

April 12, 2000

Mr. Luke B. Schmidt
National Association for PET Container Resources
2105 Water Ridge Parkway, Suite 570
Charlotte, North Carolina 28217

1482 '00 MAY -1

RE: FAP 5B4450 and FAP 5B4451

Dear Mr. Schmidt:

This is in response to your October 30, 1998, letter commenting on the potential environmental impact of FDA's approval of the two food additive petitions 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 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 food additive petitions 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.

In your letter you provided a review of research that you believe demonstrates that naphthalate-containing bottles can be compatible in the post-consumer polyethylene terephthalate (PET) recycling stream. Based on our review of the environmental record for these actions, we have found that the research you refer to does include studies showing that the presence of naphthalate copolymers below specific levels in the PET recycling stream will have no effect on the end uses of recycled PET that were tested. This finding, along with consideration of other information and data in the environmental record, led us to conclude that there is no potential for significant environmental effects to result from allowing these notifications to become effective. The documents the agency prepared as part of its environmental review for these notifications, the

95F-0129

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Findings of No Significant Impact (FONSIs) and the supplement to the environmental assessments (EAs), are enclosed. The EAs submitted by Shell Chemicals Company are displayed at the Dockets Management Branch, (HFA-305), Food 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 views to us.

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. 95-0130
Docket No. 95^F-0129

HFS-200 Rulis

HFS-205 Macon

HFS-225

HFS-245 Diachenko

HFS-246 RF/Cox/Hoffmann

FCN 000008 (formerly FAP 5B4450)

FCN 000009 (formerly FAP 5B4451)

HFS-246:EACox:eac:2/1/00 p:\eis\ead\8-ncr-lt.wpd

Revised:EACox:sgm:02/28/00

Init: HFS-246:BLHoffmann:03/16/00

HFF-200:AMRulis:04/04/00

FT:EACox:sgm:04/12/00 p:\opa\dpmu\eis\letters\8-ncr-lt.wpd