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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 01N-0234; Comments of the American Plastics Council in Response to FDA's Advance Notice of Proposed Rulemaking on Whether the Agency Should Permit the Transfer of the Rights to Manufacture and Market a Food-Contact Substance that Is the Subject of an Effective Food-Contact Notification

These comments are respectfully submitted on behalf of the American Plastics Council (APC)¹ in response to the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking (ANPR), published on May 21, 2002, in the Federal Register (67 *Fed. Reg.* 35764). In the ANPR, FDA requests input on whether the Agency should establish a procedure by which holders of the rights to manufacture and market a food-contact substance that is the subject of an effective food-contact notification (FCN) would be able to transfer those rights by sale, licensing, or otherwise.

Background

This ANPR addresses an issue that was raised in comments submitted by APC in response to FDA's proposed regulations (65 *Fed. Reg.* 43269, July 13, 2000) implementing the food-contact substance notification procedure established by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Specifically, APC proposed that FDA should allow the transfer of the rights acquired by the holder of an effective FCN.

APC's Comments

APC applauds FDA's successful implementation of the FCN process. Since FDA began implementing the process in late 1999, many substances have become available for food contact

¹ The APC is a major trade association for the U.S. Plastics Industry. It is comprised of 24 of the leading monomer and resin manufacturers, plus one affiliated trade association representing the vinyl industry. APC's membership represents more than 80 percent of the U.S. monomer and polymer production and distribution capacity.

applications in substantially less time than was required for the Agency to act on food additive petitions under the old procedure. APC fully supports this valuable procedure and looks forward to working with FDA as the process continues to evolve.

APC member companies have now had 2 years of experience with the FCN process since comments were filed to the proposed rule implementing the FCN system in 2000. The system has demonstrated the rapid clearance of food-contact substances through the FCN mechanism. This favorable experience now brings into question the need for and potential value of a right to transfer the clearance. Under the current process the filer of a FCN can simply give a copy of their FCN to a transferee/licensee and allow them to file it on their own behalf. Clearance through the FCN process should be fairly automatic since it involves the same food contact material, end uses and conditions, and should result in an effective FCN in 120 days. Furthermore, most information in a FCN is publicly available through the Freedom of Information Act (FOIA). Therefore, any company who wishes to file a “follow-on” FCN can obtain most of the information they need through FOIA.

If FDA decides to make FCNs transferable/licensable, APC recommends that the procedure be kept very simple. The limited benefits of this option do not warrant a complex process; nor is complexity required to protect the public health. It should be sufficient for the company that submitted the initial FCN to simply notify FDA that the rights have been transferred/licensed, identify the transferee/licensee, and confirm that a complete copy of the FCN has been provided to the transferee/licensee. The terms of the effective FCN will continue to govern the production and use of the food-contact substance for protection of the public. The transferee/licensee would be responsible for compliance with any limitations or specifications of the FCN.

APC does request that FDA clarify their policy for the disposition of FCNs when the owner of a FCN transfers control of a manufacturing process to another company through merger, acquisition or other mechanisms. In the preamble to its final rule for the FCN system published on May 21, 2002 (*67 Fed. Reg.* 35724, 35726), FDA stated that it will update the web site listing to reflect the change of name and/or ownership, but the acquiring company will also need documentation to demonstrate that they are authorized to produce and sell product under the pre-existing FCN. Therefore, we respectfully request that FDA reconsider its decision not to issue a revised final letter acknowledging the effective FCN with the acquiring company's name.

Conclusion

Positive experience with the FCN process and the fact that any company can bring about an effective FCN in 120 days leads APC to conclude that there is no significant benefit to be gained by implementing a procedure to transfer or license the rights to a FCN. If FDA nevertheless decides to create such a procedure, it should involve only a simple notification to the Agency that the transfer/license has occurred. Because the licensee would be obligated to conform to the conditions and limitation of the original FCN, this would have no negative impact on public health, and would not impose any additional monitoring or other obligations on FDA.

APC appreciates the opportunity to comment on this ANPR, and would be happy to discuss these comments or answer any further questions FDA may have.

Respectfully submitted,

AMERICAN PLASTICS COUNCIL

By: 

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