LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20036
(202) 457-1100

TELEX
TELECOPIER
(202) 296-7662
CABLE ADDRESS "KELMAN"
WRITER'S DIRECT DIAL NUMBER
(202) 457-1110

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. HEEMAN
WILLIAM H. BORGHESANI, JR.
MALCOLM D. MACARTHUR
WAYNE V. BLACK
MARTIN W. BERCOVICI
JOHN S. ELDRED
CAROLE C. HARRIS
MICHAEL F. MORRONE
LARRY S. SOLOMON
JOHN B. DUBEEN
PETER L. DE LA CRUZ
CHRISTINE A. HEAGNEY
SHIRLEY S. FUJIMOTO

LAWRENCE P. HALPRIN
MARK FOX EVENS
RALPH A. SIMMONS
C. DOUGLAS JARRETT
EDWARD L. ROBINEX
PETER A. SUSSER
SHEILA A. MILLAR
RUSSELL H. FOX
LEE M. WEINER
ILENE RINGEL HELLER
SUSAN J. BLUM
MARK C. HAYES*
DEREK A. BLOOM
SANDRA J.P. DENNIS
KENNETH A. GIBBS, JR.

*ADMITTED IN NEW YORK AND VIRGINIA ONLY

July 9, 1985

To: SPI Vinyl Institute
SPI Food, Drug, Cosmetic Packaging
Materials Committee
SPI Plastic Bottle Institute

Re: FDA PVC Status Report

Ladies and Gentlemen:

The purpose of this letter is to inform you about th latest intelligence we have on the status of the Food and Drug Administration's (FDA) long-awaited proposal to regulate the food-contact uses of polyvinyl chloride (PVC). As you are aware, efforts by SPI's Vinyl Institute members and others have generated correspondence between FDA and several Congressmen. The most recent example is a June 20, 1985 letter from FDA Commissioner Frank E. Young to Representative Christopher H. Smith (R-NJ). That letter states: "The agency is presently reviewing a proposal which will set forth conditions of use, including liquor bottle use, that we believe will be safe. We anticipate publishing this new proposal in the Federal Register during the current year and will do everything we can to expedite it."

To say we are disappointed and frustrated by FDA's delay in publishing a proposal is to state the obvious. We all recall that the Agency made similar promises to Congressmen last year that a proposal would be published in late 1984.

Through discussions with FDA personnel, we have been trying to establish the cause of delay and to urge prompt action. By patching together information from a variety of sources, it is our conclusion that there is still little or no concern with the substance of the draft PVC proposal. In other

words, there is no real health or safety issue in the presence of adequate controls on the levels of residual vinyl chlorid . Thus, we consider statements in Commissioner Young's letter referring to the Agency's need to reassess the carcinogenic potency of vinyl chloride monomer to be a disingenuous explanation for FDA's delay.

It is our opinion that progress on the PVC proposal is being hindered by other activities in FDA, particularly relating to color additives. We detailed the color additive situation in our letter of July 5, 1985. Given our familiarity with the toxicological and risk assessment data on vinyl chloride monomer, it appears to us that the risk presented by PVC is substantially less than that posed by certain color additives that FDA presently permits despite congressional inquiry, judicial proceedings, and mounting press attention.

The color additive proceedings have diverted the Agency's attention from other matters, including the PVC rule. As far as we can determine, the proposed rule is still inside FDA and has not been circulated to the Department of Health and Human Services (HHS) or the Office of Management and Budget (OMB) for review. Given the political and other pressures being brought to bear on FDA in relation to color additives, we would not be at all surprised if FDA was again revising the preamble to the draft PVC regulation to make it "consistent" with the Agency's more recent statements in the color additive proceedings relating to the regulation of carcinogens.

On top of all this, Commissioner Young has been clear d for the post of Assistant Secretary for Health at HHS. Although it is not yet clear when Dr. Young will change positions, if he departs before the PVC proposal is forwarded to HHS and OMB for clearance, it could lead to further delays if Young's successor at FDA does not act decisively.

Earlier this year we anticipated that a proposed rule might be published by summer. However, since FDA has yet to circulate the proposal to HHS and OMB, it now appears unlikely that the PVC proposal will appear in the Federal Register until late this year.

In light of new information on the delays that the PVC proposal is encountering, I am initiating a series of calls to

high level management officers within FDA's Center for Food Safety and Applied Nutrition to verify that there is no problem in that key organization. If there is no delay in the Center, we will then need to follow-up with the General Counsel's Office and finally the Commissioner's Office. The primary objective of the calls will be to press for prompt action on the PVC proposal. We also hope to confirm and refine our und r-standing of the status of the PVC rule.

If you have any comments or questions pending your receipt of our follow-up reports, please let us know.

Cordially yours,

Jerome H. Heckman

cc: Charles E. O'Connell
Thomas J. McGrath