Vista Polymers Inc.
A Subsidiary of
Vista Chemical Company

15990 N. Barker's Landing Rd.
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Houston, Texas 77224
Phone (713) 531-3200

A

RECEIVED

OCT 24 '85

Route: MMDS

Copy:

File: PVC

X-F:

VISTA

October 23, 1985

Peter L. de la Cruz, Esq.
Keller and Heckman
1150 17th St. N.W., Ste. 1000
Washington, DC 20036

Dear Peter:

Enclosed you will find the proposed contents of our Drug Master File which you prepared and I have reviewed. My suggested changes are, for the most part, minor and highlighted in yellow. We prefer to open the DMF in the name of Vista Polymers Inc. instead of Vista Chemical Company unless you feel particular need to do otherwise. Also, while Phil Carey is certainly flattered by your referring to him as "Assistant General Counsel," around here he is more generally known as Attorney, with aspirations.

As for the resin recipes, we would like to add to all five the use, in item #3, of Bisphenol A (2,2,-Bis(4-hydroxyphenol)propane. Please specify a use range of 0.01 - 0.03% on each recipe page.

At this time, I would also like to set up a Medical Device Master File (MDMF). I assume the contents of an MDMF for Vista Polymers would exactly resemble those of the DMF, with the exception of the department of the FDA to which the file is addressed. If this is the case, please call me with the name and address of the person at FDA to whom this material should be sent and I will generate the appropriate request on Vista letterhead.

I appreciate your assistance and look forward to receiving word from you that both an MDMF and a DMF have been established in our name by mid-November.

Sincerely,

Bruce H. Borsuk

Bruce H. Borsuk
Market Development

/eab
Enclosures

cc: R. Phil Carey

bcc: RES, JAH, HRF, ELK, TGG (w/o enclosures)

VEV-143968

File-PVC A

VISTA CHEMICAL COMPANY

DRUG MASTER FILE

FOR

POLYVINYL CHLORIDE PRODUCTS

September ___, 1985

TABLE OF CONTENTS

RECEIVED

AUG 21 '85

Interoffice Communication

VISTA

TO: R. E. Swantkowski

Route: _____

From: B. H. Borsuk

Copy: _____

Date: August 19, 1985

Subject: FDA-RAP: Clarification of Resin Approval

File: PVC

X-F: _____

Further to my IOC of 8-15 notifying you of our resins' approval by Keller & Heckman for food packaging, I must clarify. This approval is conditional upon our using certain antioxidants in the manufacturing process. Currently these are BHT or Irganox 245. Keller & Heckman saw in our recipes that these antioxidants can be used in our manufacturing process and, since they are both FDA approved, passed favorable judgement on our resins. We also use Naugard 492 & Isonox 132 as antioxidants. These are not FDA-approved and any resin produced with these would be FDA-approved only after proper migration studies are carried out, and the results are favorable according to Keller & Heckman.

Although I still support sending a letter to AHC, I must state that sending this letter and supplying "FDA-approved" resin to AHC, or any other customer, is based upon an internal committment to use only BHT or Irganox 245 or other FDA approved antioxidant. Use of Naugard 492 or Isonox 132 for resin intended for a food packaging application would invalidate such a letter to a customer.

Bruce H. Borsuk

B. H. Borsuk
Market Development

BHB/smc

CC: JAH, HRF, ELK, CMS, SEM, HJH, TGG, JF, DWH, HDG, RBQ, EJM, DRW, RPC, NJF, TFO.

VEV-143986

TO: R.E. Swantkowski

FROM: B.H. Borsuk
DATE: August 15, 1985

Interoffice Communication

SUBJECT: FDA - RAP: APPROVAL OF 5265, 5305, & 5385 RESINS

VISTA
RECEIVED
AUG 16 '85

Route: _____
_____
_____
Copy: _____
_____
File: _____
X-F: _____

I received this week the opinion letter from Keller & Heckman stating that our 5265, 5305, and 5385 resins "may properly be said to be in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable Food Additive Regulations." This does not preclude 5425 and 5465 from such compliance, Keller & Heckman simply understood that present marketing opportunities for Vista Polymers in FDA application involved our low and medium molecular weight resins.

