EXHIBIT A

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
ROCKVILLE, MD 20852

OFFICE OF THE
GENERAL COUNSEL

August 3, 1973

Jerome H. Heckman, Esq.
Keller and Heckman
Suite 1000
1150 - 17th Street, N. W.
Washington, D. C. 20036

Dear Jerry:

In response to your letter of July 20, 1973, I am returning the transcript with a minimum amount of editing. I have resisted the temptation to perfect my grammar and have limited the changes to substantive ones.

I do believe it proper for this transcript to be made publicly available. I am therefore requesting that, when you send it to the Committee and others, you also send a copy to me and to the trade press so that any member of the public who is interested will have the benefit of these remarks.

Sincerely yours,

Peter

Peter Barton Hutt
Assistant General Counsel
Food and Drug Division

Enclosure

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Exhibit B

SPI'S TROUBLE SHOOTER

FOOD, DRUG AND COSMETIC PACKAGING MATERIALS COMMITTEE

Recognizing and Nipping Problems in the Bud

Is a Quiet, Full-Time Job That Serves All Members

Because the function of SPI's Food, Drug and Cosmetic Packaging Materials Committee is to anticipate potential plastics industry difficulties and resolve them before they become major and possibly irreversible problems, the work of this group is perhaps less known than other SPI efforts marshalled to cope with three-alarm fires. In the packaging field, this committee is widely recognized as an extremely effective watchdog operation, keeping its members up to date on evolving technical and legal aspects of various types of legislation and policy that might affect them. The FDCPMC sees its primary role to be the plastics industry's eyes, ears and voice, frequently bringing cogent persuasion to bear on the Food and Drug Administration, the Department of Agriculture, and other regulatory agencies. Its day to day activities are a vast and continuous preventive maintenance program, generally resulting in the avoidance of emergency crises that could have disastrous impact on the plastics industry. It has aptly been called the industry's "public health and environmental problems early warning system."

FDCPMC maintains a constant dialogue with the federal authorities. It acts as a primary source of information--to the government regarding plastics; and to the plastics industry concerning the significance to plastics of planned government actions. It acts as a clearing house, and an information

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digesting and distributing organ, recognizing fully, for example, that the "FDA status" of a plastic resin or end product will invariably have a direct effect on the marketplace.

Typical Committee meetings receive reports and hold discussions on the technical and legal aspects of relevant pending and recently approved federal and state government regulations. Topics discussed include proposed governmental rulings and shifts in policy, reports on liaison with other organizations whose activities bear on important interests of the plastics industry, and reports of new and/or proposed legislation in the area of the Committee's responsibilities.

For example, when a revision of FDA concepts regarding a "generally recognized as safe (GRAS)" list, as well as the "prior sanctioned" rule were pending, the Committee filed Comments documenting the desirability of avoiding adverse FDA action which could severely disrupt sales of long-used materials, not only in packaging, but also in appliances, dinnerware, etc.

Another FDCPMC action filed formal Comments regarding a proposed rule that plastic food packaging materials would have to contain no more than 5 parts per million of polychlorinated biphenyls (PCB's) as an unavoidable contaminant. As a result, in part, the final proposal will not contain this limitation, since it was pointed out that no problem has been shown to exist with plastic packaging materials. Elimination of this requirement can save the plastics industry substantial costs which would otherwise be required in PCB testing and certification programs.

Comments filed by the FDCPMC regarding colorants for plastics in food contact applications are expected to remove proposed new restrictions that might have seriously limited the use of several acceptable pigments now

widely employed. In addition, the Committee set up a task force to work with a group from the carbon black industry seeking an acceptable substitute for channel black, presently being phased out of commercial production.

The FDCPMC was originally formed in 1957 to study a proposed Food Additives Amendment to the Food, Drug and Cosmetics Act which would have imposed onerous requirements for product pre-clearance. In good measure as a result of significant Committee contribution to the hearings on the amendment, most dishes, utensils, picnic ware and similar goods were exempted from the demanding specification.

The Committee subsequently published a manual to acquaint the plastics industry with the basic requirements of the Food Additives Amendment of 1958, supplemented by a later manual--lauded by FDA--designed for chemists, food packers, raw materials suppliers and others involved in plastics packaging.

During the 1960's FDCPMC was responsible for the publication of a manual on "Good Manufacturing Practices Criteria for Plastic Resins 'Prior Sanctioned' Under the Food Additives Amendment of 1958," which listed many of the basic resins that were "prior sanctioned"--something the FDA had not done. The FDA itself has referenced the manual on numerous occasions, which has consequently saved much valuable time and money which would have been required to clear these safe-for-food application plastics. The Committee has also published "Plastics Packaging for Drug Products--the Regulatory Story," which performs companion service for plastics in the drug and cosmetic fields.

Clearly, the activities of the Committee have prevented the statutory elimination of many plastic resins from a variety of applications, not

only where food and drug packages are concerned, but also, by extension, to other areas where sensitivity to consumerist and environmentalist pressures creates extreme caution.

Because the consumerist/environmentalist temper of the times will undoubtedly intensify for the forseeable future, the work of the Food, Drug, and Cosmetic Packaging Materials Committee will undoubtedly be required to increase, and remain one of the first lines of interface between the plastics industry and the government in anticipating and helping solve the kinds of problem all industry will have to deal with.

