



THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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

E. EDWARD KAVANAUGH
P R E S I D E N T

Re: Citizen Petitions
Docket No. 99N-2496
64 Fed. Reg. 66822 (November 30, 1999)

The Cosmetic, Toiletry, and Fragrance Association (CTFA) submits these comments on the proposal published by the Food and Drug Administration (FDA) to revise its citizen petition regulations, 21 C.F.R. § 10.25 and 21 C.F.R. § 10.30. CTFA appreciates the opportunity to provide comment and also recognizes and supports the comments submitted separately by the Consumer Healthcare Products Association in this matter.

INTRODUCTION

Since 1975, FDA has permitted any interested person to petition the agency to issue, amend, or revoke a regulation; to issue, amend, or revoke an order; and to take or not to take any other administrative action. FDA regulations require the agency to respond within 180 days, and eventually to rule on the petition. That ruling is final agency action, and FDA regulations define the administrative record in a petition proceeding for purposes of judicial review. FDA now proposes to sharply limit the citizen petition process.

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Founded in 1894, CTFA has an active membership of approximately 250 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States. CTFA also includes approximately 280 associate member companies from related industries, such as manufacturers of raw materials and packaging materials. CTFA members have participated in every aspect of the OTC Drug Review since its inception in 1972, because they make products that are classified as both cosmetics and drugs. CTFA and its members have used citizen petitions extensively in the OTC Drug Review, and have used the process to bring other issues pertaining to health, safety, and public policy before FDA decisionmakers.

CTFA opposes the proposal because it appears to preclude the introduction of new data and information in the OTC Drug Review. Moreover, under the proposal, many important petitions could be rejected or treated as correspondence. The alternatives to citizen petitions discussed by FDA are inadequate to ensure that the agency will engage in dialogue about these issues.

COMMENTS

A. The Proposal Appears to Preclude the Introduction of New Data and New Information in the OTC Drug Review.

Although FDA has published a tentative final monograph (TFM) for almost every therapeutic category in the OTC Drug Review, it has published a final monograph in only two-thirds of the categories. Years can elapse between the publication of a TFM and publication of a final monograph, and FDA regulations permit only twelve months of comment after publication of the TFM. That time has expired in every pending rulemaking. The manufacturers of cosmetic-drugs have turned to the citizen

petition process, asking the agency to reopen the administrative record in question or, less frequently, to amend the TFM (a “proposed rule”). Both the cosmetics industry and FDA have found the citizen petition process to be an appropriate and useful mechanism for ensuring that the final monograph reflects current information on effective conditions of marketing.

The proposed regulations appear to preclude further use of the citizen petition process in the OTC Drug Review. Under the proposed regulations, a citizen petition could only be filed if it requested the issuance, amendment, or repeal of a regulation; an existing regulation authorized petitions on the topic; or it pertained to an already-issued order. The petitions filed by cosmetic-drug manufacturers in the OTC Drug Review do not request the issuance, amendment, or repeal of a regulation, and there is no regulation specifically authorizing such petitions. Nor do they pertain to already-issued “orders.”

We believe this to be an oversight on FDA’s part. The agency should clarify that its proposal is not meant to affect the use of citizen petitions in the OTC Drug Review.

B. Under the Proposed Regulations, FDA Could Avoid Addressing the Merits of Other Important Petitions.

The proposed regulations would allow FDA to refer whole categories of petitions “for other administrative action,” including treatment as correspondence. However, neither correspondence nor the other informal means of communication cited by the agency as substitutes for petitioning -- meetings, telephone calls, electronic mail, and facsimiles -- is an adequate substitute for the petitioning process. FDA can choose

not to address the merits of such requests, and indeed not to respond at all. Any response that might issue is not binding on the agency, and the agency may argue that the decision is not “final” for purposes of judicial review.

Many of these petitions are important to the cosmetic industry and to the larger public. For instance, FDA could deny or treat as correspondence any petition that “does not involve a significant public health or consumer protection issue.” This would include citizen petitions that raise issues pertaining to the agency’s practices and procedures. It would include citizen petitions drawing the agency’s attention to the economic impact of an effective date or compliance date for labeling changes. It would include petitions requesting changes in good laboratory practices for nonclinical trials. To give another example, the proposed regulations would allow FDA to treat as correspondence any petition that “involves issues that are the subject of an ongoing or future administrative proceeding.” FDA does not explain how it plans to determine that an issue will be addressed at some undetermined point in the future, and this could be virtually limitless in scope. FDA could treat as correspondence any petition that “presents scientific or technical issues or data that are specific to a particular product or class of products.” In addition to petitions filed in the OTC Drug Review, this would include petitions relating to the safety or labeling of products already on the market.

These issues should be addressed in public proceedings, during which the agency engages in dialogue with members of the public, and after which the agency is accountable in a court of law.

CONCLUSION

The agency should clarify that citizen petitions filed in the OTC Drug Review will be treated as previously. Moreover, FDA should not place whole topics outside the citizen petition process. For the reasons discussed above, CTFA opposes the proposed regulations.

Respectfully submitted,



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