



Calorie Control Council

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July 26, 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

On June 27, 2000, the Calorie Control Council submitted the enclosed comments to the Food and Drug Administration. The comments were incorrectly submitted for Docket No. 00N-1268 -- Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additives and Food Additive Petitions. The Calorie Control Council's June 27 comments should have been submitted to 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.

We respectfully request that FDA transfer these June 27 comments from Docket No. 00N-1268 to Docket No. 00N-1262.

Thank you.

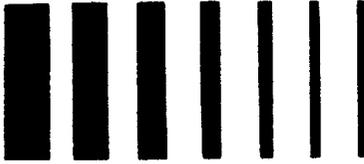
Sincerely

Lyn O'Brien Nabors
Executive Vice President

LON/vw
Enclosure

00N-1262

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- June 27, 2000

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

RE: Docket No. 00N-1268 Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additives and Food Additive Petitions

The Calorie Control Council provides the following comments on the Food and Drug Administration's request for comments on Food Additives and Food Additive Petitions. The Council is an international association of manufacturers of low-calorie and reduced fat foods and beverages, including the manufacturers and users of a variety of alternative sweeteners, fat replacers and low-calorie bulking agents. A food additive petition is required by the Food and Drug Administration in order to obtain approval for many such ingredients

In order to expedite and give greater certainty to the food additive approval process, the Council requests the following changes in regulations:

1. §171.1(c). Amend the Food Additive Petition form:

(a) by replacing the first sentence inside the parenthesis in Paragraph E with the following:

“(A petition may be regarded as incomplete unless it includes full reports of adequate tests whose procedures take into account the guidelines contained within the Organization for Economic Cooperation and Development's (OECD) “Guidelines For Testing of Chemicals” or the Agency's “Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food,” commonly referred to as the “Redbook,” in effect at the time of the initiation of the tests; petitions submitted prior to the issuance of any edition of the “Guidelines” or “Redbook” must contain tests reasonably applicable to show whether or not the food additive is safe for its intended use . . .)

(b) by replacing the third sentence under Paragraph G with the following:

“A supplemental petition must be submitted for any change beyond the variations provided for in the regulation issued on the basis of the original petition unless data in the possession of the petitioner or other marketer of the food additive, and made available to the Agency upon request, show that daily usage of the additive from all known uses will not exceed safe daily intake levels publicly adopted by the Commissioner or recognized international authorities (e.g., the Joint FAO/WHO Expert Committee on Food Additives).”

2. §171.1(i)(2). Insert before the final sentence:

“Upon publication of the notice, the Commissioner will place on public display at the Dockets Management Branch (or some other publicly accessible location specified in the notice) a copy of the petition to the extent available for public disclosure in accordance with §171.1(h)(1).”

3. §171.1(i)(3). Add a new paragraph (3) as follows:

“(3) The notice of filing in the *Federal Register* will allow a period of 60 days during which any interested person may review the petition and/or file comments with the Dockets Management Branch. Copies of all comments received shall be made available for examination in the Dockets Management Branch’s office.”

4. §171.100. Amend this section:

(a) by adding the following at the end of subsection (a):

“The regulation will be published in the *Federal Register* not more than 30 days after the completion of the review process, as provided in subsection (b) of this section.”

(b) by adding the following at the end of subsection (b):

“The Commissioner, with the agreement of the petitioner, may extend the review period for up to two additional 180-day periods (for a total of 540 days); if the petitioner does not concur, the petition will be deemed withdrawn without prejudice rather than denied. Each written request for extension to the petitioner will include a status report describing the point of review of each section of the petition and an explanation for the delay; it is contemplated that the sections of the petition will be reviewed in parallel unless the petitioner is given notice of the need for another

form of review. If for some exceptional reason the review cannot be completed within 540 days, the Commissioner will provide the petitioner with a detailed explanation and place the petition on a priority review.”

“Except as provided in §171.100(c), the Commissioner will not delay issuance of an order acting on a food additive petition for the purpose of considering or responding to comments received more than 60 days after the filing of the petition. Any comments received after this time will be deferred for consideration and treated as objections under §171.110.”

(c) by adding the following new subsection (c):

“(c) The Commissioner may at any time entertain and consider new data which reasonably support the conclusion that serious adverse health consequences are associated with the proposed use of a food additive. Any person desiring to submit such new data more than 60 days after the filing of a food additive petition shall:

- (1) demonstrate that the data were not available at an earlier date;
- (2) demonstrate that the data relate to the identical substance that is the subject of the proposed food additive petition;
- (3) identify, where applicable, the laboratory which conducted the studies and certify that the data are the product of studies performed in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter; and
- (4) certify that the data are not being submitted in bad faith or interposed for any purpose not directly related to the safety of the proposed use of the food additive.”

The perception of many of those outside FDA with an interest in the food additive process is that the process is open ended, prone to inaction and lengthy delays, and without sufficient administrative accountability. Thus, the current system discourages the submission of food additive petitions to FDA.

That has two potentially deleterious effects. First, innovative and potentially important new food ingredients never make it into the U.S. food supply because manufacturers cannot rationally plan for their approval and use. Many of these substances may assist in achieving healthier diets by substituting for fat or otherwise eliminating calories, so that delays in their approval, or decisions not to pursue the material, have costs to the public health as well as the petitioner.

The second problem relates to the process itself. When companies utilize the food additive process, they recognize that it will take many years and millions of dollars to develop the necessary data and proceed with the petition. Discussions are commonly held with FDA to assure that information provided in the petition meets FDA's requirements and needs. However, once the petition is submitted to FDA, there is little way to know how long the review will take, whether it is under active review, who is responsible for the review of various sections, who is coordinating the review, and whether there are administrative milestones to be met within the statutory time frame—no progress reports are offered during the review process.