I suggest the next step in developing our market for FDA-approved resin is to provide AHC a letter communicating the opinion of our outside counsel, thus allowing AHC to purchase 5265 and/or 5305 for use in food packaging. AHC has indicated that such approval will be sufficient for all of their food and drug packaging applications, although we may also communicate verbally to AHC our intentions to set up a Drug Master file should they find it necessary to refer to same in connection with a new drug packaging product. As for AHC's request of resin compliance specifically with 21 CFR 175.300, Keller & Heckman's opinion does include approval under that regulation; I have confirmed this verbally with Peter de la Cruz.

I have attached a draft of a letter which can be used for AHC and should properly come from you as Manager of Marketing. Please advise as to its acceptability. I have reviewed it with Phil Carey.

I have also attached copies of most of Keller & Heckman's, response, if you wish to see any of the other references specifically mentioned by Peter de la Cruz, please advise.

Tom O'Brien would like to deliver the letter to AHC at his meeting with them on August 29.

Bruce H. Borsuk
Market Development

cc: JAH, HRF, ELK, CMS, SEM, HJH, TGG, JF, DWH, HDG, RBQ, EJM
NJF, TFO, RPC (w/AHC draft letter attachment only)

BHB/rlc

VEV-143987

Dear _____

We are pleased to inform you that after careful review of Vista Polymers PVC resins by our outside counsel Keller & Heckman of Washington, D.C., we have received a favorable opinion regarding their use in food and drug packaging applications.

Specifically, we have a letter on file stating that: "when used as intended [Vista's PVC 5265 and 5305 resins] may properly be said to be in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable Food Additive Regulations." This compliance includes 21 CFR 175.300 Resinous and polymeric coatings.

We are also establishing a Drug Master File at the Food and Drug Administration. This can be useful for your future reference in connection with any new drug packaging application for which you may want to use Vista PVC resins.

We appreciate your business and look forward to continuing to supply your needs.

R.E. Swantkowski
Manager of Marketing

cc: Mr. Tom F. O'Brien
Saddlebrook, NJ

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August 12, 1985

Mr. Bruce H. Borsuk
Vista Polymers, Inc.
Vista Chemical Company
15990 North Barker's Landing Road
P. O. Box 19029
Houston, Texas 77224

Re: FDA Status of PVC Resins
5265, 5305 and 5385

Dear Bruce:

We have reviewed the information submitted in your July 9, 1985 letter and later supplemented by your July 18, 1985 telephone call and are satisfied that the products present no food additive problem. We are enclosing two letters expressing this opinion. The first letter briefly states our conclusion in a way that will not disclose the formulation of the products. Many of our clients have found such a letter useful as a marketing tool to indicate the propriety of using their materials for its intended use. The second letter details the FDA status of each component and describes the basis for our conclusion.

We trust you will find the enclosed opinion letters fully responsive to your request for our opinion. If you should have any comments or questions, please let us know.

Cordially yours,

Peter

Peter L. de la Cruz

Enclosures

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

VEV-143989

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August 12, 1985

Mr. Bruce H. Borsuk
Vista Polymers, Inc.
Vista Chemical Company
15990 North Barker's Landing Road
P. O. Box 19029
Houston, Texas 77224

Re: FDA Status of PVC Resins
5265, 5305 and 5385

Dear Bruce:

In response to your July 9, 1985 letter and our subsequent telephone conversation on July 18, 1985, we have considered the Food and Drug Administration ("FDA") status of Vista's PVC Resins 5265, 5305 and 5385 intended for use for various food and drug packaging applications. based on our careful review of the formulations and other pertinent data, it is our opinion that when used as intended these resins may properly be said to be in compliance with the Federal Food, Drug, and Cosmetic Act and all applicable Food Additive Regulations.

We trust this letter will be fully responsive to your request for our opinion. If you should have any questions or if we can be of any further assistance, please contact us.

Cordially yours,

Peter L. de la Cruz

Peter L. de la Cruz

VEU-143990

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August 12, 1985

Bruce H. Borsuk
Vista Polymers, Inc.
Vista Chemical Company
15990 North Barker's Landing Road
P. O. Box 19029
Houston, Texas 77224

Re: FDA Status of PVC Resins

Dear Bruce:

In your July 9, 1985 letter and subsequent telephone call on July 18, 1985, you provided information concerning the formulations for Vista's PVC Resins 5265, 5305 and 5385, and requested an opinion concerning their Food and Drug Administration ("FDA") status. These resins are intended for use in various food and drug packaging applications. We have analyzed the information provided and, as discussed more fully below, w have no hesitation in providing our opinion that these products may be used as intended and that such use may properly be said to be in compliance with the Federal Food, Drug, and Cosmetic Act ("Act") and all applicable Food Additive Regulations.

