

April 12, 2000

Mr. Paul Guttman  
U.S. Silica Company  
c/o Mr. De Lyle W. Bloomquist  
General Chemical  
90 East Halsey Road  
Parsippany, NJ 07054

148100 MAY -1 1999

RE: FAP 5B4450 and FAP 5B4451

Dear Mr. Guttman:

This is in response to your April 23, 1999, letter commenting on the potential environmental impact of FDA's approval of the two Food Additive Petitions (FAPs) cited above, Docket numbers 95F-0130 and 95F-0129. These petitions, submitted by Shell Chemicals Company, requested FDA approval of naphthalate-containing polyesters.

As you know, the Food and Drug Administration Modernization Act of 1997 established a premarket notification process as the primary method for authorizing a new use of a food additive that is a food contact substance. In a letter dated October 26, 1999, the Agency told petitioners who had pending food additive petitions involving the use of a food contact substance, that the petition might be eligible for premarket notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act. The sponsors were told that they could consider withdrawing the petition and resubmitting it as a notification. Subsequently, Shell Chemicals Company submitted notifications for the uses requested in FAPs 5B4450 and 5B4451, and these notifications became effective on March 23, 2000. See the agency's internet site at <http://www.cfsan.fda.gov> under FCN numbers 000008 and 000009.

We considered in depth your comments as part of our environmental review and are now providing, for your information, our response to those comments.

1. In your letter you said that Shell had underestimated the potential market for articles made with the subject copolymers, providing various reasons for this underestimation. You further said that introducing the subject copolymers as food-packaging materials could adversely affect the current recycling of various materials from municipal solid waste and the landfill capacity of this country. We note that your letter was based on the December 20, 1994, environmental assessment (EA) submitted for FAP 5B4450 and the December 28, 1994, EA submitted for FAP 5B4451 and not on the updated

95F-0129

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EAs that Shell later provided to the agency and which the agency placed at the Docket as soon as possible. The updated EAs for FAP 5B4450 are dated November 4, 1998, May 10, 1999, and August 4, 1999, and the updated EA for FAP 5B4451 is dated August 26, 1999. These EAs contain information about substantially larger market volumes, revised landfill volume estimates based on the larger market volumes, and additional studies related to recycling articles made with the subject copolymers in the current recycling stream. We have reviewed this additional information and believe that the most recently updated EAs adequately address the concerns you expressed on underestimating the market and adverse effects on recycling and landfills.

2. You questioned Shell's assertion that the relatively high cost of PEN would limit the extent to which this polymer will penetrate the market. You cited a publication that predicts that PEN prices will drop from their current level of \$4.00 per pound to about \$2.00 or \$2.50 per pound once the polymer is in use. Although the cost of PEN may drop to \$2.00 per pound, this cost is still much greater than the costs of other resins. For example, a recent publication shows the current price of polyethylene terephthalate to be about \$0.55 per pound<sup>1</sup> and shows the current price of polypropylene to be about \$0.25 per pound.<sup>2</sup> Thus, we believe that Shell's statement that cost will limit the extent to which PEN will penetrate the market is reasonable.
3. You questioned the potential for environmental impacts as a result of replacing refillable/ reusable glass beer containers with plastic bottles. Since Shell's EAs did not discuss this potential impact, we addressed this issue in our supplement to the EAs for the subject actions, a copy of which is enclosed. Based on our analyses, we believe that introduction of new containers made with the subject copolymers will result in no more than a very limited replacement of refillable beer bottles and, therefore, will not have significant environmental effects.

In summary, we have evaluated the environmental information submitted by Shell and others and have found that allowing these notifications to become effective will not have a significant effect on the human environment. The documents the agency prepared as part of its environmental review for these notifications, the Findings of No Significant Impact (FONSI) and the Supplement for the EAs, are enclosed. The EAs submitted by Shell Chemicals Company are displayed at the Dockets Management Branch, (HFA-305), Food

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<sup>1</sup> *Modern Plastics*, January 1999, page 58.

<sup>2</sup> *Modern Plastics*, January 1999, page 50.

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, under Docket Number 95F-0130 (for FAP 5B4450) and Docket Number 95F-0129 (for FAP 5B4451).

Thank you for conveying your concerns to us. We hope that the updated EAs and the enclosed documents will enable you to understand the basis for our findings on these actions.

Sincerely,

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval  
Center for Food Safety  
and Applied Nutrition

3 Enclosures:

FONSI for FCN No. 000008

FONSI for FCN No. 000009

Supplement to the EAs

cc:

– HFA-305 Docket No. 95-130  
Docket No. 95<sup>F</sup>-129

HFS-200 Rulis

HFS-205 Macon

HFS-225 (2) FCN 0000008 and FAP 5B4450

(2) FCN 0000009 and FAP 5B4451

HFS-245 Diachenko

HFS-246 RF/Cox/Hoffmann/FCN 0000008/FCN 0000009

Init: HFS-246:BLHoffmann:3/16/00

HFS-200:AMRulis:4/04/00

HFS-246:EACox:eac:2/1/00 p:\eis\eac\8-ssa-4.wpd

Revised:EACox:sgm:02/28/00

FT:HFS-246:EACox:sgm:04/05/00 p:\0pa\dpmu\eis\letters\8-ssa-4.wpd