

July 19, 2000

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

Re: Docket No. 00N-1262; Improving Premarket Review and Approval of Food and Color Additives in the Center for Food Safety and Applied Nutrition; Request for Comments; 65 Federal Register 26215 (May 5, 2000)

The undersigned food industry trade associations are pleased to have this opportunity to respond to the Food and Drug Administration's (FDA) request for comments on ways to improve the process for premarket review and approval of food and color additive petitions.¹ Descriptions of our trade associations are attached to these comments as Appendix A.

For far too many years, the petition review process has suffered from inattention, getting neither the resources nor consistent management that it needs. This has resulted, as FDA well knows, in a situation in which petition review proceeds on an uncertain pace with no firm time deadlines. The lengthy review process and the uncertain time frames for completion of the review are disincentives for research and development in new food ingredients, including those that would permit food to be more nutritious (foods lower in fat or higher in fiber, for example), more varied, or safer (foods less susceptible to microbial contamination, for example). Ongoing efforts to improve the review process must, therefore, seek to preserve the assurance of safety that FDA review provides while creating a more timely and predictable review process that will help to attract resources to food additive research and development. We believe that those dual objectives are entirely compatible.

We commend FDA for its recent efforts to improve the additive petition review process and for seeking public input on strategies to achieve additional improvements. FDA has made

¹ Although the food additive and color additive review processes differ in many respects, these comments refer to both processes in the singular. Statements regarding the "review process" therefore refer to both the food additive and color additive review processes, unless otherwise indicated.

concerted efforts in the last few years to improve communication through a variety of means, including its website and stakeholder meetings. These efforts are appreciated and will help, in the long run, to resolve problems like those with the additive review process. We encourage FDA to maintain and expand upon these efforts.

In spite of recent improvements, the food and color additive review process remains a persistent source of frustration for the food industry. Despite the agency's efforts to improve the review process, additive petition review continues to be plagued by many of the same problems of years past. Growing demands on FDA's resources from a host of issues including biotechnology, international harmonization, dietary supplements, and food safety, as well as an increasing volume of food and color additive petitions may cause the existing problem to worsen. Given this situation, we believe that improving the additive review process may require more fundamental changes than those apparently being contemplated by FDA.

These comments begin with a discussion of statutory changes we believe that FDA should consider to improve the additive review process, followed by responses to the specific questions raised by FDA.

1. FDA should consider proposing more fundamental improvements in the food and color additive review process, including statutory changes and budget increases.

FDA has significant statutory duties regarding the review and approval of new additives. With regard to food additives, the Federal Food, Drug, and Cosmetic Act (the act) requires that FDA complete its evaluation of each food additive petition within 180 days after the date of filing of the petition. 21 U.S.C. § 348(c)(2). The Food and Drug Administration Modernization Act of 1997 amended the act to make clear that the statutory deadline for petition review should be taken seriously. *See, e.g.*, 21 U.S.C. § 393(b)(1), (f)(2)(E), (F) and § 397(b)(2).

We recognize that the 180 day statutory period for the review of a petition is unreasonably short for complex petitions that seek approval of new food ingredients. Perhaps because the statutory period is so short, FDA has historically approached the review process as if there were *no* time frames or deadlines for action on petitions. It is not surprising, therefore, that, for food and color additive petitions approved in 1999, the mean review period was 34.3 months.² Meaningful improvements in the review process, including timeliness and predictability, will not be achievable under the current regime. Either by seeking revision to the act or by the adoption of appropriate performance goals, FDA must impose on itself real deadlines for completion of petition review. Neither increased management attention nor additional resources would eliminate the need for deadlines that petition reviewers understand to be real. The culture of the review process, which is the product of more than forty years of "no deadline" behavior, will not be changed effectively without the imposition of appropriate and achievable deadlines.

²FDA, *Annual Performance Report, Calendar Year 1999*, January 2000, page 4, Figure 6.

We recommend that FDA seek additional statutory changes to provide the foundation for improvements in the review process. First, FDA should seek increased appropriations for its premarket review activities. Without adequate resources, much of the effort to improve the review process will be wasted. Second, FDA should support amendment of the act to provide that food and color additive regulations are issued through notice and comment, as opposed to formal rulemaking. Although formal evidentiary hearings on food or color additive decisions have been rare, it is generally accepted that the potential for such a lengthy and time consuming administrative procedure is a source of considerable delay in the review process. This occurs because reviewers conduct the review in a way designed to permit the agency to deny any request for an evidentiary hearing, as opposed to conducting the review to the point where the agency is comfortable that the safety of the additive has been demonstrated. Until Congress acts to eliminate the opportunity for a formal evidentiary hearing, FDA should continue current efforts to expedite preparation of the preambles that accompany regulations to authorize the use of additives. Lengthy delays in the documentation of the agency's conclusion that an additive is safe bring no benefit to public health and occur at the expense of the petitioner and the public.

