

ARNOLD & PORTER

555 TWELFTH STREET, N.W.
WASHINGTON, D.C. 20004-1206
(202) 942-5000
FACSIMILE: (202) 942-5999

NEW YORK
DENVER
LOS ANGELES
LONDON

DONALD O. BEERS
(202) 942-5012
INTERNET: Donald_Beers@aporter.com

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February 28, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No. 99N-2497: Citizen Petitions

Dear Sir or Madam:

We submit this comment as interested persons, not on behalf of any of our clients. While we believe several aspects of the above-referenced proposal are objectionable, we address here one of the changes described in the proposal that we believe would be a significant mistake. The current citizen petition regulation provides a useful mechanism for resolving important disputes without litigation and, when the disputes are not resolved, facilitates judicial review. One effect of the proposed regulation would be to make the citizen petition process unavailable when a party believes that FDA may take illegal or inappropriate action to approve a competitor's product.

The current citizen petition procedure presents significant benefits, both to the public and to FDA itself, in providing an appropriate forum for matters that may, if unresolved, result in judicial review:

(1) The petition process is designed to assure that arguments are clearly stated and that all the relevant supportive information is submitted to FDA for its review.

(2) The current process is on the public record so that any other interested party can respond to the arguments made. This allows any party that would be adversely affected by the grant of the petition to understand the arguments being made to FDA and to respond to them. In addition, many petitions also result in comments by interested parties, such as public interest groups and other manufacturers, that allow FDA to understand the full ramifications of a decision for or against the position set out in the petition.

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(3) The petition process brings important issues to the attention of higher level FDA decision makers. While a letter to a center director or to the Commissioner may, as a routine matter, simply be referred for response to the same part of the agency whose action is being disputed, the resolution of a citizen petition generally does engage higher level agency decision makers.

(4) The citizen petition process also identifies for FDA those matters that have a significant litigation potential and allows FDA to involve its legal staff, including both lawyers in the Office of the Chief Counsel and lawyers within the affected centers, in the decision making and in the crafting of the response to the petitioner's arguments.

(5) While FDA does not always respond to citizen petitions in a timely manner, the current petition process at least provides FDA the opportunity to prepare a written explanation of its decision that can be analyzed in a reviewing court.

(6) When FDA does respond to a petition, the regulation requires the assembly of an administrative record to support that decision. Even when FDA does not respond to the citizen petition in a timely manner, the submissions of the petitioner and of any interested party that comments on the petition create an administrative record for judicial review.

We recognize that resolution of the sometimes complex issues presented by citizen petitions can consume agency resources. But the types of issues that have led to the filing of citizen petitions in the past are not going to go away. The preamble to the proposed regulation insists that FDA will not ignore such issues but will, instead, address the public's concerns about the approval process by responding to "letters, electronic mail, meetings, discussions, and other avenues of communication." 64 Fed. Reg. 66822, 66824 (Nov. 30, 1999). It is our experience, however, that citizen petitions are most often submitted after less formal communications have been tried and have been ignored. The citizen petition generally signals to the Food and Drug Administration that, if the points made in the petition continue to be either rejected or ignored, the petitioner will seriously consider seeking judicial intervention.

If FDA insists on the changes proposed, we ask that FDA explain how the benefits of the petition process noted above will be achieved. Specifically, how should we, as attorneys representing clients concerned that FDA will make a mistake in approving a competitor's product, appropriately seek to obtain an FDA decision before we seek judicial review?

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We note that FDA has not proposed to change 21 C.F.R. 10.45(b), which states that

A request that the Commissioner take or refrain from taking any form of administrative action must first be the subject of a final administrative decision based on a petition submitted under § 10.25(a). . . before any legal action is filed in a court complaining of the action or failure to act.

The cross-reference to § 10.25(a), after the proposed amendment, would state that “[f]or requests involving administrative action, the request may be made in any written form (e.g., letter, facsimile).” In the absence of any other guidance, it is our current interpretation of this proposal that, in a situation in which we would under the current regulation file a citizen petition, FDA is saying that we should send a letter to the Commissioner containing essentially the information that would have been contained in a citizen petition. Then, if FDA ignores or rejects the arguments made in that letter we would proceed to initiate action for judicial review.

It is a mystery how this change in procedure is better for FDA than the current citizen petition procedure. As the sending of the letter would not open a public docket, other parties would not have an opportunity to comment on the letter. There would be no requirement of creation of an administrative record to facilitate judicial review. Unless FDA set up a new internal procedure to deal with such letters, there would be no assurance that the appropriate high level officials and attorneys would focus on and decide the issues raised in such a letter before those issues are reviewed by a court.

We respectfully request that FDA reconsider its proposal to the extent that it would make the filing of a citizen petition inappropriate where issues relating to approval decisions are likely to lead to requests for judicial review. If FDA is concerned about the resources that responding to petitions of this type take, a solution might be for FDA to issue “brief denials,” as referenced in proposed 21 C.F.R. 10.30(e)(2)(ii), in those situations in which the FDA concludes that it is willing to defend, in court, its decision with respect to that petition on the basis of such a brief denial.

We believe the proposal to eliminate the citizen petition option when a company seeks to raise issues relevant to an FDA approval decision is unwise and should not be implemented. If that change is made, however, we ask that FDA state clearly its position

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on how companies will, in the future, be expected to seek resolution, prior to judicial review, of concerns about potential FDA approval of competitors' products.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Donald O. Beers". The signature is written in black ink and is positioned above the printed name.

Donald O. Beers

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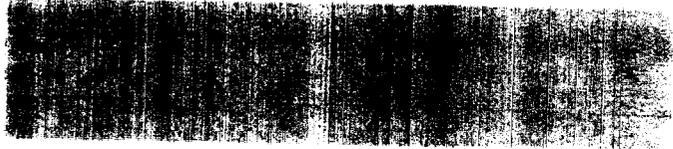
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WASHINGTON, D.C. 20004-1202



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