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February 28, 2000

Via Hand Delivery

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

Re: Proposed Rule, *Citizen Petitions; Actions that can be Requested by Petitions; Denials, Withdrawals, and Referrals for Other Administrative Action*
Docket Number 99N-2497

Dear Sir or Madam:

This letter provides the comments of Bracco Diagnostics Inc. ("Bracco") on the Food and Drug Administration's proposed rule entitled, *Citizen Petitions; Actions that can be Requested by Petitions; Denials, Withdrawals, and Referrals for Other Administrative Action* ("Proposed Rule"). This Proposed Rule was published in the November 30, 1999 Federal Register (Vol. 64, No. 229, pp. 66822-66828) and assigned Docket Number 99N-2497. While Bracco is generally supportive of the Agency's efforts to improve the citizen petition process, we believe that two of the Food and Drug Administration's ("FDA") specific proposals will have a detrimental impact upon the Agency, the public, and regulated industry. Bracco's comments on these two proposals appear below.

Restrictions On The Type of Actions That May Be Requested In A Citizen Petition

The Agency's proposed amendments to 21 C.F.R § 10.30(b) would essentially prohibit citizen petitions regarding matters pending before the Agency and issues upon which petitioners believe FDA should take action, except in two narrowly defined circumstances: (1) matters ordinarily addressed by formal regulation, as opposed to order, and (2) the approximately 20 issues about which citizen petitions are specifically invited by regulation.

99N-2497

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Bracco disagrees with the Agency's proposed amendments to 21 C.F.R. § 10.30(b). The citizen petition process is an important mechanism of communication between the FDA, the public, and regulated industry. Restricting petitioners' ability to address matters pending before the Agency deprives the Agency of relevant information during its decision making process, and deprives the public and the industry from the opportunity of being heard in advance of any pending decisions. Because opportunities to participate in FDA decision making would be severely limited, the proposal would likely result in a sharp increase in challenges to Agency decisions. Yet, postponing the Agency's consideration of competing viewpoints until after a particular decision has been made is inefficient. Similarly, limiting the ability to request future Agency action deprives the Agency of two separate, but related, types of information: (1) input concerning the issues that warrant Agency attention, and (2) suggestions as to how the Agency might best address such matters.

The preamble to the Proposed Rule discusses several reasons why FDA believes the proposed restrictions are needed, and also emphasizes that the proposal does not curtail access to the Agency because informal methods of communication remain available. As discussed below, Bracco does not believe the proffered justifications warrant the proposed restrictions on the types of actions that may be requested through a citizen petition. Nor does Bracco believe that informal means of communication are an adequate substitute for the formal citizen petition process.

FDA has suggested that the proposed restrictions are needed to deter use of the citizen petition process for improper purposes, such as to delay competition or Agency action. While Bracco fully supports the Agency's effort to prevent the filing of citizen petitions for improper purposes, we do not believe that broad restrictions on the types of actions that may be requested in a citizen petition is the most effective way to achieve this goal. The Agency's proposed rule would prohibit the filing of certain types of citizen petitions regardless of the petitioner's motive. Such a broad, overinclusive proscription is not necessary because two of the other proposed amendments to the Agency's citizen petition procedures will adequately deter the submission of petitions for an improper purpose. Specifically, the Agency's proposal to require certification that the petition "is not submitted for any improper purpose, such as to harass or to cause unnecessary delay" addresses the issue directly by prohibiting the filing of improperly motivated petitions. Relatedly, to deter the submission of frivolous or unsupported petitions, FDA has proposed to require that petitions requesting that FDA amend or revoke an order be based upon more than unsupported claims, allegations, or general descriptions of positions or arguments. Bracco believes these two proposals, coupled with the threat of Federal Trade Commission enforcement, adequately deter the filing of citizen petitions for anticompetitive purposes.