Finally, FDA should support revisions to the act that would permit it to consult with experts outside the Federal government on scientific issues that arise in the course of petition review without the need to resort to the cumbersome procedures of the Federal Advisory Committee Act. It is obvious that no amount of additional resources will permit FDA to hire sufficient personnel to always have available to it the scientific or technical expertise needed to address the complex and novel issues that increasingly arise in petition review. Current law constrains the ability of the agency to obtain outside technical advice. A simple change to current law would facilitate the ability of the agency to obtain input from academic experts when needed.

2. The review process should be made more efficient and transparent by developing a management plan for each petition, updating FDA guidance documents on the preparation and filing of petitions and supporting documentation, and establishing routine communication between reviewers and petitioners.

Even without statutory amendments or budget increases, we believe FDA can do a great deal to make the review process more efficient and transparent. First, FDA should develop a management plan for the review of each petition filed. The agency should begin development of the management plan during the pre-filing interaction and finalize the plan as soon as possible after acceptance for filing (*i.e.*, 30 to 60 days after acceptance for filing). The management plan is essentially the plan of action through which FDA will conduct and complete the review of a petition. It is the mechanism by which those charged with the responsibility of managing the review of petitions articulate to reviewers and create the environment in which reviewers operate that is consistent with review against a deadline. Without a management plan at the beginning of the petition review, there can be no reasonable assurance that the review will progress in an orderly way. The plan also should include a timeline for each stage of the review process (*e.g.*,

complete first review of toxicology studies by x date). The FDA Office of the General Counsel, and any other participants in the review process that are outside the Office of Premarket Approval, should be parties to the management plan and should agree to the plan. The management plan should be shared with the petitioner as part of the effort to make the review process more transparent.

Second, FDA should take steps to improve the quality of additive petitions. FDA should update its existing guidance documents for the food industry to address all aspects of additive petition preparation, filing, and review. Among other changes, FDA should seek to standardize the format and organization of petitions. Petition review would clearly be enhanced if petitions were submitted electronically.

Third, FDA should formalize a process for consultation with petitioners before petitions are filed (“prefiling consultation”). FDA should develop a guidance document that sets forth the possible timing and content of prefiling consultations including the issues to be covered and the mechanism by which FDA advice at the prefiling stage is to be memorialized. Prefiling consultation has the potential to benefit the review process if it helps to achieve agreement between the petitioner and the agency on the development of data to demonstrate the safety of the additive and on the scope of the safety evaluation that will ensue. Petitioners should not have to guess at what FDA’s requirement or expectations will be and should be entitled to rely on FDA’s stated requirements and expectations.

Fourth, one of the major sources of frustration with the current process is the inability of a petitioner to determine readily and with confidence the status of the review and the prognosis for action. Our other suggestions – prefiling consultation, updated guidance, effective management plans, for example, will contribute to improvements in the review process. FDA should increase transparency and responsiveness by establishing procedures for periodic (no less frequently than quarterly) communication between reviewers and petitioners. Using the petition review management plan as their roadmap, reviewers should keep a petitioner apprised of the status and progress of the review and should promptly advise a petitioner of any questions that arise. If necessary, meetings or teleconferences between reviewers and petitioners should be arranged. Greater transparency will help the petitioner to manage its own expectations about the progress of the review. More importantly, by sharing the management plan with the petitioner and then keeping the petitioner informed of progress, FDA will emphasize to its reviewers the need to maintain the pace of the review.

3. FDA should set reasonable targets for improving the timeliness of petition reviews.

We recommend that FDA set reasonable targets for improvement of the average review time for additive petitions. We think that the 1999 average review time of 34.3 months is not acceptable. The agency should publish a plan explaining how it will reduce average review time and setting target dates for improvements in timeliness. For example, FDA might set an interim

goal of 18 months as the average review time to be achieved in stages (*e.g.*, 70 percent of petitions reviewed in 18 months in year one, 80 percent in year two, 90 percent in year three, and 100 percent in year four).

Such a plan is mandated by the act. In fact, FDA was required to publish a plan no later than November 1998 "establishing mechanisms, by July 1, 1999, for meeting the time periods specified" in the statute for review of additive petitions and "eliminating backlogs" in the review of petitions by January 1, 2000. 21 U.S.C. § 393(f). We hope that FDA will immediately fulfill this mandate.