Serving as an early warning network for the entire plastics industry, the Committee anticipated such problems as the plastic bag suffocation situation, the solid waste problem, PCB, mercury and other environmental contamination, and numerous other problems. In many instances overall industry response and action laid the problems to rest. The Committee's thrust is based on the documented conviction that its numerous "quiet victories" have proven the most valuable and profitable for its industry.

EXHIBIT E

DSL - 72-900
Date: 2/6/73

Protocol

Procedure for Moisture Permeability

Prepare a saturated solution of sodium chlorate with excess undissolved (150g for each 100 ml.) in the bottom of a desiccator and allow to equilibrate for three days. This establishes a microenvironment of 75% relative humidity at 20°.

Dry a suitable amount of 4 mesh anhydrous calcium chloride, taking care to exclude any fine powder, for 1 hour at 110°. Cool in a desiccator to room temperature before use.

Select a suitable number, not less than three, of containers of the same size to be tested plus two controls. Fill the containers with the desiccant to within 13 mm of the closure*. Fill the control vials with glass beads to the approximate weight of the other containers. Seal the containers immediately. Place the containers including the controls in the humid microenvironment and maintain at 20° ± 2°. Weigh each container within one hour of the time of filling, returning it immediately to the desiccator, after 1, 7, 28 and 56 days. Subtract the average weight increase of the controls from the gross increase of each container to obtain the net increase in weight. Measure the whole volume of one of the containers by emptying an additional container, filled to the brim with water, into a suitable volumetric apparatus such as a graduated cylinder. Calculate the rate of passage of moisture into each test container in milligrams per day, per liter of container capacity.

TORQUE TABLE**	
Closure diameter in mm.	Suggested tightness in inch pounds torque as applied by hand
15	6 - 9
18	7 -11
20	8 -12
22	9 -13
24	10 -15
28	11 -17
33	13 -20
38	15 -23
43	17 -26
48	19 -29
53	21 -32
58	23 -35
63	25 -38
70	28 -42
83	34 -49
86	35 -51
89	36 -53
100	40 -60

*For small containers, fill 2/3 full.
**Owens-Illinois Torque Tester Manual.

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EXHIBIT E

Procedure for Oxygen Permeability

Reagent Solution. Prepare a solution of 150 g. of ammonium chloride in 500 ml. of nitrogen-purged distilled water and make to one liter with concentrated ammonium hydroxide.

Procedure. Take a random of sampling of sixteen containers[1]. Fill these with 30 g. to 50 g. of copper turnings for each liter of capacity, taking care that the turnings are well distributed and extend into the headspace of the container, but not high enough to come into contact with the closure when sealed. Purge each bottle with nitrogen. Fill each container with an accurately known volume of Reagent Solution to approximately 2/3 capacity, while under a nitrogen flow[2], taking care to avoid wetting the surface near the closure. Immediately secure the closures, using the proper torque for screw cap containers.

Allow the containers to stand 15 minutes. Shake one container, to dissolve any reacted copper above the solution. Open it and immediately pour the liquid through a funnel into an erlenmeyer flask, thereby separating the solution and undissolved copper turnings. Allow the filtrate to be exposed to oxygen for 15 to 20 minutes with periodic stirring or agitation. This is the procedural blank. Read the absorbance at 640 mμ[3]. At the appointed intervals, measure the absorbance of the solutions. If the observed absorbance is greater than 1.00, make a dilution of 1 to 10 ml. If it is still greater than 1.00, make a dilution of the original solution of 1 to 100 mls. Determine the amount of oxygen accumulated in the solution in each container by comparing the observed absorbance to the Standard Calibration Graph making corrections for any dilutions and subtracting the blank value.

Intervals. An initial testing frequency of 1, 7, 14, 28 and 56 days is to be used, performing the test within one hour of the time of the day the test containers were prepared. If the solutions in any of the sealed containers becomes an opaque blue or all of the copper in the headspace is dissolved, the experiment is terminated. To complete an experiment with at least four valid reading intervals, the time intervals and sample numbers are revised accordingly.

Standard Calibration Graph. Weigh 1.135 g. of copper turnings in 10 ml. of HCl (1:1 with water) and dilute to 100.0 ml. with Reagent Solution. Transfer 1.00, 3.00, 5.00 and 7.00 ml. aliquots to separate 100-ml. volumetric flasks, and dilute each to volume with Reagent Solution. Using distilled water as a reference, read the absorbance of the solutions. Plot the absorbance vs. the corresponding oxygen concentration per liter of solution (10, 30, 50 and 70 ml. of oxygen). Subsequently read from the graph the value of the ml. of oxygen per liter of Reagent Solution (X) in each container.

Calculate the ml. of oxygen per liter of container capacity by the following formula:

$$\frac{\text{(ml. of oxygen)}}{\text{(liter of container capacity)}} = X \left(\frac{\text{volume of Reagent Solution dispensed in liters}}{\text{(volume of container capacity in liters)}}\right)$$

[1]This allows triplicate container readings at each interval. Where substantial variability is experienced, larger test groups are needed.

[2]It is preferred to charge the containers in a nitrogen atmosphere to keep blank values at a minimum. This is particularly important when low oxygen permeability is anticipated.

[3]Solutions may be read on a Bausch & Lomb Spectronic 20 in 13 mm (OD) cells, or a suitable spectrophotometer and 1 cm. cells.