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February 10, 1986

Mr. Bruce Borsuk
Vista Chemical Company
P. O. Box 19029
Houston, Texas 77224

Re: FDA Status of Bisphenol-A

Dear Bruce:

In our December 16, 1985 letter, we recommended that, as a matter of prudence, the residual bisphenol-A (BPA) level be determined in Vista's polyvinyl chloride (PVC) resin. You have now completed this work and have informed us in a January 30, 1986 telephone conversation with Chuck Breder that the resin contains 185 parts per million (ppm) of BPA. Based on this data, and for the reasons discussed more fully below, we have no hesitation in providing our opinion that BPA can be used as a polymerization termination agent (kill agent) in the manufacture of PVC in full compliance with the Federal Food, Drug and Cosmetic Act ("Act") and all applicable Food Additive Regulations.

A. Regulatory Framework

To put our opinion into prospective, it may help to review the legal/regulatory background applicable to food contact substances. Section 201(s) of the Act defines a "food additive" in pertinent part as:

> [A]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its

> becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized . . . to be safe under the conditions of its intended use; except that such term does not include--
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> * * *
>
> (4) any subtance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act.

This definition is repeated in section 170.3(e) of the Food Additive Regulations which adds, again in relevant part, the following explanatory information:

> A material used in the production of containers and packages is subject to the definition [of "food additive"] if it may reasonably be expected to become a component . . . directly or indirectly of food packed in the container. . . . . 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.

Thus, a substance that is reasonably expected to become a component of food when employed in a food contact application must be: (a) the subject of an applicable Food Additive Regulation, (b) the subject of a prior sanction or approval, or (c) deemed generally recognized as safe (GRAS). If the substance is not reasonably expected to become a component of food under the intended conditions of use, it is not a food additive, and it may be so employed without any prior action by or consultation with the Food and Drug Administration (FDA).

B. Basic Resin Doctrine

As further background information, Food Additive Regulations are all issued on the premise that substances must be evaluated (and cleared where appropriate) on a generic rather

than a proprietary basis. In the case of plastics resins, as long as the basic resin is: (a) listed in a regulation or otherwise cleared, (b) manufactured in accordance with good manufacturing practices, and (c) complies with any applicable extraction requirements, then the resin is covered by that regulation--even though different manufacturers may make the resin by different processes.

FDA stated many years ago that a "basic resin" is the material that comes out of the polymerization kettle, i.e., a basic resin is the product that results when the polymerization process has been carried to commercial completion. Substances such as catalysts, chain regulators, chain transfer agents, and all other materials required to produce the basic resin are considered part of the basic resin and not subject to independent regulatory consideration. Thus, the clearance afforded the basic resin automatically clears those substances which are necessarily used during the polymerization stage to produce it. We are enclosing relevant portions of a report to the Food Packaging Materials Committee of The Society of the Plastics Industry, Inc. (SPI), in December of 1966. The report covers a presentation by an FDA spokesperson in which the "basic resin" doctrine was addressed.

The basic resin doctrine merely reflects the practical reality that FDA could never hope to write generic regulations for food packaging materials that describe and specifically clear every substance that might properly be a component or contaminant of the packaging material as a result of every conceivable manufacturing process that yields a suitable resin. Since trace quantities of these "unregulated" substances are not perceived to present a public health hazard, FDA has wisely chosen not to subject such substances to the burdensome preclearance provisions of section 409 of the Act that apply to food additives.

On the other hand, the basic resin doctrine does not apply to substances [adjuvants] added to the basic resin in order to prepare a technologically useful plastic packaging material but not essential to the polymerization process itself. Thus, stabilizers, plasticizers, pigments, lubricants, and the like, which may be added to a basic resin to facilitate its further processing or to affect the technological properties of the final plastic product, must be considered as matters separately from the clearance afforded the basic resin.

C. FDA Status of BPA

Turning now to a consideration of the use of BPA as a kill agent, it is, as described above, considered part of the basic PVC resin and, as such, is of no regulatory concern. The fact that its use also seems to convey some thermal and color stability characteristics to the final resin can be considered to be an advantageous side effect. Nevertheless, the basic resin doctrine clearly permits the intended use of BPA.

As a matter of prudence, you have conducted tests and informed us that Vista's PVC resin contains 185 parts per million (ppm) of residual BPA. Using this information, we have made several very conservative assumptions to calculate the maximum potential level of BPA in the daily diet resulting from food-contact articles prepared from such a resin. These assumptions are: (a) no BPA is lost during subsequent high heat mixing and calendaring of the resin; (b) the maximum thickness of the resulting calendared sheet will be 30 mils (0.030 inches); and (c) less than 5% of the residual BPA will migrate to food under the most severe conditions of use (Section 176.170, Table 2, Condition of Use E, room temperature filled and stored).

These assumptions are considered conservative because, firstly, some loss of BPA will very likely occur during subsequent high heat processing to yield lower residual levels in the final product. Secondly, most food contact surfaces will be thinner than 30 mils and less BPA will be available for migration from such articles. Finally, when tin stablizers are used in PVC at a level of 2% (20,000 ppm), less than 0.01% migrates to food. Thus, our use of a 5% migration factor represents a large conservatism.

Using the above assumptions, we have calculated that BPA would not be detected in the diet using an analytical method sensitive to 50 parts per billion (ppb). These calculations are contained in a separate memorandum by Chuck Breder which is enclosed for your files. Such calculations can also be used to estimate the maximum potential BPA concentration in the daily diet arising from PVC food-contact articles of different thicknesses and from other PVC resins containing different BPA residual levels.

Besides being covered by the basic resin doctrine it is unlikely that BPA will become a component of food under its intended conditions of use in rigid and semi-rigid contact articles. Accordingly, it can be employed in full compliance with the Act and all applicable Food Additive Regulations. By making calculations similar to those shown in the enclosed memorandum, and by assuming that all of the BPA migrates to food because migration from plasticized articles is generally higher, it can also be shown that no BPA will be detected in the diet in contact with flexible PVC films of 3 mils or less (30% plasticizer) using an analytical method sensitive to 50 ppb. Thus, PVC flexible films can also be employed in full compliance with the Act and all applicable Food Additive Regulations.

We trust you will find that we have been responsive to your request for our opinion concerning the FDA status of BPA for use as a kill agent in the manufacture of PVC. If you should have any questions, or if there is any other way we may be of help, please do not hesitate to contact me.

Cordially yours,

Peter

Peter L. de la Cruz

Enclosure

cc: William L. McClain, Esquire
R. Phillip Carey, Esquire