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**Drug Development & Technology**

Division of Berlex Laboratories, Inc.

340 Changebridge Road  
P.O. Box 1000  
Montville, NJ 07045-1000  
Telephone: (973) 276-2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20857

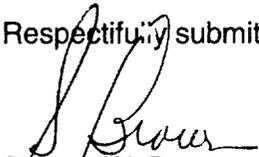
Dear Sir/Madam:

**Re: Docket No. 99N-2497**

Berlex Laboratories, Inc. submits the following comments to Docket No. 99N-2497, regarding the Food and Drug Administration's (FDA's) proposed rule concerning the actions that can be requested by a citizen petition.

Please contact the undersigned at (973) 276-2162 if you have any questions regarding this submission.

Respectfully submitted,

  
Sharon W. Brown  
Associate Director  
Drug Regulatory Affairs

SWB/letter/clim006

99N-2497

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Berlex Laboratories, Inc. (Berlex) submits these comments on the Food and Drug Administration's (FDA's) proposed rule regarding the actions that can be requested by the filing of a citizen petition.

FDA proposes to limit the types of actions that may be requested by a citizen petition to the following: (1) the issuance, amendment, or revocation of a regulation, (2) the amendment or revocation of an order that FDA has issued or published, and (3) a request for agency action as "specifically authorized by another FDA regulation." 64 Fed. Reg. 66822 (Nov. 30, 1999). FDA states that requests for agency action that are outside the scope of the proposal would have to be submitted to FDA through informal correspondence, such as telephone calls and letters. *Id.* FDA additionally proposes to increase its flexibility in responding to citizen petitions so that it may treat certain petitions as correspondence or refer them to other agency proceedings. *Id.* FDA believes that these proposed changes to the citizen petition process will, among other things, reduce the citizen petition backlog, allow FDA to respond to requests for agency action faster, and prevent the submission of frivolous petitions. *Id.* at 66822-23.

Berlex supports several of FDA's proposed changes to the citizen petition process, but Berlex opposes FDA's proposed limit on the types of action the agency can be requested to take. The benefits from having the citizen petition process to formalize and finalize the agency's position on important matters that fall outside proposed § 10.30(b) cannot be replicated through the submission of informal correspondence to the agency. Moreover, FDA's proposed limits on the types of issues that may be requested by a citizen petition will not necessarily eliminate the problems that the agency is encountering with the citizen petition process and, as further discussed below, will generate new problems that the agency will have to solve. Furthermore, Berlex believes that the problems FDA is experiencing with the citizen petition process can be taken care of through other means, such as management reform, which would improve the efficiency of the petition process.

Nevertheless, in the event FDA adopts proposed § 10.30, Berlex urges that it not be applied retroactively to those petitions that have already been filed with FDA's Dockets Management Branch. "Retroactivity is not favored in the law." Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 212 (1988). It would be fundamentally unfair to apply the rule to those petitions already filed with the agency. The filing of a citizen petition requires time, effort, and expense. Those who have filed petitions have done so because they believed that such costs were worth receiving a comprehensive agency review of a matter and a final administrative response. Thus, for these reasons, FDA should apply the rule prospectively only.

## **I. THE ORIGIN, PURPOSE, AND TRACK RECORD OF THE CITIZEN PETITION PROCESS**

At its inception, the citizen petition process was intended to provide the public a means to petition the FDA to either issue, amend, or repeal a regulation. 31 Fed. Reg. 3003, 3004 (Feb. 22, 1966). Almost ten years later, however, the agency, in recognizing the Administrative Procedure Act's requirement that "any interested person [have] the right to petition for the issuance, amendment, or repeal of a rule," and in recognizing the First Amendment to the Constitution, which "explicitly recognizes the right of the people to petition the government for a redress of grievances," proposed that the citizen petition process "cover every form of agency administrative activity, including a refusal to act." 40 Fed. Reg. 40682, 40686 (Sept. 3, 1975). FDA believed that this change to the petition process, which the agency ultimately adopted, was necessary to afford the public a known framework within which they could request FDA to take or refrain from taking administrative action and receive a formal agency response. *Id.* FDA also believed that the change would provide guidance to the agency as to how to handle and respond to the public's requests for various types of agency action. *Id.*

FDA is now proposing to exclude from the citizen petition process the very types of requests the agency felt necessary to include in the petition process, as evidenced by the agency's 1975 changes to the rule, and FDA is proposing to exclude such requests without demonstrating how or why the purpose of using the citizen petition process for such requests is less important today. The citizen petition process continues to provide the public with a structured procedure to follow when requesting agency action on matters not falling under proposed § 10.30(b), and it continues to ensure that requests made by a citizen petition will receive a structured agency response. It is therefore no less valuable to the public today than it was when FDA revised the petition process 25 years ago.

FDA states that changes to the citizen petition process are needed because the process, as it currently operates, is not working well. 64 Fed. Reg. at 66823. If there are problems with the citizen petition process, however, the logical first step is to attempt to make the process work better, not to disqualify a large proportion of petition requests from receiving its benefits. *See* discussion *infra* part III. Furthermore, the changes FDA is proposing – that requests outside of proposed § 10.30(b) be submitted via informal correspondence – would reestablish the very mechanisms to contact the agency that FDA regarded as insufficient in 1975 and that caused the agency to expand the types of requests that may be made by a citizen petition. Nowhere in the proposal does FDA explain how the value of the citizen petition process, in providing a known, certain administrative procedure, will be achieved by reverting to exclusive reliance on the informal methods of contacting the agency that the citizen petition was intended to augment.

Informal methods of bringing matters before the agency serve a useful purpose. Indeed, they are indispensable. Most issues between FDA and the public are addressed through correspondence, meetings, and phone calls. But there are situations where those procedures are inadequate. In such cases, the public should continue to have the option of requesting action through the citizen petition process so that a formal and final agency response can be obtained.

## **II. FDA LACKS A BASIS FOR AT LEAST TWO OF ITS PROPOSED CHANGES TO THE CITIZEN PETITION PROCESS**

Although Berlex believes that some of FDA's proposed changes to the citizen petition process are good and will help make the process more efficient and effective, Berlex opposes two of FDA's proposed changes, those excluding from the citizen petition procedure requests relating to future "orders" and requests to take or refrain from taking action other than as specifically provided. These changes would make the citizen petition procedure unavailable with respect to major categories of FDA administrative activity having potentially significant public health, legal, regulatory, and economic consequences. FDA fails to provide adequate evidence or to cite logical grounds for why it makes sense to single out FDA activity not amenable to a regulation, and not the result of an existing order, for exclusion from the citizen petition process. FDA also fails to explain why the agency has decided not to improve the management of the citizen petition process as a means of addressing the difficulties it says it is experiencing.

### **A. FDA Has No Basis to Prevent Requests Relating to Agency Orders and Requests for FDA to Take or Refrain From Taking Agency Action From Being Made Through the Citizen Petition Process**

FDA's proposed rule would prohibit persons from petitioning the agency to "amend pending FDA orders or issue future FDA orders" or from requesting it to "take or refrain from taking any other form of administrative action" unless the request pertains to the issuance, amendment, or repeal of a regulation or is "specifically provided by regulation." 64 Fed. Reg. at 66823-24. FDA has not demonstrated, however, how the types of requests that FDA is proposing to eliminate from the citizen petition process are different from the types of requests that FDA intends to allow through such a process. The purpose of the citizen petition mechanism – to provide an open, known administrative process – is just as valuable for requests to FDA to amend a pending order or issue or refrain from issuing a future order, or to request the agency to take or refrain from taking administrative action, as it is for requests to the agency to amend, issue, or revoke a regulation or amend or revoke an existing order. Regardless of the type of request, the citizen petition process provides the public with an established, structured procedure to follow that requires a formal agency response.

