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President

September 25, 2000

Hand Delivered

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

1249 .00 SEP 25 P2:19

**RE: Proposed Rule, Food Additives: Food Contact Notification System
[Docket No. 99N-5556]**

As President of the Foodservice & Packaging Institute, Inc. (FPI), I am respectfully submitting the comments of our members on the above-referenced Proposed Rule that was published in the *Federal Register* on July 13, 2000 (65 *Fed. Reg.* 43269).

FPI supports and endorses the four issues identified in the comments of the Society of the Plastics Industry on the Proposed Rule. However, our members have raised several specific issues.

Of particular concern to FPI is the SPI's call for clarification of the Proposed and/or Administrative Guidance document as it relates to the beginning of the 120-day review period.

Section 409(h) of the Federal Food, Drug and Cosmetic Act states that "notification submitted under paragraph (1) shall become effective 120 days after the date of the receipt by (FDA)," unless the Agency objects within that time period. The language in Section 170.104(b) of the Proposed Rule, however, is in conflict with the statute since the Proposed Rule states that "in order for the 120-day review period to begin, FDA must accept that notification."

It is our understanding that the agency intends to follow the starting point for the Food Contact Notification review period as defined in the language of the law passed by Congress. The language of the Proposed Rule should be changed accordingly.

99N-5556



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Another issue our FPI members feel is important is that of referencing the FDA notification review process by its historical designation, i.e. the FDA *Food Contact Notification* (FCN) process.

As you know, the U.S. Environmental Protection Agency (EPA) uses the designation "Pre-Market Notification" (PMN) to describe its pre-manufacture notice process under the Toxic Substances Control Act. It may be a small point, but we would encourage FDA to continue to emphasize its oversight and authority over food-related regulatory issues by continuing to use its historical Food Contact Notification designation for the new approval process rather than switch to using EPA's PMN term.

Thank you for allowing us the opportunity to comment on FDA's Proposed Rule and Administrative Guidance. Should you have any questions about these comments, please do not hesitate to contact me.

Respectfully,



John R. Burke
President