Brent Flickinger, Ph.D.
VP, Product Quality, Regulatory and Scientific Affairs
Archer Daniels Midland Company
4666 Faries Parkway
Decatur, IL 62521

Re: Food Allergen Labeling Petition 004 – Archer Daniels Midland Company's Soy Lecithin

Dear Dr. Flickinger:

This letter is in response to a petition from Archer Daniels Midland Company (ADM, the petitioner), received October 29, 2015, and designated as FALP 004. ADM provided additional information supporting its petition on April 13, 2016, and August 25, 2016. The petition was filed pursuant to section 403(w)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 343(w)(6)). Section 403(w)(6) of the FD&C Act states that "Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) [of the FD&C Act] from the allergen labeling requirements of this subsection." This section also states that "The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health."

The petition informs the Food and Drug Administration (FDA) of ADM's view that specific uses of certain soy lecithin products should be exempt from the food allergen labeling requirements under section 403(w) of the FD&C Act. The products identified in FALP 004, as amended, are Ultralec P, Ultralec F, Yelkin SS, Yelkin Gold, Beakin LV1, Beakin LV2, Beakin LV3,[1] Thermolec 200, Thermolec 57, Beakin LV30, Yelkin 1018, and Performix E. The petitioned use of ADM's soy lecithin product is as a component of release agent formulations when applied to food contact surfaces.

ADM describes the manufacturing process for the soy lecithin products that are the subject of the petition. ADM provides specifications for its petitioned soy lecithin products, including limits on the hexane insoluble matter (HI) content of its products (<0.05%). ADM also provides analytical data noting that the mean concentration of HI in its soy lecithin products was 0.01 %, as measured in the years 2011-2015 with 4,445 samples. ADM further notes that an enzyme-linked immunosorbent assay (ELISA) kit

[1] The ADM product Beakin LV3 was inadvertently identified as "Beakin VL3" in FDA's original response letter signed on June 6, 2017. This version of the letter corrects that error and clarifies the name of that petitioned product.

was used to quantify soy protein in 71 samples of its soy lecithin products, where 69 samples were reported to contain less than 2.6 parts per million (ppm), and with no samples higher than 25 ppm.

In its petition, ADM provides an exposure estimate by estimating soy protein intake arising from consumption of foods where its soy lecithin products would be used as a component of release agent formulations applied to food contact surfaces. ADM also reviews the scientific literature and other relevant documents on soy allergy.

Recent guidance issued by FDA entitled, "Guidance for Industry: Food Allergen Labeling Exemption Petitions and Notifications," discusses that risk-based approaches may be used to provide evidence that an ingredient does not cause an allergic response in situations, such as the current petition, where direct clinical or challenge data on the specific product are not available. Thus, the clinical evidence and rationale to demonstrate that ADM's soy lecithin products do not cause an allergic response that poses risk to human health relies on a risk-based approach. ADM uses an approach in which calculations of the worst case soy protein intake exposures from consumption of its soy lecithin products, when used as a component of release agent formulations applied to food contact surfaces, are compared to and were found to be significantly lower than exposures based on a reference risk dose, or threshold level, of soy protein.

FDA evaluated the literature cited in the petition on soy allergy and possible thresholds for clinical sensitivity to soy in the soy allergic population. We also conducted an independent literature review to confirm that there are no additional published studies that should be considered. From the data contained in the petition and other available data, we determined the Lowest Observed Adverse Effect Levels (LOAEL) and No Observed Adverse Effect Levels (NOAEL) for soy protein consumption. We applied appropriate uncertainty factors to be used with the NOAEL and LOAEL to calculate an assessment dose level (FDA assessment dose) for evaluating whether a particular exposure to ADM's soy lecithin products would cause an allergic response that poses a risk to human health. We also evaluated the estimated levels of exposure to soy protein that would result from consumption of the food products that typically use soy lecithin release agent products like those described in the petition. These exposure estimates looked at levels of usage of the soy lecithin release agent products for the specified applications, levels of soy lecithin and soy protein in release agent product formulations, as well as information on consumption levels for the food products that typically use soy lecithin release agent products. We then compared the estimated exposure to soy protein from ADM's soy lecithin products to the assessment dose level that we calculated to evaluate whether a particular exposure to the petitioner's soy lecithin products would cause an allergic response that poses a risk to human health. We did not consider an exposure below the assessment dose level to cause an allergic response that poses a risk to human health.

Based on this review, we conclude that the scientific evidence available at this time demonstrates that each of the ADM soy lecithin products (Ultralec P, Ultralec F, Yelkin SS, Yelkin Gold, Beakin LV1, Beakin LV2, Beakin LV3, Thermolec 200, Thermolec 57, Beakin LV30, Yelkin 1018, and Performix E.), as derived by the method specified in the petition, will not cause an allergic response that poses a risk to human health within the meaning of section 403(w)(6) of the FD&C Act when used as a component of a release

agent applied to food contact surfaces.

We have carefully considered the potential environmental effects of this action. We have concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required.

Sincerely,

Michael A. Adams -S

Digitally signed by Michael A. Adams -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300042713, cn=Michael A. Adams -S
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