Experiences reported to the Council, and our own experience with the cyclamate petition, are that petitions are routinely handled by several consumer safety officers (CSO) and may be in the hands of a number of review teams before approval, without centralized tracking or expectation of completion. Part of the problem is that CSO's and reviewers leave the agency before completion of the review or even major phases. This leads to re-review, which is costly in time, money and resources for both FDA and industry.

Another problem is the current method of handling outside comments. At the present time, whenever new nonpetitioner submissions are made, FDA feels impelled to place a hold on the approval process until the data are reviewed, and that review is incorporated into the overall petition process. If, as is sometimes the case, there are persons interested in slowing a petition review for asserted public interest or competitive reasons, the careful timing of their submissions can hold up a review numerous times just short of approval, while either new or even repetitive submissions are combed and responded to.

Finally, and most importantly, there does not appear to be a sufficient commitment on the part of FDA to decision making, particularly for innovative substances, or ones that appear controversial, whether for historical reasons, as in the case of cyclamate, or due to outside criticism. We recognize FDA's difficulty in making decisions that may be criticized but this should not prevent FDA's making appropriate decisions.

A related perception is that FDA applies a double standard to petitioner and nonpetitioner submissions, where the petitioner properly is held to high standards of data integrity and scientific review, while nonpetitioner submissions are accorded a full review without hard data, or peer review, and when indeed they often are no more than opinion.

We also are concerned that reviewing scientists appear to operate in isolation, without any opportunity for interaction with the petitioner to clarify data or other elements of the submission. Often issues presented as requiring a restarting of the review clock could have quickly been resolved (with proper documentation) without awaiting the collection of major points to resolve. We are concerned, additionally, about the opposite problem;

that of repeated restarting of the review clock on the pretext of missing trivial data where the result is simply to avoid decision making.

The proposals we make are designed to address all of these issues. **FIRST, we propose administrative accountability in the food additive review process.** Guidelines should detail how the process is conducted, the units responsible for scientific and administrative review, and the internal milestones of the review process; **regulations** should fix maximum review periods, and public accountability for the status of the review and any extraordinary delays; and they should be adhered to. More detailed guidelines and regulations should not only increase petitioners and other interested parties' understanding of the approval process but should also facilitate FDA's accomplishing the job at hand.

SECOND, we urge that nonpetitioner submissions on a petitioned food additive outside the 60-day comment period be deferred to the post-decision period unless they present previously unavailable data of petition quality that demonstrably relate to serious health concerns. This should expedite the approval process by allowing FDA to proceed with the review without justifying decisions before they are even finalized. Removing interruptions, interference and controversy from the process should increase the continuity and fairness of the review.

THIRD, we urge greater clarity in review criteria for evaluating the safety of substances added to food. Guidelines can be helpful here as well, as the "Redbook" has been since its first publication. While the "Redbook" represents a structured approach to toxicological review, it should not be literally applied on a retroactive basis to studies conducted before its creation, just as "good laboratory practices" in their current form cannot have a literal application to earlier studies.

FOURTH, we urge a more interactive review process. Reviewers should be able to seek clarification of minor points and petitioners should be able to respond without formal stopping and restarting of the review clock. Moreover, there should also be comprehensive assessments at regular intervals that will provide both a management tool for FDA and an assurance of progress for the petitioner. We commend FDA for FDA's Management Assignment Tracking System (MATS) referred to in FDA's "Management programs policies and procedures—policies, authority, and procedures for food and color additive petitions and GRAS affirmation petitions," known as the Staff Manual Guide (SMG), and encourage it to be used for both internal FDA management and periodic updates to the petitioner.

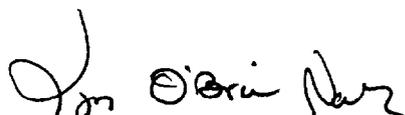
FIFTH, we urge FDA to establish an abbreviated process for approving additional uses of an approved food additive. Once the Commissioner has set an acceptable daily intake (ADI) based on a complete data package, industry should be able to rely on that figure in developing new uses for additives without going through the entire review process. Adoption of an abbreviated process could assist with FDA's announcement that

it "wants to increase the effectiveness and efficiency of the review process," and to "clear work from the pending inventory of active petitions as quickly as the petitioners desire . . . consistent with upholding the standard of safety."¹

SIXTH, we support the June 1992 citizen petition submitted by Covington & Burling on behalf of McNeil Specialty Products Company requesting that FDA clarify the schedule for submission of, and for the agency's response to, comments submitted after the publication of a notice of filing of a food additive petition. The Council's comments reiterate a number of McNeil's requests and we urge the Commissioner to expedite the review of the McNeil petition and to take appropriate action to implement requests therein.

FINALLY, we urge that steps be taken to conserve and enhance FDA's scientific expertise and human resources. They are the key to timely, rational, competent, and reliable reviews. FDA should assure that adequate training is undertaken, and that positions are classified and graded in a way that is competitive with other scientific positions throughout government, in particular with EPA, USDA, OSHA, and similar agencies having scientific review components that compete for the same talent pool.

Respectfully submitted,


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Robert C. Gelardi
President

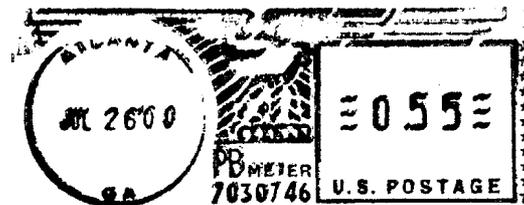
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¹A. Rulis and L. Tarantino, *The Food Additive Petition Process: Recent Data*, 48 Food and Drug L.J., 137, 141 (1993).



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