## **1. Advantages of the Citizen Petition Process**

There are significant advantages in allowing requests for future FDA orders and requests for FDA to take or refrain from taking administrative action to be made by a citizen petition. The advantages include the following:

### **a. An Institutional Response**

The citizen petition procedure requires the FDA both to research and examine the regulatory, scientific, medical, legal, and economic issues raised by citizen petitions and to “coordinate internal agency review and clearance of the petition response.” *Id.* at 66822. Thus, the submission of a citizen petition requires an agency response as opposed to the response of an individual FDA employee. An employee’s response to an informal contact may provide helpful guidance or useful insights. But it does not represent FDA’s institutional position. Agency activity other than regulations and orders is certainly capable of creating issues that may warrant an institutional response by the agency. The notice of proposed rulemaking (NPRM) identifies no reason for concluding that issues arising from such FDA activity are inherently less important than issues related to a rule or an order.

### **b. An Open, Public Process That Ensures That the Agency Applies Its Policies in a Fair and Consistent Manner**

Citizen petitions are filed in FDA’s Dockets Management Branch so that the public may view the contents of the petitions and submit comments on the issues they raise. 21 C.F.R. § 10.30(c), (d). In addition, the subject matter of and decisions made on citizen petitions are often disseminated in the media, which provides another means of informing the public of issues addressed by the agency. Public awareness of issues addressed by FDA ensures that FDA applies its policies in a fair and consistent manner. This advantage of the citizen petition process is more, not less, important for issues arising from FDA authority that is unrelated to rulemaking and already issued orders. Rules and orders are subject to other administrative procedures, whose utilization by the agency and the public assures openness and fairness without regard to the citizen petition mechanism. It was the very lack of such established administrative procedures for other areas of FDA activity that led FDA to extend the citizen petition into those areas – where it constitutes the only formally structured body of procedures available to persons outside the agency to address important matters. The agency’s proposal would thus eliminate the citizen petition mechanism in those areas where it is most needed.

### **c. Deliberate Formal Agency Consideration of Important Scientific Questions Having Public Health Implications**

As FDA noted in its proposal, the agency thoroughly and carefully reviews the issues presented in citizen petitions. See 64 Fed. Reg. at 66822. Thus, scientific matters

having public health implications are assured a meticulous and well thought-out institutional review. Important public health and scientific issues are not found only in contexts in which a regulation has been, or should be, issued, or in matters that have been the subject of an order. If the citizen petition process increases the likelihood that FDA will give an appropriately intensive review to important issues, then the procedure should continue to be available for any matter in which an important issue arises, rather than being arbitrarily limited to those occasions when important issues happen to arise in a regulation or an already-issued order.

**d. Final Agency Action**

FDA regulations provide that the Commissioner's final decision on a citizen petition constitutes "final agency action," which allows the subject matter of the petition to be reviewed in court. 21 C.F.R. § 10.45(d). The finality of the agency's decision and the possibility of judicial review of the decision are incentives for the agency to ensure that it has thoroughly considered the petition and that those FDA officials having agency decision-making authority have collectively agreed upon the agency's position. As with other advantages of the citizen petition process, the finality of a citizen petition response and the availability of judicial review based on the results of focused, high-level FDA decision-making, are just as important for issues not involving rulemaking or orders. For those issues, it is an advantage that is available only because of the current citizen petition procedure. Rules and orders are subject to separate procedures for assuring finality. Withdrawing the citizen petition procedure from other types of FDA activity has the paradoxical effect of eliminating it as a means of obtaining judicially reviewable final agency action for those matters where only the citizen petition can assure final agency action, while continuing to provide the citizen petition for use in matters where it is unnecessary for that purpose.

**e. A Mechanism for the Public to Petition FDA and Receive a Structured Response**

As discussed in part I, the citizen petition process provides the public with a knowable, objective procedure to make a request of the agency, and it guarantees that those requesting agency action on an issue will receive a suitable institutional decision. In addition, the citizen petition process provides FDA with a procedure to follow in issuing responses to petitions. The existence of a citizen petition procedure encourages, and was meant to encourage, persons outside the agency to pursue their right to make a request of the agency to take, or not to take, action. If the citizen petition process is restricted, persons will be less likely to take advantage of their right to make requests of the agency. It may be that, as a result, FDA will be less burdened with requests, but this is a bureaucratic convenience that will be achieved at the expense of abandoning an important civic value.

**f. FDA's Awareness of Petitions**

The public nature of the citizen petition process, the requirement that FDA must respond to citizen petitions, and the fact that the agency's responses to petitions are subject to judicial review guarantee that the agency will become aware of the petition and, at some point, review the contents of the petition. See 21 C.F.R. §§ 10.30(e)(1), 10.45(d). It is true, as FDA says, that persons outside the agency can convey requests and views by informal means, such as letters and phone calls. However, because such communications lack the defined procedural framework of the citizen petition process, there is less assurance that the agency will respond to them in a direct and timely fashion. Letters, phone calls, and meetings have always been available; they have been, and continue to be, the most significant mechanism for raising and resolving issues. But there are occasions when those mechanisms are inadequate. That is why the agency created the citizen petition. FDA is now pointing to the problem – inadequate informal communications – and calling it the solution. The real problem now is that the citizen petition process receives inadequate management attention. The solution is for FDA to provide the necessary management attention, not to cut back the citizen petition from the areas of FDA's activity where it is most needed.

**2. The Alternatives FDA Has Proposed for Requests Not Meeting the Requirements of Proposed § 10.30(b) Are Inadequate**

In the proposal, FDA states that the public may “contact FDA on matters outside the three types of actions described in proposed § 10.30(b) . . . through other means, such as correspondence, electronic mail, telephone calls etc., and FDA will respond to such correspondence and other communications promptly.” 64 Fed. Reg. at 66824. However, requests submitted through these other modes of communication with the agency are not afforded the same safeguards of procedural regularity that are provided for requests submitted in a citizen petition. Indeed, these other means of communicating with the agency are not adequate at all because if they were, the agency would not have revised the citizen petition process in 1975 to allow requests typically made through informal correspondence to be made by a citizen petition. See discussion supra parts I and II.A.1.b.

**a. FDA's Response to Informal Correspondence Does Not Constitute an Institutional Response**

FDA's response to informal correspondence, whether by letter, telephone, or electronic mail, is not subject to the “internal agency review and clearance of [a] petition response.” 64 Fed. Reg. at 66822. Rather, individual FDA employees respond to informal correspondence, which can result in different FDA employees giving inconsistent or incorrect versions of agency policy. For example, if a letter is sent or a

phone call is placed to FDA requesting the agency to address a particular issue, the letter or phone call could be directed to an FDA employee who, believing that he or she knows the agency's position on the matter, mistakenly gives an incorrect response.<sup>1</sup> However, had the letter or phone query been in the form of a citizen petition, it would have been thoroughly reviewed and addressed by the appropriate agency officials, resulting in an accurate institutional response to the letter. Moreover, the FDA employee's response to the letter or phone query could be changed at a later date – either by the employee or by another agency official. Institutional responses, on the other hand, remain the same unless the agency modifies its response through appropriate administrative procedures.

