U.S. FOOD & DRUG ADMINISTRATION

Memorandum

Date: March 24, 2017

To: Richard Bonnette, M.S., Division of Biotechnology and GRAS Notice Review (HFS-255)

Through: Suzanne Hill, Environmental Supervisor, Office of Food Additive Safety (HFS-255)

Suzanne Hill -S

Digitally signed by Suzanne Hill -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001511836, cn=Suzanne Hill -S
Date: 2017.03.24 11:11:24 -04'00'

From: Biologist, Environmental Team, Division of Biotechnology and GRAS Notice Review (HFS-255)

Subject: Finding of No Significant Impact for food-allergen labeling petition (FALP) 004 Request for an exemption from the Section 403(w)(1) labeling requirements as described in Section 403(w)(6) for soy lecithin products produced by Archer Daniels Midland, Co., when used as release agents applied to food-contact surfaces.

Petitioner: Archer Daniels Midland, Co. (ADM)

Attached is the Finding of No Significant Impact (FONSI) for FALP 004. After this petition is approved, copies of this FONSI and the environmental assessment, dated August 25, 2016, may be made available to the public.

Please use the following paragraph in the final decision memo for the petition:

> The agency has determined that approval of this petition will not have a significant impact on the quality of the human environment and, therefore, an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, will be publicly available after the effective date of the petition.

Please let us know if there is any change in the subject of the petition.

Leah D. Proffitt -S

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000397946, cn=Leah D. Proffitt -S
Date: 2017.03.24 10:56:20 -04'00'

Leah D. Proffitt

Attachment: Finding of No Significant Impact

cc: HFS-255 Proffitt
File: FALP 004

FINDING OF NO SIGNIFICANT IMPACT

A Food Allergen Labeling Petition (FALP No. 003), submitted by Archer Daniels Midland, Co., requesting an exemption from the Section 403(w)(1) labeling requirements as described in Section 403(w)(6) for soy lecithin products ULTRALEC™ E, BEAKIN™ , PERFORMIX™, YELKIN™, and THERMOLEC™.

The Office of Food Additive Safety has determined that allowing this FALP to become effective will not significantly affect the quality of the human environment and, therefore, an environmental impact statement will not be prepared. This finding is based on information submitted by the petitioner in an environmental assessment, dated August 25, 2016. The EA is incorporated by reference in this Finding of No Significant Impact, and is briefly summarized below. The EA was prepared in accordance with 21 CFR 25.40.

Lecithin from all sources is authorized for use in food with no limitation other than current good manufacturing practice under 21 CFR 184.1400(a)[1] which states that "Commercial lecithin is a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol, with smaller amounts of other lipids. It is isolated as a gum following hydration of solvent-extracted soy, safflower, or corn oils."

No new uses of lecithin are authorized as a result of the requested labeling exemption; soy is already being used in industrial food processing as a release agent on food-contact surfaces. The effect of this action would be to exempt industry from the requirement to label products processed with soy lecithin release agents as containing soy. Based on information contained in the FALP, FDA has determined soy lecithin, when used as release agents, presents negligible risk to soy allergic individuals. Although the action may result in increased production of soy lecithin, we do not expect significant impacts on species survival, agricultural practices, or land use patterns, as soy is major a field crop in the US, and lecithin production is a small subset of the larger soy market.

[1] See also 21 CFR 184.1(b)(1)

The no action alternative to approval of the requested action would be the continued current practice of labeling products as containing soy. Such action would have no environmental impact. The data provided in the EA serve to illustrate the robust and expanding nature of the U.S. soybean oil market, and support the position that FDA approval of this food allergen labeling petition for ADM soy lecithin used as a release agent applied food-contact surfaces will not significantly affect the human environment. Therefore an environmental impact statement will not be prepared.

Prepared by Leah D. Proffitt -S Digitally signed by Leah D. Proffitt -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000397946, cn=Leah D. Proffitt -S Date: 2017.03.24 10:57:44 -04'00' Date: see electronic signature

Leah D. Proffitt
Biologist
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration

Approved by Suzanne Hill -S Digitally signed by Suzanne Hill -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Suzanne Hill -S, 0.9.2342.19200300.100.1.1=2001511836 Date: 2017.03.24 11:10:56 -04'00' Date: see electronic signature

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