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Ralph A. Simmons
(202) 434-4120
simmons@khlaw.com

Hand Delivery

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 Society of the Plastics Industry's Food, Drug, and Cosmetic Packaging Materials Committee 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 Society of the Plastics Industry's (SPI) Food, Drug, and Cosmetic Packaging Materials Committee¹ in response to the Food and Drug Administration's (FDA) Advance Notice of Proposed Rulemaking (ANPR) (Docket No. 01N-0234), 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.

¹ Founded in 1937, The Society of the Plastics Industry, Inc. is the trade association representing the fourth-largest manufacturing industry in the United States. SPI's 1,500 members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers. The U.S. plastics industry employs 1.5 million workers and provides \$330 billion in annual shipments. The Food, Drug, and Cosmetic Packaging Materials Committee is composed of SPI members with particular interest and expertise in packaging for food and other FDA-related products. The Committee has a long history of working cooperatively with FDA on regulatory issues relating to packaging.

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Background

This ANPR addresses an issue that was raised in one set of comments submitted 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, the commenter proposed that FDA should allow the transfer of the rights acquired by the holder of an effective FCN.

SPI's Comments

Since FDA began implementing the FCN system in late 1999, over 170 FCNs have become effective in substantially less time than was required for the Agency to act on food additive petitions under the old procedure. SPI congratulates FDA on the success of the FCN process to date; we hope that this valuable procedure will continue to evolve and become even more efficient.

In our view, the relatively rapid clearance of food-contact substances through the FCN mechanism significantly reduces the potential value of a right to transfer the clearance. The transfer option was the subject of passing consideration during the discussions between FDA and Keller and Heckman LLP (representing SPI) in developing the FCN legislation, but it was decided that there was no need for a provision of this type because of the expedited schedule for FDA review of FCNs. Furthermore, once an FCN becomes effective, most of the content of the notification is available to other companies under the Freedom of Information Act (FOIA), except for trade secrets or other confidential business information (predominantly the details of the manufacturing process). Therefore, other companies can file their own FCNs based on the data of the first filer, and have an effective "me too" FCN in relatively short order. For these reasons, SPI does not believe there is a strong demand for an FCN transfer procedure.

In the event that FDA decides to make FCNs transferable, SPI 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, identify the transferee, and confirm that a complete copy of the FCN has been provided to the transferee. The terms of the effective FCN will continue to govern the production and use of the food-contact substance, and ensure protection of the public.

While SPI does not find a compelling need for a procedure to allow transfers of FCNs among separate entities, it would be helpful for FDA to confirm in writing the process for amending the identity of the manufacturer/supplier with respect to an effective FCN in the case of a change in corporate name or corporate ownership or control. In our experience, this type of amendment is accomplished easily by submission to FDA of written documentation of the

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change in name or ownership/control. In accordance with our experience, the preamble to the final rule implementing the FCN program (67 *Fed. Reg.* 35724, May 21, 2002) describes one experience with the sale of the manufacturing unit of a notified food-contact substance from one company to another. In that instance, the original manufacturer verified the sale and FDA changed the name of the manufacturer in the listing for the FCN on the Agency's internet site. FDA also stated in the preamble to the final rule on FCNs that confirmation of this procedure was being provided in the document now entitled "Preparation of Food Contact Notifications: Administrative." We have not been able to locate any discussion of this subject in the administrative guidance document, however. SPI believes that it would be helpful for FDA to confirm this simple procedure in the guidance for notifiers. It also would be helpful for industry if FDA would issue amended FCN effectiveness letters with the new name of the manufacturer/supplier. SPI recognizes that FDA is not obligated to issue effectiveness letters at all, and correction of the website inventory certainly is helpful. Industry wants to make FDA aware, however, that the effectiveness letters are a very important tool for assuring customers of FDA compliance. The letters are particularly significant since the FCN system is new and not yet widely understood, especially outside the United States.

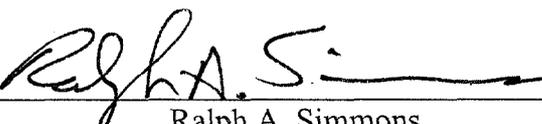
Conclusion

The facts that any company can bring about an effective FCN in 120 days and that much of the data underlying an effective FCN can be obtained by other companies through an FOIA request lead SPI to conclude that there is no significant benefit to be gained by adding a procedure to transfer the rights acquired by an FCN. If FDA nevertheless decides to create such a procedure, it should involve only a simple notification to the Agency that the transfer has occurred. SPI also requests FDA to provide guidance on the procedure to amend the name of the manufacturer/supplier in the event of a corporate name change or change in ownership or control.

SPI appreciates the opportunity to comment in response to this ANPR.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

By: 
Ralph A. Simmons