PVCTECH CORP
ENGINEERED POLYMER FILMS

Dec. 28, 2010

PVC TECH CORP

APET, RPET, GPET & GAG FILMS
AS SUPPLIED BY FENC

FDA CONFORMITY

The following resins noted below used to produce PET (APET, RPET, GPET & GAG) films as supplied by PVC Tech Corp conform to US FDA CFR 21 § 175 & 177 as certified by our manufacturer:

RESIN	US REGULATION
CB-600H, CB-602, CB-213 **Used to produce various grades of APET, RPET, GPET & GAG films**	**FDA CFR 21 § 175 & 177**

The manufacturer's statement along with the FDA approval letters attest that the above resins are in compliance for production of films to be used for food contact applications.

Signed:

Clair Eitel – President

G;/COMPLIANCE /FDA/FET FDA APET.PETG 12.28.10

PVC Tech Corp. • 1931 E. Vista Bella Way, Dominguez Hills, CA 90220-6106 • Ph (310) 608-1115, Fax (310) 898-1080 www.pvctech.com

遠東新世紀股份有限公司 化纖營運總部
Far Eastern New Century Corporation Chemical Fiber Plant
新竹縣新埔鎮文山路亞東段 369 號
369 Ya-Tung Sec. Wen Shan Rd, Hsinpu Sinchu, Taiwan ROC
Tel: 886-3-6209000, Fax: 886-3-6209057

Statement

Guarantee Letter

This letter is guaranteed that all grades of FENC APET 、RPET 、 GPET and GAG sheet are produced from our CB-602, CB600H and CB-213 resins which had already gotten FDA approvals. Besides, all kinds of the additive have SGS reports and FDA statements. We will check the additive regularly to ensure our quality.

We, Far Eastern New Century Corporation, hereby certified that APET 、RPET& PETG sheet produced in Taiwan, is fully in compliance with the following FDA regulations:

The polymeric raw material is produced in accordance with:

- US regulations: As specified in FDA CFR 21 § 175 & 177

Thanks for your choice of our products and we would be glad to answer any of your additional questions.

SSP PET Sheet Plant Manager

Ming-Tung Chang 28/Dec. 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

July 28, 1989

CB-602

Mr. James J.D. Luo
Far Eastern Textile Ltd.
128 Yen Ping South Road
Taipei
TAIWAN

Dear Mr. Luo:

This is in response to your letter of July 7, 1989, requesting an opinion on whether or not your polyethylene terephthalate-isophthalate copolymer (Eastern Pet CB-602) complies with 21 CFR 177.1630(f),(g),(h) and (i).

We have reviewed your request and conclude that your polyethylene terephthalate-isophthalate copolymer meets the end test extractives specifications of subsections (f)(1) and (g)(1) of 21 CFR 177.1630 and, therefore, is acceptable for use under the conditions described in (f)(2) and (g)(2). However, your copolymer does not meet the specifications of (h)(1) and, therefore, cannot be used under conditions of use (h)(2). With respect to condition of use (i)(2), it is not clear whether or not any of your extractions were performed on polyethylene terephthalate-isophthalate spun-bonded nonwoven fabric which is the subject of subsection (i) and is described in subsection c of section 177.1630. Therefore, we cannot comment on the use of your copolymer under the conditions described in 177.1630(i)(2).

If you have any questions, please do not hesitate to contact us.

Sincerely yours,

Edward Machuga

Edward Machuga
Indirect Additives Branch, HFF-335
Division of Food and Color Additives
Center for Food Safety
and Applied Nutrition

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

February 3, 2009

Dr. Chi-yun Ko
Far Eastern Textiles Ltd.
Chemical Fiber Plant
369 Ya Tung Sec
Wen Shang Road
Hsinpu, Hsinchu,
Taiwan, R.O.C.
albertko@fetcfp.com.tw

Dear Dr. Ko:

This is an updated response based on the information that you recently provided on February 1, 2009. In this response you were able to more clearly define the identity of your product and its intended use. This is an update to the response provided for correspondence tracking system (CTS#) 2008-87215.

