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January 10, 2000

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

Re: Draft Guidance for Industry on Food-Contact Substance Notification  
System: Docket Nos. 99D-4575 and 99D-4576

Dear Ladies and Gentlemen:

The American Plastics Council (APC) is a major trade association for the U.S. Plastics Industry. APC is comprised of 26 of the leading plastics manufacturers in the United States, with many members having a strong global market presence. APC's membership represents 80% of the U.S. resin production capacity. APC submits these comments in response to the notice published in the Federal Register on November 12, 1999 (62 Fed. Reg. 61648) announcing the availability of two draft guidance documents for industry regarding the preparation of premarket notifications (PMN's) for food-contact substances (FCS's), "Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations" and "Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations." The Notice requested written comments on the collection of information be filed by January 11, 2000, and comments on the guidance documents be filed by February 14, 2000. These comments respond to both requests.

99D-4575  
99D-4576

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With respect to the collection of information, FDA requested comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated techniques, when appropriate, and other forms of information technology.

As an initial matter, we note that both of the draft Recommendations documents anticipate the promulgation of regulations and an Administrative Recommendations guidance. APC looks forward to the opportunity to review and provide comments on these documents when they become available.

We strongly support the premarket notification system as an efficient means for FDA to carry out its function of assuring the safety of materials used in contact with food. The PMN process represents a progressive approach for FDA in fulfilling its mandate of assuring public safety, and we look forward to working with the Agency in its continuing effort toward that goal.

Regarding ways to enhance the quality, utility, and clarity of the information, APC makes the following comments. We suggest that Section IV.4.C.1.b of the Toxicology Recommendations be separated into two subparagraphs. The second sentence of the current subparagraph b does

not directly follow from the first, and in fact provides a requirement for a different class of substance. The first sentence applies to a substance of unknown carcinogenicity, while the second sentence applies to "a carcinogenic constituent of a food contact substance." For clarity, we suggest separating these two independent categories into two subparagraphs by making the second sentence of current subparagraph b into a new subparagraph c.

We would also like to offer several comments on the proposed FCN form, FDA Form 3480, as attached to the Toxicology Recommendations document. The form is also available in PDF format on FDA's web site. For the form to provide full utility to the industry, however, it must be possible to enter and edit information directly on the form. As most companies are now using computers for their word-processing, unless the form is available in a word-processing-compatible format, it could actually take more time to use the form than not. Making the form available in a format compatible with widely-used word processing applications, such as Word or WordPerfect, would greatly increase the utility of the form. Further, the form should be pilot tested to ensure its compatibility throughout the industry.

Regarding the utility of the form, APC understands and agrees with the desirability of presenting the information necessary for a PMN in a uniform manner. This will undoubtedly assist the Agency in processing the information under its relatively tight time limit. It is not clear, however, that Form 3480 will assist in that process. The form contains several places where the necessary information could only be included on a continuation sheet or attachment, for example: Part II, Section A.2.b (manufacturing process); Part II, Section D.1.c (results of migration testing); Part II, Section D.2 (EDI); Part III, Section B.1 (adverse toxicity effects); and

Part III, Section B.2 (ADI). This causes the form to be a many-segmented document, forcing the reader to jump around within the document. A document is most useful when it presents all necessary information clearly and succinctly, without causing the reader to jump back and forth between attachments and continuations. With this form, however, much of the necessary information will be contained on the attachments and continuation sheets, so the required information will be located in several places for each category.

The idea of the standardized format embodied by the form, however, is laudable. Rather than providing an extensive form, if the Agency instead called for a summary form, with all supporting information attached to the form in a specified format, that could provide greater utility to both industry and the Agency. For example, if the different headings on the form were used as section headings for the PMN format, that would more simply serve the Agency's interest in uniformity among submissions. All PMN's would contain the same category of information in the same place within the submission, as dictated by the format, and each category would not be broken up by starting on the form and then continuing on the attachment, as the form currently contemplates. Industry would also be served in that it would have a predictable format to follow, yet it could utilize its currently existing resources to produce the PMN within that format.

As an additional point, we recommend that a reference to FDA's regulation defining trade secrets and commercial or financial information that is privileged or confidential, 21 C.F.R. § 20.61, be included on the front of FDA Form 3480 in the "Confidentiality of Information" section. This

will help clarify to industry respondents what information is appropriately considered confidential, and what standards will be applied to claims of confidentiality.

Regarding ways to minimize the burden on respondents, we have the following comments. For the Chemistry Recommendations, we express our support of the Agency's inclusion of 100% migration calculations and migration modeling as providing an acceptable basis upon which to base exposure estimates. These means can be much more efficient than conducting the actual migration studies, both in the development and the analysis of the data, saving the valuable resources of both industry and the Agency. Using this information has been the common practice, and APC supports FDA in its acceptance of more efficient means for providing the Agency with the data necessary to evaluate the safety of food ingredients.

Regarding the Toxicology Recommendations, we express our support for the idea in Section IV.4.C.1 of a category of substances for which, based on exposure, no toxicity studies are required. Not only will this enable the PMN system to effectively replace the current burdensome Threshold of Regulation process (21 C.F.R. § 170.39), but it will also make all PMN submissions more efficient, as FDA will not expend time or resources investigating components of no safety concern. We note that this is the same policy and exposure level underlying FDA's Threshold of Regulation policy. In this regard, we suggest the exposure limit for this category be amended to reflect the exposure levels established in the recently published article by M.A. Cheeseman, et al, "A Tiered Approach to Threshold of Regulation," *37 Food and Chem. Tox.* 4:387-412 (1999). This would provide for the most efficient use of resources as the substances posing only insignificant risks would have very little or no data required, and FDA

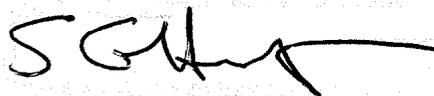
would be able to focus on the data submitted for those materials with a more significant exposure level.

FDA Form 3480 indicates that an environmental assessment (EA) or claim of categorical exclusion from the requirement of filing an EA pursuant to 21 C.F.R. § 25.32 will be required for PMN's. While we anticipate that the proposed rule and Administrative Recommendations documents will provide further clarification on this point, APC wants to express its support for the Agency's efforts to refine the EA requirements and exclusions. We note that FDA has indicated that it plans to issue guidance on the preparation of a claim for categorical exclusion from the requirements of an EA. 64 Fed. Reg. 61881, 61889 (November 15, 1999). We strongly support this effort, and express our willingness to work with the Agency throughout its development of this guidance.

Also, providing for the submission of the information necessary for a PMN in an entirely electronic submission would reduce the burden on both industry and the Agency. APC supports those efforts the Agency may make in this direction.

We look forward to working with the Agency in its efforts to implement the PMN process. In particular, we would be interested in working with the Agency to pilot test the PMN form and eventually a fully electronic version of the PMN submission.

Sincerely



Steven G. Hentges