

## FDA's Food Contact Notification Program

The Food and Drug Administration's (FDA) proposed FY 2009 budget allocates \$2.4 billion, a 5.7% increase over the FY 2008 budget appropriations for the agency. The new budget proposes \$182 million in funding for FDA's Center for Food Safety and Applied Nutrition (CFSAN), an increase of \$10 million from FY 2008 funding levels. The FDA's budget document provides that, if this level of funding is passed by Congress, the Foods Center will have sufficient resources to continue operation of the Food Contact Notification (FCN) program in FY 2009. Indeed, as stated in that budget proposal: "Our current estimates assume continued funding of the FCN program in FY 2008 and FY 2009." This is a significant victory in light of the fact that the FCN program had previously been slated to be eliminated in the FY 2007 and FY 2008 budgets.

### What is FCN, and why is it a Model Program?

The FCN Program is an excellent example of good government; it was developed cooperatively by FDA, Congress and industry. It allows efficient introduction of new packaging materials into the market, while fully protecting public health. FCNs also are used to provide safety assurances to customers for the use of products in other areas, such as products used in toys, consumer products, medical devices, and drug packaging. The FCN program involves a complete and thorough safety evaluation that is as rigorous as the food additive petition process. The Program also allows U.S. manufacturers to develop new products that better protect food and improve its shelf life. The ability to bring new materials to market in a faster time frame results in a stronger economy and job creation.

### Why Congress Should Continue Funding

Consumers benefit from food packaging innovations. New food-contact materials have enhanced the safety and security of the U.S. food supply while increasing the availability of environmentally friendly products. The FCN program provides an enormous benefit to manufacturers seeking clearances for new food-contact materials to be introduced in the U.S. marketplace. FCNs become effective within 120 days of filing, unless FDA considers the submission incomplete or objects to the notification. Furthermore, the FCN program provides a rigorous and cost-effect pathway to market for new food-contact substances and new uses of food-contact substances, compared to the food additive petition process, which can take up to five years without providing any additional protection to consumers. Prior to commencement of the FCN program in FY 2000, FDA took between two and five years to finalize the rulemaking needed to complete the petition process. If the industry were forced to rely solely on petitions, the delay would severely impact the innovation of new and safer food packaging materials. In addition, manufacturers and suppliers would lose the proprietary advantage of the FCN program because petitions result in regulations that may be relied on by any company. In short, the loss of this program would impede new job creation and stifle America's ability to innovate and compete in the global marketplace.

### Additional Background

In the 1950's, the Society of the Plastics Industry, Inc. (SPI), represented by the law firm of Keller & Heckman (K&H), lobbied Congress to not regulate "indirect additives," now more properly referred to as food-contact substances, under the same procedures being legislated to govern direct food additives, such as new sweeteners. Instead, SPI advocated the enactment of a more streamlined notification system and advanced a bill, H. R. 8112, for this purpose. Unfortunately, at the time all of the focus was on chemicals added to foods and the bill did not pass. To clear a food-contact substance from 1958 - 2000, it was necessary to file a Food Additive Petition and wait for a full rulemaking action by the Agency. Even though the law ordered FDA to act on such petitions within 180 days with a possible extension of another 180 days, it took as much as five years to act on some petitions and almost none were handled in less than two years.

For 40 years there was widespread dissatisfaction with all elements of FDA's handling of food additive petitions. In 1996 the time was right for change and innovation. SPI and K&H introduced remedial legislation, and the resulting bill became part of the Food and Drug Administration Modernization Act of 1997. It included the notification concept for food-contact substances along with a provision stating that the Notification Program would only operate in fiscal years where at least \$6M is appropriated for the program and that the budget for the Center for Food Safety and Applied Nutrition, equals or exceeds the amount appropriated in 1997, excluding new programs. It was not until FY 2000 when FDA commenced the notification program due to a special appropriation for this purpose.

#### Action Needed

Members of the Food Packaging Industry Coalition are working to continue the necessary funding to continue FDA's Food Contact Notification program in 2009 and beyond. During the upcoming congressional budget appropriations process, this Coalition of allied associations, Fortune 500 corporations and small businesses will ask their representatives in Congress to support the FDA's proposed FY 2009 budget of \$182 million for CFSAN that includes the needed funding for the FCN Program.