Specifically, you indicated that in order to produce your product, BT-213, you have to "produce CB-213 (trade name) a PET polymeric resin, first. CB-213 is a kind of modified PET which has 15mol% neopentyl glycol (NPG) and is obtained in two stages: esterification and solid state polymerization." You also noted that "BT-213 is a three-layer structure polymeric sheet, where the middle layer, made from PET, accounts for 88% of the polymeric resin, whereas the upper and lower layers, made from PET with the addition of 15 mol % NPG (CB-213), account for the remaining 12% of the polymeric resin." You use an extruding machine (extruder) to produce the finished product. Finally, you indicated that your company is a professional PET manufacturer and that you would like to use CB-213 and BT-213 together to create a packaging material for use with various food types (i.e. mineral water, soda, juice, alcoholic beverages, cake, bread and fruit) that are permitted for use similar PET polymer resins.

As previously explained, the use **2,2-dimethyl-1,3-propanediol** as a monomer is not listed under 177.1630 and therefore is not permitted for use under §177.1630. However, **2,2-dimethyl-1,3-propanediol** (CAS Reg. No.126-30-7) is regulated in several other parts of 21 C.F.R. (see table below).

Compound	Regulation	Permitted Use
Neopentyl glycol (NPG) also know as 2,2dimethyl-1,3-propane diol (CAS Reg. No.126-30-7)	175.105	Adhesives
	175.260	Partial phosphate acid esters of polyester resins
	175.300*	Resinous and polymeric coatings
	175.320*	Resinous and polymeric coatings for polyolefin films
	177.1390*	Laminate structures for use at temperatures of 250 °F and above
	177.1680	Polyurethane resins
	177.2420	Polyester resins, cross-linked

* Coatings must meet the prescribed conditions as listed in paragraph (a) of the regulation.

The regulations in the table above list where **2,2-dimethyl-1,3-propanediol** is permitted for safe use as a component of polymeric resins (films, articles, or coatings) intended for use in contact with food, when used in accordance with the permitted conditions of use and specifications. These regulations prescribe safe conditions of use for this compound in various food contact materials.

Again as you correctly noted, §175.300 permits for the use of a polymeric resin as a coating* component prepared from terephthalic acid, isophthalic acid, succinic anhydride, ethylene glycol, dimethylene glycol and 2,2-**dimethyl-1,3-propanediol** for use in contact with aqueous foods and alcoholic foods containing not more than 20 percent (by volume) of alcohol under conditions of use D, E, F, and G described in table 2 of § 176.170. It also states that the resin shall contain not more than 30 weight percent of **2,2-dimethyl-1,3-propanediol**. Likewise §175.320 permits for the use of resinous and polymeric coatings* that can be formulated with the optional substance of **2,2-dimethyl-1,3-propanediol.** Under §177.1390, **2,2-dimethyl-1,3-propanediol** is permitted for use as a component of laminate structures for use at temperatures 250 °F and above. In the previous mentioned coating applications, 2,2-dimethyl-1,3-propanediol is used as either a cross-linking agent or polymerization control agent. Therefore, you can use your modified PET product as intended as long as it meets the specifications and limitations as described in the regulations listed above.

Finally, we recognize that opinion letters from the agency can serve as a valuable tool of assurance for consumers and for this reason we are available to assist the manufacturer in producing compliant products by providing interpretations of food additive regulations or policy. However, it is the manufacturer's responsibility to ensure that their products comply with all appropriate regulations whenever the products enter into interstate commerce in the U.S.

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

Vivian Gilliam
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety
And Applied Nutrition

cc: HFA-224 HFS-200 HFS-275 HFS-225 HFS-246
Letter No.2008-87215
R/D::VGilliam:HFS-275:02/03/09

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

May 9, 2006

Ching-Tsu Peng,
Vice Manager,
Far Eastern Textiles Ltd.
Chemical Fiber Plant
369 Ya Tung Sec
Wen Shang Road
Hsinpu, Hsinchu
TAIWAN, R.O.C.

Dear Mr. Peng:

This responds to your recent inquiries requesting FDA to evaluate the compliance of your products, (Trade names: CB-617 and CB-600H), which are formulations of polyethylene phthalate (PET) polymer resins for use in contact with foods containing not more than 50 percent ethanol by volume in compliance with 21 CFR 177.1630.

