

Summary of the application: Xia Powder 435

Applicant: Access Business Group International LLC, 7575 Fulton Street East Ada, MI 49355-0001, USA

This is an application for authorisation to place on the market a partially defatted chia seed powder, called Xia Powder 435, for use in food supplements and various foodstuffs.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283. The Novel Food consists in a partially defatted chia seed powder. Whole chia seeds and chia oils are authorized in Europe, but no product containing Xia Powder 435 is available on the EU market. The novel food is to be used in food supplements at a maximum daily intake of 12 g, and in a range of various foodstuffs including breakfast cereals, vegetable-based dishes, bread and bakery pre-mixes, pasta, extruded puffs, food bars, and crackers. The target population is the general population. Seeds used in the productions of Xia Powder 435 are non-GMO and cultivation is in accordance with Good Agricultural Practices. Xia Powder 435 is manufactured starting from cleaned seeds pressed to separate oil. The pressed seeds are then cooled to a temperature lower than 30°C because of an increased temperature during the pressing step (< 45°C). After metal detection, the pressed cake is ground to obtain a size of particle below 435 microns. After a second metal detection, the Xia powder 435 is packed and stored for further dispatch. No toxicity study has been conducted in Xia Powder 435, but since this ingredient is a partially defatted chia seed powder, safety studies on chia seeds can be extrapolated to Xia Powder 435. The available studies have shown the lack of mutagenicity (AMES test and in vivo micronucleus test), and the lack of acute toxicity in mice. In addition, to date, 13 human clinical trials have examined the effects of chia seeds in humans, and have not reported any sign of adverse effects for doses up to 35 g/day of chia flour. Regarding allergenicity, despite the huge consumption of chia seeds, only two cases of allergic reaction to chia have been reported in the scientific literature. The allergenicity of Xia Powder 435 can be considered as similar as for chia seeds since no step of the manufacturing process may affect the characteristics of the proteins. In 2009, EFSA has not considered chia seeds has a high risk allergen, and despite the dramatic increase in chia seed consumption in Europe since the first novel food approval, no sign of allergic reaction to chia seeds have been published. To conclude, Xia Powder 435 is well-characterized and compliant with European Regulations. Moreover, the product has been shown to be safe and does not present consequently any potential hazard for the European population.