



June 23, 2006

Rec'd VL

Ms. Vickey Lutwak
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

JUN 27 2006

Re: ADM BeneFlax™ Flax Lignan Extract NDI (Additional Reference Materials)

Dear Ms. Lutwak:

As a follow-up to our teleconference, I am providing additional reference papers cited in Appendix L ("Summary of literature review on animal and human studies using flaxseeds or flax lignans"), except those papers which are already cited in the text of the dossier and were provided in our NDI notification submitted to the FDA on 6/6/06. For your convenience, papers in the binder are arranged in alphabetical order.

The relevance of these papers to BeneFlax™ Flax Lignan extract are in the areas of observed physiological effects when flaxseeds, flax lignans, secolariciresinol or secolariciresinol diglucoside (SDG) are used in the experimental diets, or when enterolactone or enterodiol which are the metabolites of SDG are discussed. As disclosed in our NDI notification, BeneFlax™ Flax Lignan extract contains SDG as the active component.

I am also providing an updated version of Appendix L which includes some minor editorial changes and the addition of the Hallund et al., 2006 paper in the chart. *Kindly replace the previous version of Appendix L in our NDI notification with this new version.* Pages have been numbered accordingly.

One original and two copies of the reference papers and updated Appendix L are enclosed.

Thank you for your attention. Kindly acknowledge receipt of these documents by e-mail or by telephone. Best Regards.

Sincerely yours,

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Cc: James S. How, Ph.D.