

INTERNATIONAL  
**Food  
Additives  
Council**

SUITE 500-G • PEACHTREE-DUNWOODY ROAD • ATLANTA, GEORGIA 30342  
(404) 252-3663 • FAX (404) 252-0774 • E-mail: ifac@asmby.com

11:57 AM '00 AUG 22 10:11

August 15, 2000

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

Re: Docket No. (98N-0359)

The International Food Additives Council (IFAC) is the trade association representing the interests of manufacturers of high purity substances that are used as direct food additives. We routinely participate in a large number of food regulatory activities in the United States. Our members serve on the Committee on Food Chemicals Codex, we have participated in the CFSAN Advisory Committee and comment and provide information we believe useful on CFSAN's regulatory programs.

IFAC has viewed with interest the above-identified docket and submits the following comments, which largely support the agency's program priorities for the fiscal year 2001.

1. In its July 18, 2000 Program Priorities Progress Report, CFSAN stated its intention to apply new resources made available in the FY2000 Congressional appropriations, to make enhancements in the review program for direct food and color additives. This would include greater use of pre and post-filing conferences with petitioners. IFAC strongly endorses CFSAN's proposal and advocates a requisite number of pre and post-filing conferences on food additive petitions so that such may be completed in a timely and scientifically sound manner.
2. IFAC opposes the proposal to move from the "A" to "B" priority list (a) development of a final GRAS notification rule and (b) development of guidance for pre-filing interactions with the agency, for new direct additives. Prompt finalization of the GRAS notification rule is necessary to clarify the process and resolve pending issues of interpretation that might exist. IFAC reiterates its strong feelings that pre-filing guidance can and will significantly reduce administrative burdens on petitions, may well eliminate unnecessary testing and would promote the best uses of FDA's limited resources.

98N-0359

C43

August 15, 2000  
Page 2

3. IFAC supports the proposal to give "A" priority to regulation of food biotechnology, including development of labeling guidance and a rule requiring premarket notification. IFAC is particularly interested in participating in the rulemaking process that involves food additives, which have utilized as starting materials substances encompassing this new biotechnology. The unique promise of food biotechnology can only be realized, and unfounded opposition overcome, through a strong, transparent and science-based FDA regulatory process. A number of IFAC scientists have experience in biotechnology and are available to participate in this important regulatory development. IFAC urges the agency to utilize the best available scientific expertise from academia, industry and other knowledgeable sources, which may be called upon to serve as this new technology is developed.
4. IFAC supports the proposal to retain pre-market review of food ingredients as one of CFSAN's priority program areas. FDA has made significant progress during the last few years in improving the food additive review process. However, much remains to be done to achieve an efficient, predictable, timely and science-based process, a goal which we have all desired to ascertain.

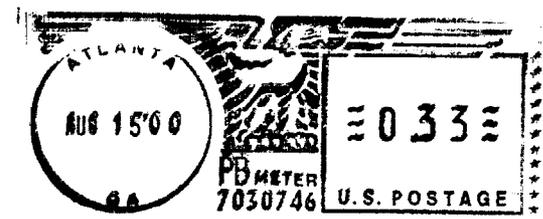
IFAC appreciate this opportunity to comment on CFSAN's Program Priorities for 2001.

Sincerely,



Andrew G. Ebert, Ph.D.  
President

AGE/jcr



Dockets Management Branch  
(HFA-305)  
FDA  
5630 Fishers Lane - Room 1061  
Rockville, MD 20852

INTERNATIONAL  
**Food  
Additives  
Council**

5775 PEACHTREE LN SW OAKLEY RD SUITE 500 D ATLANTA GEORGIA 30348  
20857-0001