In our previous responses to you, we provided you with general information about how to make a self-determination of your product's compliance status with the existing regulations for the use of polyethylene phthalate (PET) polymer resins. We pointed out that PET polymer resins as described in 21 CFR 177.1630 may be safely used as, or components of plastics (films, articles, or fabric) intended for use in contact with food, when used in accordance with the specifications listed in the regulation.

Again, we point out that PET polymer resins as described in 21 CFR 177.1630 may be safely used as components of plastics (films, articles, or fabric) intended for use in contact with food, when used in accordance with the specifications listed in the regulation. Specifically, PET polymers regulated for use in contract with food are listed in 21 CFR 177.1630, *Polyethylene phthalate polymers*. Paragraphs (a), (b), and (c) provide for the identity of the polyethylene phthalate polymers that may be used in contact with food. Paragraph (d) provides for the quantity of any optional substances and paragraph (e) provides for substances employed in the production of polyethylene phthalate plastics, and paragraphs (f) through (j) provide specifications and conditions of safe use for these polymers. Of these paragraphs, only the polymeric formulations of PET listed in paragraphs (g), (i), and (j) are suitable for use with alcoholic beverages (see each paragraph for details).

In the table below we have summarized the unique characteristics of your products along with the applicable regulatory compliance:

Product/ Characteristics	**CB-617*** Dated: Apr. 24, 2006	**CB-600H*** Dated: Apr. 24, 2006	**Regulatory Status**
Intended Use	Water bottles; Soft-drink and non-alcoholic beverage PET bottles	Large size water bottles; Soft-drink and non- alcoholic beverage PET bottles	
Monomers	TPA, IPA, EG	TPA, EG	177.1630(e)(4)(i)
Catalyst	Antimony Trioxide (Sb_2O_3)	Antimony Trioxide (Sb_2O_3)	177.1630 (e)(3)
Stabilizer	Phosphoric acid (H_3PO_4)	Phosphoric acid (H_3PO_4)	177.1630 (e)(3)

TPA= Terephthalic acid
IPA= Isophthalic acid
EG= Ethylene glycol
* For use in contact with food containing not more that 50 percent ethyl alcohol.

In a detailed review of 21 CFR 177.1630, paragraph (a) permits the use polyethylene phthalate films consisting of a base sheet of ethylene terephthalate-isophthalate copolymers to which has been added optional substances, either as constituents of the base sheet or as constituents of coating applied to the base sheet. Paragraph **(e)(4)(i)** describes a base sheet of ethylene terephthalate-isophthalate copolymers as being prepared by the condensation of terephthalic acid and isophthalic acid with ethylene glycol. Thus, if your product formulations meet the requirements for preparing the base sheet described above, then it is acceptable, provided it meets the appropriate end test extractives limitation as described below

As for the use optional substances, paragraph **(e)(3)** permits the use of substances regulated in parts 174,175, 176, 177, 178, and 179.45 as components of resinous or polymeric food-contact surfaces, provided that it meets the provisions of such regulation. Paragraph (d) states that the quantity of any optional substance employed in the production of polyethylene phthalate plastics does not exceed the amount reasonable required to accomplish the intended physical or technical effect or any limitations further provided.

In addition, the specifications described in paragraph (g)(1) of 177.1630 require that the food contact surface, when exposed to 50 percent ethyl alcohol at 120°F for 24 hours, yields chloroform-soluble extractives not to exceed 0.5 mg/in^2 of food contact surface exposed to the solvent. In your test reports from SGS, you have provided analytical results using the appropriate extractive testing conditions. Since the results indicate that the chloroform-soluble extractives do not exceed the specification for extractives of 0.5 mg/in^2, it is clear that these batches of PET

formulations meet the requirements of 177.1630 for the use in contact with foods containing not more than 50 percent ethanol by volume.

Finally, it is to be understood that provided that your PET polymer products, as described in your letters, as being produced by the condensation of terephthalic acid and/or isophthalic acid with ethylene glycol, using the catalysts, and stabilizers listed in the table above, comply with the specifications listed in 21 CFR 177.1630, no additional pre-market review is needed.

Sincerely,

Vivian Gilliam

Vivian Gilliam
Division of Food Contact Notifications, HFS-275
Office of Food Additive Safety
Center for Food Safety And Applied Nutrition