An example of agency policy on an issue that was not cleared by appropriate government officials is the recent letter from the Occupational Safety and Health Administration (OSHA) to a company informing the company that its “normal workplace safety obligations also apply to employees who do their work at home.” See “Labor Department Does About-Face on Home Office Letter” (visited Jan. 7, 2000) <<http://cnn.com/2000/US/01/05/home.office.apl>>. The letter, which was placed on the Department of Labor's web site, was written by OSHA officials in response to the company's request for “advice about moving some of its sales executives into home offices.” *Id.* The Secretary of Labor “acknowledged that the ‘letter of interpretation’ had never been received by her office for policy review,” and, as a result of industry's reaction to the letter, she withdrew the letter, stating that it was an “informal [letter] and was not intended to be taken as a statement of policy for the entire business community.” See “Labor Chief Retreats on Home Offices” (visited Jan. 10, 2000) <<http://www.msnbc.com/news/354129.asp>>. Had this issue been addressed by the appropriate OSHA officials, the response would likely have been very different. This incident demonstrates how agency policy can be misstated when not addressed by or, at a minimum, discussed with top administrative officials.

**b. Issues Brought Before FDA Through Informal Correspondence Are Not Part of a Public Review Process**

The issues presented to FDA through informal correspondence and FDA's responses to such issues are not subject to a public review process as are citizen petitions. Thus, the public has no way of knowing the types of issues that the agency is addressing,

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<sup>1</sup> Similarly, even if a person knows which FDA officials have decision-making authority and requests the presence of those officials in a meeting with the agency, the request does not guarantee that those particular FDA officials will attend the meeting. 21 C.F.R. § 10.65(d)(2) (“FDA will determine which representatives of the Agency will attend the meeting.”).

let alone the agency's responses to them. Without this knowledge, the public will have no idea whether FDA is applying its policies in a fair and consistent manner. For example, an FDA employee may respond to a person's telephone inquiry with a completely different answer than that given by another FDA employee to a person asking the same question. If a question is placed in a public docket, however, the public is aware of the issue before the agency and can determine whether the agency is applying its policies in a fair and consistent manner.

Although correspondence to and from the agency and summaries of informal meetings held with FDA may be placed in an administrative file (and therefore may be subject to public disclosure through a Freedom of Information Act request), see 21 C.F.R. §§ 10.65(g), (h); 10.70, the administrative file is of no use to those persons not originally aware of the correspondence or meetings, because those persons have no way of knowing that the issues have been brought before the agency by the use of informal communications.<sup>2</sup>

**c. Scientific Issues Having Important Public Health Implications Will Not Be as Thoroughly or Carefully Considered**

If FDA adopts the rule as proposed, then requests for agency action on matters outside proposed § 10.30(b) that are of a highly scientific nature and that have important public health ramifications will have to be made by the submission of informal correspondence. 64 Fed. Reg. at 66824. Moreover, FDA is proposing to give itself the option of treating as correspondence those requests that are properly submitted under § 10.30(b) and that “[p]resent[] scientific or technical issues or data . . . specific to a particular product or class of products.” Id. at 66828 (proposed § 10.30(e)(4)(i)(B), (F)).

Persons presenting to FDA scientific questions having public health implications should have the option of requesting that the questions be addressed in a citizen petition, where they are more likely to receive a thorough agency review. Such a review advances the interests not only of the person submitting the petition but those of the public as well.

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<sup>2</sup> The Department of Labor posts on its web site at least some of the letters it writes in response to correspondence submitted by the public. The controversial OSHA letter, discussed above, was spotted by those in industry who read the letter on the Department's web site. But for the letter being public, no one would have known how OSHA intended to apply its policy to a particular company, and industry would not have been able to express its concern over the contents of the letter. FDA does not affirmatively make informal correspondence publicly available.

For example, on June 12, 1998, Berlex and 3M Pharmaceuticals, a division of Minnesota Mining & Manufacturing Company (3M), submitted a citizen petition to the agency requesting that FDA not approve a generic version of Climara® (estradiol transdermal system) for which an abbreviated new drug application (ANDA) pending or filed in the future has been submitted citing Climara® as the reference listed drug (RLD) until the agency has established approval standards for generic transdermal estradiol patches. Under FDA's proposed rule, Berlex and 3M's citizen petition would have had to have been submitted to the agency as informal correspondence because it requests an administrative action outside proposed § 10.30(b).<sup>3</sup> However, Berlex and 3M's citizen petition addresses regulatory and scientific issues, such as the establishment of bioequivalence parameters for transdermal products, and FDA's decisions on these issues will have a profound impact on women's health. Such issues deserve a careful and thorough agency review of the type the agency states is required by the citizen petition process, and Berlex would fully expect FDA to engage in such a careful review of the petition irrespective of whether the issues raised in the petition were presented in a letter, a meeting, or a phone call. However, Berlex submits that those issues are of a type and magnitude that warrant the formal, public proceeding, and institutional, administratively final, FDA response that the citizen petition procedure provides for. These issues do not lack sufficient public health importance to qualify for such a proceeding merely because they do not fit the "regulation" or "order" categories in the agency's proposal.

**d. FDA's Response to Informal Correspondence Does Not Constitute Final Agency Action**

FDA's response to informal correspondence submitted to the agency – including phone calls, electronic mail, and letters – as well as any statements FDA makes in the course of any meetings with the public, does not constitute "final agency action" and, therefore, is not subject to judicial review. 21 C.F.R. §§ 10.45(a), 10.65(a). FDA has not explained how a person can obtain final agency action on an agency response to a request made in an informal communication.

**e. Informal Communications Are Less Likely to Receive the Agency's Focused Attention**

Because informal communications with the agency are not subject to judicial review, are not a part of a public process, and do not require an institutional response,

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<sup>3</sup> In fact, Berlex and 3M first attempted to resolve their issue with FDA through informal means, by meeting with FDA. It was because their meeting with the agency to discuss the establishment of approval standards for generic transdermal estradiol patches proved unable to resolve all of the significant scientific issues that Berlex and 3M submitted this citizen petition.

requests made in such communications will be less likely to catch the attention of the agency as a whole. Thus, it will be difficult for persons to make the agency aware of important, substantive public health matters arising in contexts not involving regulations or already-issued orders if such matters are addressed by the agency only through informal means, as proposed by FDA.

**B. FDA's Reasons for Limiting the Citizen Petition Process to Matters in Proposed § 10.30(b) Are Inadequate**

In the proposal, FDA makes several attempts to justify why requests relating to future orders and requests for FDA to take or refrain from taking administrative action should not be submitted through the citizen petition process. As explained below, FDA's reasoning is unpersuasive.

FDA states that its proposed changes to § 10.30(b) "will enable FDA to focus its resources on addressing substantive issues or controversies, rather than devote resources to speculating about future orders or to addressing subjects which may not be an agency priority or present any significant public health issues," 64 Fed. Reg. at 66823 (emphasis added), even though later in the proposal, FDA suggests that citizen petitions raising "substantive scientific issues" should not be handled through the citizen petition process, id. at 66825.