A. Regulatory Background

To put our opinion into perspective, 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--
>
> * * *
>
> (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(d) 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 becom 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).

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 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 ("FPM") of The Society of the Plastics Industry, Inc. (SPI), in December of 1966. The report covers a presentation by an FDA spokesperson to the FPM Committee in which the "basic resin" doctrine was set forth.

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 wis ly 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 those substances added to the basic resin in order to prepare a technologically useful plastic packaging material. Thus, stabilizers, plasticizers, pigments, lubricants, and the like, which may be added to a basic resin in order to facilitate its processing or to affect the technological properties of the final plastic product, must be considered as matters separate from the clearance afforded the basic resin.

B. **FDA Status of Vista PVC Resins**

Turning now to a consideration of the specific formulations for Vista Resins 5265, 5305 and 5385, we note that the three products are each comprised of greater than 99 weight percent of PVC basic resin along with fractional percentages of calcium stearate and antioxidants. The formulations for the three PVC resins vary only in the ratio of reagents used and the specific initiator and suspending agents employed. The antioxidants used are butylated hydroxytoluene (BHT) and/or Irganox 245. Also, odorless mineral spirits may be added and subsequently removed during polymer finishing to provide certain property advantages.

The major component of these formulations, polyvinyl chloride ("PVC") is prior-sanctioned for use as the basic resin in food packaging applications and presents no food additive concerns, assuming it is produced in accordance with good manufacturing practices.

As you know, FDA proposed in 1975 to ban all rigid and semirigid PVC products while allowing continued use of thin film and coatings or closure liners. The Agency has never finalized its 1975 proposal. Continuous refinements in PVC production techniques have reduced the level of residual vinyl chloride monomer in rigid products to levels which are hardly measureable and which are of little safety and regulatory concern. This opinion was expressed by the Agency in a 1979 letter, a copy of which is enclosed for your information.

For years the Agency has promised a new regulation for PVC. In fact, we're now told to expect something before "the end of the year." It is our understanding that a new proposal will be issued reaffirming the acceptability of rigid and semirigid PVC products provided they meet certain residual monomer specifications. Informed rumor leads us to believe that a limit of 10 parts per billion (ppb) residual monomer will be placed on such products. Lower limits of residual monomer are anticipated for plasticized films and other plasticized products. In any event, we recommend that when Vista PVC resins are formed into various food contact surfaces, the residual monomer levels in those surfaces should be no higher than the aforementioned levels. If you are interested, we can provide

analytical methodology which is suitable to determine the residual vinyl chloride levels in your materials.

The materials used to prepare the basic PVC resin include suspending agents, initiators, chain transfer agents, and killing agents. These are all considered part of the basic resin and, as such, are of no regulatory concern. Calcium stearate, which is used as an antistatic agent, is considered GRAS in section 184.1229. The antioxidant BHT is prior-sanctioned in section 181.24, while the other antioridant, Irganox 245 (ethylene bis(oxyethylene)-bis-(3-tertbutyl-4-hydroxy-5-methylhydrocinnamate)), is cleared in section 178.2010 for use at levels not to exceed 0.2% by weight of rigid vinyl chloride plastics prepared from vinyl chloride homopolymers and/or vinyl chloride copolymers used in accordance with a prior-sanctioned or applicable regulations. A copy of this regulation is enclosed for your files. We note that the formulations for Vista PVC Resins 5265, 5305 and 5385 all use less than 0.2% Irganox 245. Because these substances are GRAS, prior-sanctioned, used in accordance applicable regulations or subsumed under the basic resin doctrine, they may be used as intended.

