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March 2, 2007

Writer's Direct Access George G. Misko (202) 434-4170 misko@khlaw.com

Via Electronic and U.S. Mail

Mr. Tom Inglis General Manager Bi-Ax International, Inc. P.O. Box 848 Wingham, Ontario N0G 2W0 Canada

Re: FDA Status of Bi-Ax's Films when Used in Food Contact Applications; Our

File No. BI13632

Dear Mr. Inglis:

The purpose of this letter is to respond to your request for our opinion regarding the status, under the laws and regulations administered by the U.S. Food and Drug Administration (FDA), of Bi-Ax International, Inc.'s (Bi-Ax) multi-layer films for use in food-contact applications. Specifically, you asked us to evaluate your plain film, heat seal film, and sheet, each having a slightly different composition and thickness.

Based on the information that you have provided regarding the structure and composition of the films, we have no hesitation in providing our opinion that Bi-Ax's plain film, heat seal film, and sheet may be used as intended in contact with food in compliance with the U.S. Federal Food, Drug, and Cosmetic Act and all applicable food additive regulations, provided that (1) the plain film is used only under Conditions of Use B ("Boiling water sterilized") through H ("Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in the container at time of use"), (2) the heat seal film is used only under Conditions of Use C ("Hot filled or pasteurized above 150°F") through G ("Frozen storage (no thermal treatment in the container)"), and (3) the sheet is used only in accordance with the let down ratio of 1 to 100 for the 9200D Bluetone component and only under Conditions of Use B through H.¹

We trust that you will find this letter fully responsive to your request for our opinion.

FDA's Conditions of Use are set forth at 21 C.F.R. § 176.170(c), Table 2.

Washington, D.C.

Brussels

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Shanghai

KELLER AND HECKMAN LLP

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Should you have any questions regarding this matter, or if we may be of assistance in any other way, please do not hesitate to contact us.

Cordially yours,

George G. Misko