



Bruce Spurlock
Amy Larson
CoPack Strategies, LLC
2815 100th St., Suite 316
Des Moines, Iowa 50322

Re: GRAS Notice No. GRN 000704

Dear Mr. Spurlock and Ms. Larson:

The Food and Drug Administration (FDA, we) is granting CoPack Strategies, LLC's (CoPack Strategies) request to cease our evaluation of GRN 000704, which we filed on June 2, 2017. We received your request on September 18, 2017.

The subject of the notice is corn oil (by-product of ethanol production) for use as an ingredient in food where vegetable oil would be used, such as in baked goods and confections, and in processes where standard corn oil would be used, such as frying and cooking. According to CoPack Strategies, corn oil (by-product of ethanol production) is intended for use "at levels deemed appropriate based on common uses of foods." The notice informs us of CoPack Strategies' view that these uses of corn oil (by-product of ethanol production) are GRAS through scientific procedures.

In a telephone conversation on September 8, 2017, we discussed deficiencies in CoPack Strategies' notice and suggested that CoPack Strategies ask FDA to cease our evaluation. We stated that the notice contains factual errors and is missing data and information that we would expect it to contain for a GRAS conclusion based on scientific procedures. We did not discuss the full list of deficiencies noted by the technical reviewers assigned to evaluate GRN 704 but rather highlighted several examples.

- The chemical identity of corn oil (by-product of ethanol production) is mischaracterized. Among other issues, CoPack Strategies states that it has a molecular weight of zero and provides the molecular structure for the antiretroviral protease inhibitor "lopinavir," whereas corn oil is largely composed of a mixture of triglycerides (generally greater than 95 percent).
- The method of manufacture section of CoPack Strategies' GRAS notice provides a broad explanation of general processes for obtaining oil from corn (e.g., wet and dry milling) and oil refining processes common to vegetable oil production, but does not provide relevant information on its starting oil material, which CoPack Strategies obtains after ethanol production. The notice does not discuss the potential impurities deriving from fermentation that might be present in the starting material, nor does it discuss residual levels of these impurities that remain after standard oil refining processes.

- The dietary exposure section discusses recommendations for dietary fat and vitamin intakes for U.S. consumers, but does not provide estimates of the amount of corn oil (by-product of ethanol production) consumers are likely to ingest in the diet. It also does not provide estimates of exposure for other constituents of the oil, such as relevant vitamins and essential fatty acids or potential residues of fermentation.
- The basis for CoPack Strategies' GRAS conclusion appears to rest on CoPack Strategies' evidence of similarity between corn oil (by-product of ethanol production) and conventionally produced corn oil, including results of sensory testing. However, the narrative does not address compositional or manufacturing-related differences between corn oil (by-product of ethanol production) and conventional corn oil. The narrative also does not address whether such differences affect the safety of corn oil (by-product of ethanol production) relative to conventional corn oil.
- Information provided in the notice regarding cited references and GRAS Panel credentials is incomplete or incorrect and contains unverifiable information.

On September 8, 2017, following the telephone conversation, FDA sent an email to CoPack Strategies with the detailed list of deficiencies noted by the technical reviewers.

In its request, CoPack Strategies stated that they tried to update and answer FDA's questions but were unable to do so within the timeframe requested by FDA. CoPack Strategies reserves the right to resubmit later.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000704 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.

Carlson -S

Digitally signed by Susan J. Carlson -S
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