We understand that odorless mineral spirits may be added during polymerization of the vinyl chloride and subsequently removed during the polymer drying process. This treatment increases the porosity of the PVC resin which, in turn, improves drying and subsequent blending with other materials. No residues of the odorless mineral spirits are expected to remain in the finished PVC resin after drying. As such, the mineral spirits are not anticipated to be a food additive. Nevertheless, and as an added measure of comfort, odorless mineral spirits are cleared for use as a direct food additive in section 173.340 as a defoaming agent for use in processing beet sugar and yeast. It is our opinion that when a material is cleared for direct food additive use, it may be considered GRAS in indirect additive applications provided the anticipated levels in food resulting from contact with the packaging material is far less than that permitted from the cleared direct food contact uses. This is the case with the use of mineral spirits here.

To summarize briefly, all components of Vista's PVC Resins 5265, 5305 and 5385 are either prior-sanctioned, GRAS, or cleared under an appropriate Food Additive Regulation.

We trust you will find we have been responsive to your request concerning the FDA status of Vista's PVC resins. If you should have any questions concerning this matter, or if there is any other way we may be of help, please do not hesitate to contact us.

Cordially yours,

Peter

Peter L. de la Cruz

Enclosures

AAAG => FDA

TO: Distribution

FROM: B. H. Borsuk
DATE: July 19, 1985

Interoffice Communication

VISTA

SUBJECT: FDA-RAP UPDATE

Peter de la Cruz is sending me an opinion letter stating that, provided BHT or Irganox 245 are used as the antioxidant, our 5385, 5265 and 5305 resins are suitable for use in food packaging. He will also state that we would comply with the regulations mentioned by AHC and RJR Filmco. We also discussed the following:

1. RVCM LEVELS: Resin should start with RVCM levels of 0.5 - 1.0 ppm. The blending process should reduce this level to 15-20 ppb. Processors can then achieve their self-imposed level of 10 ppb on finished sheet and film. The FDA's RVCM regulation is not forthcoming. It seems the FDA's issues with carcinogenic food color additives may effect the draft pending for the PVC regulation. (See attached letter.)

2. VISTA RESIN RECIPES: Peter informs me there are no major problems with our resins for food and drug applications. Use of all additives (with the exception of the Naugard antioxidant) are cleared as follows:

ADDITIVE	CURRENT STATUS
Na tri-polyphosphate	part of basic resin doctrine
Methocel	direct food additive
PVA	prior-sanctioned as indirect food additive
All named initiators	part of basic resin doctrine
alpha-methylstyrene	part of basic resin doctrine
CTA's	part of basic resin doctrine
Ca Stearate	generally recognized as safe (GRAS)
OMS	regulated as indirect food additive
BHT	prior-sanctioned

The amount of each additive used in any reactor should be "only that amount which is necessary to achieve the desired effect." Therefore, Peter made no specific comments on the additive ranges.

3. NAUGARD 492: Antioxidants are not part of the basic resin doctrine. In order to use one it must be -
subject to a specific regulation
or prior-sanctioned for use as a food additive
or GRAS
or "not reasonably expected to become a component of food"

In order to use the Naugard 492 or Isonox 132 in FDA applications, we must demonstrate to K&H zero extraction using methods sensitive to 50 ppb. K&H will provide us with proper protocol. The extractions can be done by the supplier, by Vista, or by an outside independent testing lab, although K&H prefers the first two options for us.

In the absence of extraction testing, such as for Isonox 132, K&H can manually calculate the maximum potential migration (which assumes 100% antioxidant migration from each square inch of PVC packaging).

4. DRUG MASTER FILE: should list the amounts of VCM, water, Ca stearate, and (generically identified) antioxidants used to produce each resin. No other recipe details are necessary. Prior to the FDA's assigning a Master File number, we can inform Klockner and AHC that such a file has been established and they may refer to it when notifying the FDA of their intention to use Vista resin to manufacture their drug packaging. Peter does not anticipate the FDA's having any problem with the use of a Naugard 492 or Isonox 132 because drug consumption is infrequent and periodic compared to food consumption, therefore potential risk is lower. We would also list, generically, BHT and Irganox 245.

5. Phil Carey and I will meet with Peter and Dan Dixler on August 22nd to get a short course in "PVC in FDA Applications" as well as continue to discuss RVCM, Master Files, calculated migrations, and Medical Device liability.

Bruce H. Borsuk

Bruce H. Borsuk
Technical Sales Representative

/jsh

DIST: RDM RES HRF ELK RPC CMS SEM HJH DWH JF HDG [redacted]
EJM RBQ