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FDA has also suggested that restrictions on the type of actions that may be requested through citizen petitions are needed to reduce the overall number of citizen petitions submitted to the Agency, in light of the significant resources required to respond to each citizen petition. 64 Fed. Reg. 66822, 66822-23. Bracco believes that other aspects of the proposed rule will serve to either reduce the number of non-meritorious petitions submitted to the Agency or reduce the level of Agency effort required to respond to petitions. Specifically, the certification requirement and limitations on the proper bases for citizen petitions mentioned above should deter the submission of unsupported and improperly motivated petitions. Proposed changes to § 10.30(e) allowing brief denials and withdrawal, or consolidation of petitions will permit the expeditious processing of many petitions. While these proposed amendments should reduce FDA's workload, there is no basis to conclude that the proposed restrictions on the type of actions that may be sought by citizen petition would have the same effect. Should the Agency severely limit public participation in FDA decision making, as proposed, one can anticipate an increase in post-decision citizen petitions and litigation. These petitions and lawsuits may well require more Agency resources than are currently required to address citizen petitions.

Throughout the preamble to the Proposed Rule, FDA emphasizes that informal avenues of communication with the Agency remain available, and thus the Proposed Rule does not curtail access to the Agency. 64 Fed. Reg. 66822, 66822-24. Bracco appreciates the ability to contact the Agency informally, and agrees with FDA that many issues are appropriately discussed in such a manner. Nevertheless, informal contact is not a suitable replacement for the formal citizen petition procedure. First, informal communications with the Agency would not necessarily be publicly available, thus depriving both the Agency and industry of the public dialog and resulting record generated by the citizen petition process. Second, though the Agency has undertaken to consider information presented informally and respond "promptly," this undertaking is no substitute for formal procedures associated with the petition process. Finally, FDA has acknowledged that unlike citizen petitions, telephone calls and letters will not be subject to formal processing. 64 Fed. Reg. 66822, 66822. Under such circumstances, it is unclear how one would seek judicial review of Agency action or inaction on informal communications. Yet without the ability to seek judicial review, informal contact is useful in only limited circumstances. Thus, should the Agency proceed in the manner proposed, it must amend its regulations at 21 C.F.R. § 10.45 to expressly provide that submission of an informal communication satisfies a litigant's obligation to exhaust their administrative remedies before proceeding to court.

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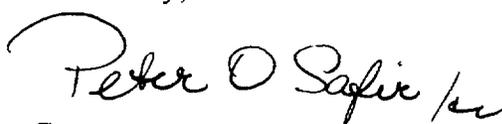
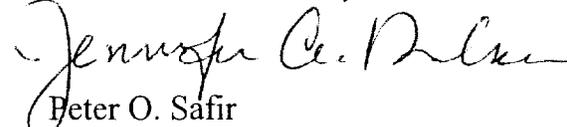
Provision Allowing FDA To Refer Certain Citizen Petitions For Other Administrative Action

The Agency's proposed 21 C.F.R. § 10.30(e)(4)(i) would allow the FDA to "refer" citizen petitions on a wide range of issues for unspecified "other administrative action" whenever FDA deemed such referral to be appropriate. The proposal also allows FDA to treat these citizen petitions as simple correspondence pursuant to 21 C.F.R. § 10.65. As a result, Agency action on these type of petitions would not be subject to judicial review. See 21 C.F.R. §§ 10.65; 10.45. As proposed, § 10.30(e)(4)(i) gives FDA unfettered discretion to "refer" a host of citizen petitions, including all petitions involving a subject that FDA believes "is appropriately addressed by other administrative action."

This proposal suffers from the same procedural defects discussed immediately above. It would allow FDA on its own initiative to transform various types of citizen petitions into simple correspondence, thus insulating FDA action on these petitions from judicial review. While referral may be appropriate in certain limited circumstances (e.g., a petition concerning an issue that is the subject of an ongoing rulemaking), Bracco objects to any proposal that would preclude judicial review and suggests that the proposal be amended to provide that "referral" constitutes a "denial" for purposes of judicial review.

Should you have any questions regarding these comments, please contact me. Thank you in advance for your consideration.

Sincerely,



Peter O. Safir
Jennifer A. Davidson
Counsel to Bracco Diagnostics Inc.

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