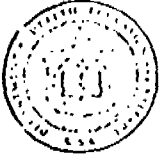


APPENDIX A



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

August 21, 1970

Mr. Jerome H. Heckman
Law Offices
Keller and Heckman
1712 N Street, N. W.
Washington, D. C. 20036

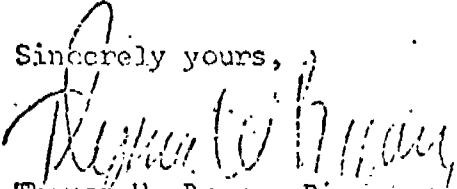
Dear Mr. Heckman:

This is in response to your letter of July 23, 1970 in which you ask for our views concerning section 121.1(e) of the food additive regulations. This is the section which states in the next-to-last sentence: "If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive."

Your question concerns subsection(s) (21 U.S.C. 321), particularly as it relates to migration of substances from food packaging materials. It is our position, as regards such substances, that if a food manufacturer, or his food packaging supplier(s) has migration data which establishes that there is no reasonable likelihood of migration to food, he need not seek confirmation of his decision from the Food and Drug Administration that the packaging material is not a food additive. However, if he desires such confirmation he should furnish the details of his scientific (extraction) studies. Where the review of the extraction studies confirms a lack of potential for migration, no regulation is necessary.

We trust this statement of our position is responsive to your letter.

Sincerely yours,


Thomas W. Brown, Director
Office of Compliance
Bureau of Foods, Pesticides and
Product Safety