This unresolved paradox in FDA's explanation for the proposal is indicative of the agency's failure to identify any policy-based principle – indeed, any principle at all – for distinguishing the types of actions FDA proposes to disqualify from the citizen petition procedure from those that will remain subject to it. For one thing, it is not clear what FDA means by "substantive." The word is usually contrasted with "procedural," but the agency does not say that persons are burdening it with citizen petitions relating to procedural issues. By "substantive," FDA probably means "important." If so, the agency makes no attempt to explain why only issues relating to rules or orders are important enough to warrant the significant effort it claims is necessary to organize a response for a citizen petition, requiring it to examine regulatory, "scientific, medical, legal, and sometimes economic issues."

A possible dividing line could be between matters of broad, general interest and those relating to a specific product. Yet the agency's explanation does not suggest that the basis for the proposal is its belief that the citizen petition process should be reserved for matters affecting categories of products or agency actions, or cross-cutting agency policies or standards. On the contrary, under FDA's revised approach, the citizen petition process would be available to raise issues relating to "orders," which generally have a very specific focus and restricted applicability, often affecting a specific product or person.

In sum, FDA's proposal does not articulate any reasoned basis for changing the citizen petition procedure in the ways proposed, except for several practical considerations, which are discussed below. Connecticut Light and Power Co. v. Nuclear Regulatory Comm'n, 673 F.2d 525, 530 (D.C. Cir. 1982) (stating that a notice of proposed rulemaking should provide an accurate picture of the reasoning that has led the agency to the proposed rule).

The practical considerations FDA relies on to justify the proposed restriction of the citizen petition procedure are similarly unconvincing. First, FDA suggests that its proposed changes to the citizen petition process will save the agency time. They will not. Under FDA's existing regulations, for example, FDA can act swiftly upon those citizen petitions that do not warrant extensive consideration by the agency, but FDA has infrequently exercised this option. Conversely, under FDA's proposal, "requests" for future orders or other administrative action that raise serious public health issues will still have to be given appropriately in-depth consideration by the agency – even if not submitted as citizen petitions – because not addressing them properly would be contrary to the public interest and inconsistent with legal requirements. The only appreciable differences between the citizen petition mechanism and FDA's proposed changes to that mechanism, then, are that the changes will make FDA consideration of significant categories of requests less public and less predictable. Thus, FDA's proposed changes are not defensible on the ground of cost-effectiveness.

FDA implies that its proposal will save time by eliminating a large number of requests that are currently subject to the agency's thorough and comprehensive citizen petition review. FDA states that it must research and examine the scientific and medical issues raised by matters brought to the agency's attention in citizen petitions. 64 Fed. Reg. at 66822. FDA does not say, however, that these requests raise unmeritorious issues, or issues that do not require the agency to engage in substantive scientific review. FDA states that "it may be more appropriate for the agency to investigate the scientific issues or conduct a meeting to discuss those issues," *id.* at 66825, without explaining either how proceeding in this fashion will result in a significant reduction in its administrative burden or why the use of those procedures is incompatible with the issuance of a response to a citizen petition.

It is certainly possible that FDA could reduce its administrative burden by requiring persons to use alternative methods of raising issues, if the agency is operating on the assumption that such vehicles of communication as letters, phone calls, and meetings do not require it to give as much consideration to issues pursued in those ways as to issues submitted in citizen petitions. If that were FDA's reasoning, it would be improper. An administrative agency should conscientiously attempt to resolve all issues on their merits. The time and resources it applies to that process should be commensurate with the importance and difficulty of the issues, not with the procedural format in which the issues are raised.

FDA does not state that alternatives to the citizen petition will avoid the burden on the agency of providing a well thought-out response to a legitimate issue. However, FDA does suggest that alternative mechanisms may be a quicker and more efficient means than the citizen petition of obtaining the agency's position. See id. at 66822. This suggestion is belied by experience. Informal communications such as correspondence are subject to the same administrative delays as are citizen petitions. For example, letters are staffed and subject to a time-consuming decision-making process, and drafting responses has to compete with other agency priorities. Thus, FDA's proposed changes to the citizen petition process will not result in faster agency responses to matters submitted through informal mechanisms.

FDA's belief that issues relating to actions yet to be taken are not as important as issues relating to actions already taken is wrong. FDA proposes to "remove a person's ability to petition FDA to issue an order or to affect a pending order" and suggests that persons wishing to submit information to the agency regarding future or pending orders do so through letters, electronic mail, or other informal correspondence. Id. at 66824. FDA states that if it "receives important information before it makes a decision, it will make appropriate use of that information." Id. However, issues are no less important if they relate to an action yet to be taken than if they relate to an action already completed. For example, Berlex and 3M's citizen petition requests future agency action – the development of approval standards for generic transdermal estradiol patches – and this request is as important as any request relating to actions the agency has already taken. More importantly, the citizen petition procedure is currently used in some circumstances for the specific purpose of influencing an FDA action before the action is taken. This is done in recognition that the agency may be more open to considering counter proposals and alternatives before it takes an action than it is likely to be after it has reached a decision and issued a public position. See, e.g., National Tour Brokers Ass'n v. United States, 591 F.2d 896, 902 (D.C. Cir. 1978) ("People naturally tend to be more closed-minded and defensive once they have made a 'final' determination.") (footnote omitted). Moreover, many "future" FDA actions (e.g., the approval of an ANDA submitted by a third party) directly affect, but do not specifically relate to, persons who submit citizen petitions. For those persons, the citizen petition is an important administrative remedy. Although FDA says it will respond appropriately to information brought to its attention by informal means, 64 Fed. Reg. at 66826, the agency does not explain why such a response cannot be in the form of a response to a citizen petition.

Finally, FDA suggests that current § 10.30(b) is used for "improper purposes, such as delaying competition . . . or delaying agency action." Id. at 66822. However, FDA does not offer any evidence that it has received such petitions or that any agency action has ever been inappropriately delayed as a result. Furthermore, if a petition submitted for an "improper purpose" lacks merit, it should not take FDA a long time to dispose of it, because a meritless petition would not require the agency to address the

type of genuine, substantive issues that require a careful review. If the petition raises issues requiring a significant evaluation and response by the agency, on the other hand, it follows that the issues are meritorious. FDA does not explain why it would be proper for it to disregard meritorious issues based on the agency's belief that they were put before the agency for an ulterior purpose, or why it is "improper" to request the agency not to approve a competitor's product on the basis of scientific, medical, and technical considerations explained in the petition. Nor does FDA explain why channeling such efforts into "informal communications" will save time or improve FDA's administrative efficiency if, as FDA insists, it intends to provide a substantive scientific review and response to issues raised by informal mechanisms.

### **III. FDA SHOULD IMPLEMENT MANAGEMENT REFORMS TO MAKE THE CITIZEN PETITION PROCESS WORK BETTER**

In its 1998 report on FDA's citizen petition process, the Department of Health and Human Services' (HHS') Office of Inspector General (OIG) concluded that FDA "does not have an effective process for handling citizen petitions in a timely manner." See OIG, HHS, Review of the Food and Drug Administration's Citizen Petition Process, at 3 (July 1998) (hereinafter "OIG Report"). The OIG noted several factors that contribute to the problems FDA is experiencing with the process, including:

(1) the absence of uniform policies and procedures; (2) an inadequate process for screening and prioritizing petitions; (3) the tentative response option that enables FDA to meet its 180-day requirement while allowing petitions to go unanswered for years; and (4) [the] lack of central management and oversight of the process at a high level within FDA . . . .