4. FDA should not broaden the eligibility criteria for expedited review.

We believe that expedited review should only be available for petitions that present a compelling public health justification. We cannot think of any rationale other than food safety for moving an additive petition to the head of the FDA line. Broadening the criteria for expedited review without additional resources would only dilute the agency's efforts and increase the backlog of additive petitions.

Expedited review is a response to the delays in the operation of the current review process. While that response is commendable as a temporary accommodation to avoid excessive delays in the introduction of new food safety technologies, it is not a solution to the serious problems caused by the current delays. The expedited review procedure has costs, as well as benefits. Expediting certain petitions means that other petitions, which are legally entitled to timely consideration, are delayed far beyond the statutory time frame. Expanding eligibility for expedited review would leave those petitions still ineligible for expedited review with even longer review times.

Further delay of petitions not eligible for expedited review is something that should be avoided. The unacceptably long review times now being confronted by these petitions pose a major disincentive to the development of new technologies that may enhance consumers' health, convenience or preferences. This problem should be remedied by expediting and improving the review process, not by making further changes in the order in which petitions are reviewed.

5. The increased appropriation for premarket review should be allocated to hiring and training of new personnel and making improvements in the review process (discussed in 2 above).

We believe that specific resource allocation decisions are very difficult and best left to the agency itself. FDA managers, not public commenters, are in the best position to determine how best to allocate funds to address the significant deficiencies in the premarket review of additives. However, in allocating these additional resources, we believe that the following considerations should guide FDA decisions:

- An important limitation on the FDA's ability to provide timely review of additive petitions is its limited personnel resources. Hiring and training new personnel takes time; much more time is required for new personnel to acquire the experience needed to achieve high levels of efficiency. Therefore, we believe the new resources should be generously allocated to hiring and training of new personnel as quickly as possible. To the extent that FDA cannot hire sufficient qualified personnel as fulltime employees, it should continue to allocate funds for contractual support for review of studies in petitions, with FDA retaining, the responsibility to make final determinations.
- Reviewer efficiency can be increased by such simple measures as improving the quality of petitions and enhancing electronic data systems. The quality of petitions submitted has been documented as an important factor affecting the timeliness of reviews. Prefiling consultations are an acknowledged means of improving the quality of petitions. Improved guidance for prospective petitioners regarding the format and content of petitions and other matters would likely further improve the quality of petitions. Enhancement of electronic data management systems can improve the efficiency of agency personnel. Some of the new resources at FDA's disposal should be devoted to the improvements in the review process suggested in 2 above.
- Given the still lengthy delays in the review of pending petitions, the high quality of the FDA review process, and Congress' purpose that additional monies should be devoted to improving premarket reviews,³ the above listed activities should receive the vast majority of additional funds. Acquiring or monitoring new safety information on already approved additives should be a low priority for allocation of additional monies.

We believe that FDA should give the highest priority to the hiring, training, and efficient integration of new personnel to review additive petitions. FDA's next priority should be implementing the improvements in the review process discussed in 2 above. The agency's third highest priority should be consideration of statutory changes that would significantly improve the efficiency of the review process.

³S. Rep. No. 106-80, at 126 (1999).

We appreciate this opportunity to share our thoughts on ways to improve the food and color additive review process, and we look forward to working with FDA to achieve this goal.

Respectfully submitted,



Allen Matthys, Ph.D.
Vice President, Regulatory Affairs
National Food Processors Association

Richard H. Adamson, Ph.D.
V.P., Scientific and Technical Affairs
National Soft Drink Association

Susan M. Stout
Senior Director, Federal Affairs
Grocery Manufacturers of America

APPENDIX A

National Food Processors Association

NFPA is the voice of the \$460 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, and consumer affairs. NFPA's three scientific centers, its scientists, and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications, and crisis management support for the Association's U.S. and international members. NFPA's members produce processed and packaged fruits, vegetables, grain products, meat products, poultry products, seafood products, snacks, drinks and juices. In addition, NFPA's non-processor members provide ingredients, equipment, supplies, and services to the processed food industry.

National Soft Drink Association

The National Soft Drink Association (NSDA) is a nationwide trade association comprised of soft drink manufacturers, bottlers and distributors. NSDA's members produce approximately 95 percent of all soft drinks consumed annually in the United States.

Grocery Manufacturers of America

The Grocery Manufacturers of America (GMA) is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.



NFPA

The Food Safety People

**NATIONAL
FOOD
PROCESSORS
ASSOCIATION**

1350 I Street, NW
Suite 300
Washington, DC 20005

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(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

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