably expected to be safe
FDA Guidance on NDI Notification

- August 2016 FDA Draft Guidance (revising much criticized July 2011 draft)
- Guidance remains controversial
- Relationship between GRAS ingredient and NDI
Intended Use

- Key to all ingredient options/pathways is intended use
- Ingredient can occupy multiple categories, depending on intended use
Polsinelli provides this material for informational purposes only. The material provided herein is general and is not intended to be legal advice. Nothing herein should be relied upon or used without consulting a lawyer to consider your specific circumstances, possible changes to applicable laws, rules and regulations and other legal issues. Receipt of this material does not establish an attorney-client relationship.

Polsinelli is very proud of the results we obtain for our clients, but you should know that past results do not guarantee future results; that every case is different and must be judged on its own merits; and that the choice of a lawyer is an important decision and should not be based solely upon advertisements.

© 2016 Polsinelli PC. In California, Polsinelli LLP.
Polsinelli is a registered trademark of Polsinelli PC.