Id. at 5. The OIG noted that FDA had already studied the citizen petition process and that although FDA had "developed several options for reducing the citizen petition backlog," the agency had "not implemented most of them." Id. at 7. The OIG recommended that FDA "promptly" implement, "where practical," the options FDA developed to improve the citizen petition process and consider the additional approaches the OIG recommended to further improve the process.

FDA has begun to implement some of the options it developed as a means to improve the citizen petition process. This proposed rule is one of those options. See id. at 7. However, Berlex believes that FDA's proposal puts the cart before the horse. FDA should first try to improve the citizen petition process. Only if that effort proves inadequate should the agency consider eliminating the types of requests that can be made by citizen petition. FDA states that it "has taken, or is exploring, various administrative approaches to reduce its citizen petition backlog and improve its handling of citizen petitions." 64 Fed. Reg. at 66823. One administrative approach FDA is exploring is the improvement of its "managerial and oversight responsibility for citizen petitions," which

is what OIG recommended to FDA in its report. Id.; see OIG Report at 7. It makes no sense for FDA to take the drastic measure of proposing to eliminate certain types of requests from being addressed through the citizen petition mechanism before implementing the administrative approaches it and OIG have developed to improve FDA's handling of citizen petitions. The implementation of OIG's recommendations, in combination with some of FDA's proposed changes to the citizen petition process, will make the citizen petition process more efficient and effective and thus may make FDA's proposed changes unnecessary.<sup>4</sup>

For example, Berlex supports FDA's proposal to issue brief denials for those citizen petitions not warranting a lengthy response. See 64 Fed. Reg. at 66824 (proposed § 10.30(e)(2)(ii)). If a petition makes a meritless request, for instance, there is no reason why FDA should prepare a lengthy analysis of the technical basis for the request. Berlex also supports FDA's proposal to consolidate petitions involving the same product or subject matter. See 64 Fed. Reg. at 66825 (proposed § 10.30(e)(4)(iv)). It makes sense that the agency should be permitted to dispose of an issue once instead of having to address it multiple times. Finally, Berlex supports FDA's proposals to allow itself to seek clarification of a petitioner's request, see 64 Fed. Reg. at 66825 (proposed § 10.30(e)(4)(ii)), and to consider a citizen petition to be withdrawn when the petitioner no longer exists, cannot be located, or has stated that it no longer desires a response, see 64 Fed. Reg. at 66825 (proposed § 10.30(e)(4)(iii)). These two changes are practical and will help the agency become more efficient.

In sum, FDA is ahead of itself in proposing to alter the citizen petition process instead of first trying to make the process work better. Berlex believes that OIG's recommendations and those changes to proposed § 10.30 that Berlex supports would significantly improve the citizen petition process without having to limit the types of requests that may be made in a citizen petition. At a minimum, these changes should be

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<sup>4</sup> Indeed, it was the very lack of FDA managerial and oversight responsibility for citizen petitions that required Berlex and 3M to file supplements to their June 12, 1998, citizen petition. In the January 8, 1999, supplement, Berlex and 3M brought to FDA's attention the absence of several letters submitted to the agency on the issue of Berlex and 3M's citizen petition that were not placed in the public docket as required by FDA regulations. See 21 C.F.R. §§ 10.30(d), 10.30(i). In the March 24, 1999 supplement, Berlex informed FDA that another letter sent to the agency on the subject of Berlex and 3M's citizen petition was also not added to the docket. These two supplements to Berlex and 3M's citizen petition would probably have been unnecessary had FDA had in place appropriate managerial and oversight responsibility for citizen petitions.

given a chance to work before a decision is made to limit the public's procedural options in seeking redress from the agency.

#### **IV. SHOULD FDA ADOPT THE PROPOSED RULE, FDA SHOULD NOT APPLY IT RETROACTIVELY**

Should FDA adopt the rule as proposed, it would be fundamentally unfair to apply the rule to those citizen petitions already filed with the agency. The filing of a citizen petition requires a considerable amount of time, effort, and expense. In many cases, those filing petitions have sought the advice of outside counsel and scientific and economic experts, and have expended an extensive amount of their own time and resources in putting a petition together. So much effort is placed into the drafting of a citizen petition because a petitioner submits a petition with the expectation that the petition's contents will be public and thoroughly reviewed by those high-level FDA officials having decision-making authority. In addition, FDA's decision on a citizen petition is subject to judicial review, so petitions are carefully drafted with this in mind. With all of the effort, time, and expense put forth in the filing of a citizen petition, applying proposed § 10.30 to those petitions already filed with FDA would be unfair.

Retroactive application of administrative rules is "not favored in the law." Bowen, 488 U.S. at 208. In Bowen, the petitioners challenged the retroactive effect given by the Department of Health and Human Service (HHS) to a wage-index rule for calculating the limit on reimbursable wage costs under the federal health care reimbursement programs. Id. at 207. The Supreme Court held that HHS did not have the authority to promulgate a retroactive rule. Id. at 215. The Court stated that "[e]ven where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant." Id. at 208-09; see also Motion Picture Ass'n of America, Inc. v. Oman, 969 F.2d 1154, 1156 (D.C. Cir. 1992) ("Agencies do not have authority to promulgate retroactive rules unless Congress gives them that authority in express terms.").

FDA derives its rulemaking authority from § 553 of the APA and § 701 of the Federal Food, Drug, and Cosmetic Act (FDC Act). The APA defines a "rule," in pertinent part, as "an agency statement of general or particular applicability and future effect." 5 U.S.C. § 551(4) (emphasis added); see also Bowen, 488 U.S. at 216 (Scalia, J., concurring). Although rules of "agency organization, procedure, or practice" are exempt from specified requirements, 5 U.S.C. § 553(b), they are otherwise subject to the APA's rulemaking requirements. Neither the APA nor the FDC Act provide for the retroactive application of administrative rules. See 5 U.S.C. § 553; 21 U.S.C. § 371(a). Under Bowen, therefore, FDA lacks the authority to apply proposed § 10.30 retroactively.

## V. CONCLUSION

In sum, the citizen petition process was developed by FDA for important reasons, and now, in experiencing some difficulties with the process, the agency is proposing to change it. However, FDA lacks a basis for at least two of its proposed changes, and FDA has proposed these changes without having taken the first logical step to make the citizen petition process work better: establish management and oversight responsibility for the citizen petition process, as recommended by the OIG.

FDA should first implement management reform in order to make the citizen petition process work better. Only if this fails should FDA consider eliminating some of the types of requests that may be made by a citizen petition. However, if FDA adopts the rule as proposed, then FDA should apply the rule prospectively only. To apply the rule to those petitions already submitted to the agency would be fundamentally unfair, and the retroactive application of administrative rules is not favored in the law.

Berlex Laboratories, Inc. (Berlex) submits these comments on the Food and Drug Administration's (FDA's) proposed rule regarding the actions that can be requested by the filing of a citizen petition.

