

# Procter & Gamble

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February 28, 2000

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

Re: FDA Docket No. 99N-2497  
64 Fed. Reg. 66822, November 30, 1999  
Citizen Petitions; Actions That Can be  
Requested by Petition; Denials,  
Withdrawals, and Referrals for Other  
Administrative Action

Procter & Gamble respectfully submits comments in response to the FDA proposed regulations for "Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action."

Procter & Gamble supports the intent of the agency to improve and streamline the citizen petition mechanism. However, for the following reasons we believe the proposed regulations will substantially limit the citizen petition process. First, we believe petitions that relate to issues of importance to over-the-counter drug businesses could be rejected. Second, it is unclear whether the proposed regulations would permit the introduction of new data into the OTC Drug Review. And, last, the alternative communication mechanisms do not ensure adequate responses will be provided regarding the issues submitted.

### Acceptance of Petitions

The proposed regulation restricts citizen petitions to requests that relate to 1) issuance, amendment or revocation of a regulation, 2) amendment or revocation of an order, or 3) taking an action as specifically authorized by another FDA regulation. Additionally, the proposal further enables FDA the ability to deny a petition that does not involve a significant public health or consumer protection issue. The narrowed scope of the proposal could significantly limit the ability of OTC drug manufacturers to file petitions to broaden the scope of OTC monographs, particularly those that are not final and could be considered pending regulations. Additionally, many petitions filed for OTC drugs do not involve matters involving significant public health or consumer protection issues, yet these petitions are important to consumers and industry. For example, petitions related to compliance timing for regulations are an important mechanism to alert FDA to implementation issues associated with the regulation, but which are not related to a public health or consumer protection issue.

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OTC Drug Review

We seek clarification that the proposed regulation does not preclude filing a citizen petition to reopen a Tentative Final Monograph (TFM) whose official comment period has officially closed. While proposed 10.30(b) states that a petition could request that the agency take an action as specifically authorized by another FDA regulation, we would like to know with certainty that the proposal does not seek to eliminate petitions on non-final OTC rulemakings. The citizen petition process has been used extensively to amend over-the-counter drug monographs during the years that may elapse between publication of a TFM and a final monograph. New scientific standards and emerging data have been effectively assimilated into the monographs via the petition process. Therefore, it is important that the petition process remain in place for this purpose.

Alternative Mechanisms

Informal, alternative communication methods listed in the proposed regulations such as telephone calls, faxes, electronic mail, letters or meetings are clearly very useful tools of communication between FDA, industry, and the general public and should be continued even to a greater extent than today. However, they are not acceptable substitutes for citizen petitions for contacting the FDA. The proposal provides no mechanism to assure a timely FDA response, or indeed any response, on issues which may be critical to business. If a response is received, it will be informal and potentially not binding, whereas a response to a citizen petition is a document which may be considered "final" for purposes of judicial review. Further, the informal response does not guarantee involvement or concurrence of appropriate personnel within the agency. Net, the types of communication proposed are not necessarily adequate to provide the assurance that industry or the general public needs to take action on the FDA response.

Summary

For the reasons discussed above, we believe the proposed rule, which seeks to clarify the types of requests that may be the subject of a citizen petition and to increase FDA's flexibility in responding to or taking action in response to a citizen petition, will actually limit the citizen petition process. While the agency emphasizes that this proposed rule is not intended to reduce or curtail access to or discussions with the agency, the alternative types of communication suggested have no time periods established for the FDA to respond and the types of responses received would not be actionable.

In addition, Procter & Gamble supports the position of the CHPA as submitted to this docket.

We thank the agency for its consideration of these comments.

Sincerely,

 RTS  
2/25/00

Douglas Ws. Bierer, Ph.D.  
Director, Regulatory Affairs

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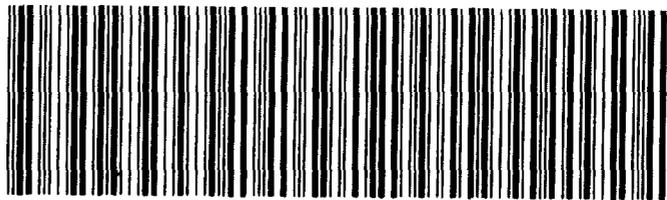
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