FDA proposes to limit the types of actions that may be requested by a citizen petition to the following: (1) the issuance, amendment, or revocation of a regulation, (2) the amendment or revocation of an order that FDA has issued or published, and (3) a request for agency action as "specifically authorized by another FDA regulation." 64 Fed. Reg. 66822 (Nov. 30, 1999). FDA states that requests for agency action that are outside the scope of the proposal would have to be submitted to FDA through informal correspondence, such as telephone calls and letters. *Id.* FDA additionally proposes to increase its flexibility in responding to citizen petitions so that it may treat certain petitions as correspondence or refer them to other agency proceedings. *Id.* FDA believes that these proposed changes to the citizen petition process will, among other things, reduce the citizen petition backlog, allow FDA to respond to requests for agency action faster, and prevent the submission of frivolous petitions. *Id.* at 66822-23.

Berlex supports several of FDA's proposed changes to the citizen petition process, but Berlex opposes FDA's proposed limit on the types of action the agency can be requested to take. The benefits from having the citizen petition process to formalize and finalize the agency's position on important matters that fall outside proposed § 10.30(b) cannot be replicated through the submission of informal correspondence to the agency. Moreover, FDA's proposed limits on the types of issues that may be requested by a citizen petition will not necessarily eliminate the problems that the agency is encountering with the citizen petition process and, as further discussed below, will generate new problems that the agency will have to solve. Furthermore, Berlex believes that the problems FDA is experiencing with the citizen petition process can be taken care of through other means, such as management reform, which would improve the efficiency of the petition process.

Nevertheless, in the event FDA adopts proposed § 10.30, Berlex urges that it not be applied retroactively to those petitions that have already been filed with FDA's Dockets Management Branch. "Retroactivity is not favored in the law." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988). It would be fundamentally unfair to apply the rule to those petitions already filed with the agency. The filing of a citizen petition requires time, effort, and expense. Those who have filed petitions have done so because they believed that such costs were worth receiving a comprehensive agency review of a matter and a final administrative response. Thus, for these reasons, FDA should apply the rule prospectively only.

## **I. THE ORIGIN, PURPOSE, AND TRACK RECORD OF THE CITIZEN PETITION PROCESS**

At its inception, the citizen petition process was intended to provide the public a means to petition the FDA to either issue, amend, or repeal a regulation. 31 Fed. Reg. 3003, 3004 (Feb. 22, 1966). Almost ten years later, however, the agency, in recognizing the Administrative Procedure Act's requirement that "any interested person [have] the right to petition for the issuance, amendment, or repeal of a rule," and in recognizing the First Amendment to the Constitution, which "explicitly recognizes the right of the people to petition the government for a redress of grievances," proposed that the citizen petition process "cover every form of agency administrative activity, including a refusal to act." 40 Fed. Reg. 40682, 40686 (Sept. 3, 1975). FDA believed that this change to the petition process, which the agency ultimately adopted, was necessary to afford the public a known framework within which they could request FDA to take or refrain from taking administrative action and receive a formal agency response. Id. FDA also believed that the change would provide guidance to the agency as to how to handle and respond to the public's requests for various types of agency action. Id.

FDA is now proposing to exclude from the citizen petition process the very types of requests the agency felt necessary to include in the petition process, as evidenced by the agency's 1975 changes to the rule, and FDA is proposing to exclude such requests without demonstrating how or why the purpose of using the citizen petition process for such requests is less important today. The citizen petition process continues to provide the public with a structured procedure to follow when requesting agency action on matters not falling under proposed § 10.30(b), and it continues to ensure that requests made by a citizen petition will receive a structured agency response. It is therefore no less valuable to the public today than it was when FDA revised the petition process 25 years ago.

FDA states that changes to the citizen petition process are needed because the process, as it currently operates, is not working well. 64 Fed. Reg. at 66823. If there are problems with the citizen petition process, however, the logical first step is to attempt to make the process work better, not to disqualify a large proportion of petition requests from receiving its benefits. See discussion infra part III. Furthermore, the changes FDA is proposing – that requests outside of proposed § 10.30(b) be submitted via informal correspondence – would reestablish the very mechanisms to contact the agency that FDA regarded as insufficient in 1975 and that caused the agency to expand the types of requests that may be made by a citizen petition. Nowhere in the proposal does FDA explain how the value of the citizen petition process, in providing a known, certain administrative procedure, will be achieved by reverting to exclusive reliance on the informal methods of contacting the agency that the citizen petition was intended to augment.

Informal methods of bringing matters before the agency serve a useful purpose. Indeed, they are indispensable. Most issues between FDA and the public are addressed through correspondence, meetings, and phone calls. But there are situations where those procedures are inadequate. In such cases, the public should continue to have the option of requesting action through the citizen petition process so that a formal and final agency response can be obtained.

## **II. FDA LACKS A BASIS FOR AT LEAST TWO OF ITS PROPOSED CHANGES TO THE CITIZEN PETITION PROCESS**

Although Berlex believes that some of FDA's proposed changes to the citizen petition process are good and will help make the process more efficient and effective, Berlex opposes two of FDA's proposed changes, those excluding from the citizen petition procedure requests relating to future "orders" and requests to take or refrain from taking action other than as specifically provided. These changes would make the citizen petition procedure unavailable with respect to major categories of FDA administrative activity having potentially significant public health, legal, regulatory, and economic consequences. FDA fails to provide adequate evidence or to cite logical grounds for why it makes sense to single out FDA activity not amenable to a regulation, and not the result of an existing order, for exclusion from the citizen petition process. FDA also fails to explain why the agency has decided not to improve the management of the citizen petition process as a means of addressing the difficulties it says it is experiencing.

### **A. FDA Has No Basis to Prevent Requests Relating to Agency Orders and Requests for FDA to Take or Refrain From Taking Agency Action From Being Made Through the Citizen Petition Process**

FDA's proposed rule would prohibit persons from petitioning the agency to "amend pending FDA orders or issue future FDA orders" or from requesting it to "take or refrain from taking any other form of administrative action" unless the request pertains to the issuance, amendment, or repeal of a regulation or is "specifically provided by regulation." 64 Fed. Reg. at 66823-24. FDA has not demonstrated, however, how the types of requests that FDA is proposing to eliminate from the citizen petition process are different from the types of requests that FDA intends to allow through such a process. The purpose of the citizen petition mechanism – to provide an open, known administrative process – is just as valuable for requests to FDA to amend a pending order or issue or refrain from issuing a future order, or to request the agency to take or refrain from taking administrative action, as it is for requests to the agency to amend, issue, or revoke a regulation or amend or revoke an existing order. Regardless of the type of request, the citizen petition process provides the public with an established, structured procedure to follow that requires a formal agency response.

## **1. Advantages of the Citizen Petition Process**

There are significant advantages in allowing requests for future FDA orders and requests for FDA to take or refrain from taking administrative action to be made by a citizen petition. The advantages include the following:

### **a. An Institutional Response**

The citizen petition procedure requires the FDA both to research and examine the regulatory, scientific, medical, legal, and economic issues raised by citizen petitions and to “coordinate internal agency review and clearance of the petition response.” *Id.* at 66822. Thus, the submission of a citizen petition requires an agency response as opposed to the response of an individual FDA employee. An employee’s response to an informal contact may provide helpful guidance or useful insights. But it does not represent FDA’s institutional position. Agency activity other than regulations and orders is certainly capable of creating issues that may warrant an institutional response by the agency. The notice of proposed rulemaking (NPRM) identifies no reason for concluding that issues arising from such FDA activity are inherently less important than issues related to a rule or an order.

### **b. An Open, Public Process That Ensures That the Agency Applies Its Policies in a Fair and Consistent Manner**

Citizen petitions are filed in FDA’s Dockets Management Branch so that the public may view the contents of the petitions and submit comments on the issues they raise. 21 C.F.R. § 10.30(c), (d). In addition, the subject matter of and decisions made on citizen petitions are often disseminated in the media, which provides another means of informing the public of issues addressed by the agency. Public awareness of issues addressed by FDA ensures that FDA applies its policies in a fair and consistent manner. This advantage of the citizen petition process is more, not less, important for issues arising from FDA authority that is unrelated to rulemaking and already issued orders. Rules and orders are subject to other administrative procedures, whose utilization by the agency and the public assures openness and fairness without regard to the citizen petition mechanism. It was the very lack of such established administrative procedures for other areas of FDA activity that led FDA to extend the citizen petition into those areas – where it constitutes the only formally structured body of procedures available to persons outside the agency to address important matters. The agency’s proposal would thus eliminate the citizen petition mechanism in those areas where it is most needed.

### **c. Deliberate Formal Agency Consideration of Important Scientific Questions Having Public Health Implications**

As FDA noted in its proposal, the agency thoroughly and carefully reviews the issues presented in citizen petitions. *See* 64 Fed. Reg. at 66822. Thus, scientific matters

having public health implications are assured a meticulous and well thought-out institutional review. Important public health and scientific issues are not found only in contexts in which a regulation has been, or should be, issued, or in matters that have been the subject of an order. If the citizen petition process increases the likelihood that FDA will give an appropriately intensive review to important issues, then the procedure should continue to be available for any matter in which an important issue arises, rather than being arbitrarily limited to those occasions when important issues happen to arise in a regulation or an already-issued order.

**d. Final Agency Action**

FDA regulations provide that the Commissioner's final decision on a citizen petition constitutes "final agency action," which allows the subject matter of the petition to be reviewed in court. 21 C.F.R. § 10.45(d). The finality of the agency's decision and the possibility of judicial review of the decision are incentives for the agency to ensure that it has thoroughly considered the petition and that those FDA officials having agency decision-making authority have collectively agreed upon the agency's position. As with other advantages of the citizen petition process, the finality of a citizen petition response and the availability of judicial review based on the results of focused, high-level FDA decision-making, are just as important for issues not involving rulemaking or orders. For those issues, it is an advantage that is available only because of the current citizen petition procedure. Rules and orders are subject to separate procedures for assuring finality. Withdrawing the citizen petition procedure from other types of FDA activity has the paradoxical effect of eliminating it as a means of obtaining judicially reviewable final agency action for those matters where only the citizen petition can assure final agency action, while continuing to provide the citizen petition for use in matters where it is unnecessary for that purpose.

**e. A Mechanism for the Public to Petition FDA and Receive a Structured Response**

As discussed in part I, the citizen petition process provides the public with a knowable, objective procedure to make a request of the agency, and it guarantees that those requesting agency action on an issue will receive a suitable institutional decision. In addition, the citizen petition process provides FDA with a procedure to follow in issuing responses to petitions. The existence of a citizen petition procedure encourages, and was meant to encourage, persons outside the agency to pursue their right to make a request of the agency to take, or not to take, action. If the citizen petition process is restricted, persons will be less likely to take advantage of their right to make requests of the agency. It may be that, as a result, FDA will be less burdened with requests, but this is a bureaucratic convenience that will be achieved at the expense of abandoning an important civic value.

## **f. FDA's Awareness of Petitions**

The public nature of the citizen petition process, the requirement that FDA must respond to citizen petitions, and the fact that the agency's responses to petitions are subject to judicial review guarantee that the agency will become aware of the petition and, at some point, review the contents of the petition. See 21 C.F.R. §§ 10.30(e)(1), 10.45(d). It is true, as FDA says, that persons outside the agency can convey requests and views by informal means, such as letters and phone calls. However, because such communications lack the defined procedural framework of the citizen petition process, there is less assurance that the agency will respond to them in a direct and timely fashion. Letters, phone calls, and meetings have always been available; they have been, and continue to be, the most significant mechanism for raising and resolving issues. But there are occasions when those mechanisms are inadequate. That is why the agency created the citizen petition. FDA is now pointing to the problem – inadequate informal communications – and calling it the solution. The real problem now is that the citizen petition process receives inadequate management attention. The solution is for FDA to provide the necessary management attention, not to cut back the citizen petition from the areas of FDA's activity where it is most needed.

### **2. The Alternatives FDA Has Proposed for Requests Not Meeting the Requirements of Proposed § 10.30(b) Are Inadequate**

In the proposal, FDA states that the public may “contact FDA on matters outside the three types of actions described in proposed § 10.30(b) . . . through other means, such as correspondence, electronic mail, telephone calls etc., and FDA will respond to such correspondence and other communications promptly.” 64 Fed. Reg. at 66824. However, requests submitted through these other modes of communication with the agency are not afforded the same safeguards of procedural regularity that are provided for requests submitted in a citizen petition. Indeed, these other means of communicating with the agency are not adequate at all because if they were, the agency would not have revised the citizen petition process in 1975 to allow requests typically made through informal correspondence to be made by a citizen petition. See discussion supra parts I and II.A.1.b.

#### **a. FDA's Response to Informal Correspondence Does Not Constitute an Institutional Response**

FDA's response to informal correspondence, whether by letter, telephone, or electronic mail, is not subject to the “internal agency review and clearance of [a] petition response.” 64 Fed. Reg. at 66822. Rather, individual FDA employees respond to informal correspondence, which can result in different FDA employees giving inconsistent or incorrect versions of agency policy. For example, if a letter is sent or a

phone call is placed to FDA requesting the agency to address a particular issue, the letter or phone call could be directed to an FDA employee who, believing that he or she knows the agency's position on the matter, mistakenly gives an incorrect response.<sup>1</sup> However, had the letter or phone query been in the form of a citizen petition, it would have been thoroughly reviewed and addressed by the appropriate agency officials, resulting in an accurate institutional response to the letter. Moreover, the FDA employee's response to the letter or phone query could be changed at a later date – either by the employee or by another agency official. Institutional responses, on the other hand, remain the same unless the agency modifies its response through appropriate administrative procedures.

An example of agency policy on an issue that was not cleared by appropriate government officials is the recent letter from the Occupational Safety and Health Administration (OSHA) to a company informing the company that its “normal workplace safety obligations also apply to employees who do their work at home.” See “Labor Department Does About-Face on Home Office Letter” (visited Jan. 7, 2000) <<http://cnn.com/2000/US/01/05/home.office.apl>>. The letter, which was placed on the Department of Labor's web site, was written by OSHA officials in response to the company's request for “advice about moving some of its sales executives into home offices.” *Id.* The Secretary of Labor “acknowledged that the ‘letter of interpretation’ had never been received by her office for policy review,” and, as a result of industry's reaction to the letter, she withdrew the letter, stating that it was an “informal [letter] and was not intended to be taken as a statement of policy for the entire business community.” See “Labor Chief Retreats on Home Offices” (visited Jan. 10, 2000) <<http://www.msnbc.com/news/354129.asp>>. Had this issue been addressed by the appropriate OSHA officials, the response would likely have been very different. This incident demonstrates how agency policy can be misstated when not addressed by or, at a minimum, discussed with top administrative officials.

**b. Issues Brought Before FDA Through Informal Correspondence Are Not Part of a Public Review Process**

The issues presented to FDA through informal correspondence and FDA's responses to such issues are not subject to a public review process as are citizen petitions. Thus, the public has no way of knowing the types of issues that the agency is addressing,

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<sup>1</sup> Similarly, even if a person knows which FDA officials have decision-making authority and requests the presence of those officials in a meeting with the agency, the request does not guarantee that those particular FDA officials will attend the meeting. 21 C.F.R. § 10.65(d)(2) (“FDA will determine which representatives of the Agency will attend the meeting.”).

let alone the agency's responses to them. Without this knowledge, the public will have no idea whether FDA is applying its policies in a fair and consistent manner. For example, an FDA employee may respond to a person's telephone inquiry with a completely different answer than that given by another FDA employee to a person asking the same question. If a question is placed in a public docket, however, the public is aware of the issue before the agency and can determine whether the agency is applying its policies in a fair and consistent manner.

Although correspondence to and from the agency and summaries of informal meetings held with FDA may be placed in an administrative file (and therefore may be subject to public disclosure through a Freedom of Information Act request), see 21 C.F.R. §§ 10.65(g), (h); 10.70, the administrative file is of no use to those persons not originally aware of the correspondence or meetings, because those persons have no way of knowing that the issues have been brought before the agency by the use of informal communications.<sup>2</sup>

**c. Scientific Issues Having Important Public Health Implications Will Not Be as Thoroughly or Carefully Considered**

If FDA adopts the rule as proposed, then requests for agency action on matters outside proposed § 10.30(b) that are of a highly scientific nature and that have important public health ramifications will have to be made by the submission of informal correspondence. 64 Fed. Reg. at 66824. Moreover, FDA is proposing to give itself the option of treating as correspondence those requests that are properly submitted under § 10.30(b) and that “[p]resent[] scientific or technical issues or data . . . specific to a particular product or class of products.” Id. at 66828 (proposed § 10.30(e)(4)(i)(B), (F)).

Persons presenting to FDA scientific questions having public health implications should have the option of requesting that the questions be addressed in a citizen petition, where they are more likely to receive a thorough agency review. Such a review advances the interests not only of the person submitting the petition but those of the public as well.

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<sup>2</sup> The Department of Labor posts on its web site at least some of the letters it writes in response to correspondence submitted by the public. The controversial OSHA letter, discussed above, was spotted by those in industry who read the letter on the Department's web site. But for the letter being public, no one would have known how OSHA intended to apply its policy to a particular company, and industry would not have been able to express its concern over the contents of the letter. FDA does not affirmatively make informal correspondence publicly available.

For example, on June 12, 1998, Berlex and 3M Pharmaceuticals, a division of Minnesota Mining & Manufacturing Company (3M), submitted a citizen petition to the agency requesting that FDA not approve a generic version of Climara® (estradiol transdermal system) for which an abbreviated new drug application (ANDA) pending or filed in the future has been submitted citing Climara® as the reference listed drug (RLD) until the agency has established approval standards for generic transdermal estradiol patches. Under FDA's proposed rule, Berlex and 3M's citizen petition would have had to have been submitted to the agency as informal correspondence because it requests an administrative action outside proposed § 10.30(b).<sup>3</sup> However, Berlex and 3M's citizen petition addresses regulatory and scientific issues, such as the establishment of bioequivalence parameters for transdermal products, and FDA's decisions on these issues will have a profound impact on women's health. Such issues deserve a careful and thorough agency review of the type the agency states is required by the citizen petition process, and Berlex would fully expect FDA to engage in such a careful review of the petition irrespective of whether the issues raised in the petition were presented in a letter, a meeting, or a phone call. However, Berlex submits that those issues are of a type and magnitude that warrant the formal, public proceeding, and institutional, administratively final, FDA response that the citizen petition procedure provides for. These issues do not lack sufficient public health importance to qualify for such a proceeding merely because they do not fit the "regulation" or "order" categories in the agency's proposal.

**d. FDA's Response to Informal Correspondence Does Not Constitute Final Agency Action**

FDA's response to informal correspondence submitted to the agency – including phone calls, electronic mail, and letters – as well as any statements FDA makes in the course of any meetings with the public, does not constitute "final agency action" and, therefore, is not subject to judicial review. 21 C.F.R. §§ 10.45(a), 10.65(a). FDA has not explained how a person can obtain final agency action on an agency response to a request made in an informal communication.

**e. Informal Communications Are Less Likely to Receive the Agency's Focused Attention**

Because informal communications with the agency are not subject to judicial review, are not a part of a public process, and do not require an institutional response,

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<sup>3</sup> In fact, Berlex and 3M first attempted to resolve their issue with FDA through informal means, by meeting with FDA. It was because their meeting with the agency to discuss the establishment of approval standards for generic transdermal estradiol patches proved unable to resolve all of the significant scientific issues that Berlex and 3M submitted this citizen petition.

requests made in such communications will be less likely to catch the attention of the agency as a whole. Thus, it will be difficult for persons to make the agency aware of important, substantive public health matters arising in contexts not involving regulations or already-issued orders if such matters are addressed by the agency only through informal means, as proposed by FDA.

**B. FDA’s Reasons for Limiting the Citizen Petition Process to Matters in Proposed § 10.30(b) Are Inadequate**

In the proposal, FDA makes several attempts to justify why requests relating to future orders and requests for FDA to take or refrain from taking administrative action should not be submitted through the citizen petition process. As explained below, FDA’s reasoning is unpersuasive.

FDA states that its proposed changes to § 10.30(b) “will enable FDA to focus its resources on addressing substantive issues or controversies, rather than devote resources to speculating about future orders or to addressing subjects which may not be an agency priority or present any significant public health issues,” 64 Fed. Reg. at 66823 (emphasis added), even though later in the proposal, FDA suggests that citizen petitions raising “substantive scientific issues” should not be handled through the citizen petition process, id. at 66825.

This unresolved paradox in FDA’s explanation for the proposal is indicative of the agency’s failure to identify any policy-based principle – indeed, any principle at all – for distinguishing the types of actions FDA proposes to disqualify from the citizen petition procedure from those that will remain subject to it. For one thing, it is not clear what FDA means by “substantive.” The word is usually contrasted with “procedural,” but the agency does not say that persons are burdening it with citizen petitions relating to procedural issues. By “substantive,” FDA probably means “important.” If so, the agency makes no attempt to explain why only issues relating to rules or orders are important enough to warrant the significant effort it claims is necessary to organize a response for a citizen petition, requiring it to examine regulatory, “scientific, medical, legal, and sometimes economic issues.”

A possible dividing line could be between matters of broad, general interest and those relating to a specific product. Yet the agency’s explanation does not suggest that the basis for the proposal is its belief that the citizen petition process should be reserved for matters affecting categories of products or agency actions, or cross-cutting agency policies or standards. On the contrary, under FDA’s revised approach, the citizen petition process would be available to raise issues relating to “orders,” which generally have a very specific focus and restricted applicability, often affecting a specific product or person.

In sum, FDA's proposal does not articulate any reasoned basis for changing the citizen petition procedure in the ways proposed, except for several practical considerations, which are discussed below. Connecticut Light and Power Co. v. Nuclear Regulatory Comm'n, 673 F.2d 525, 530 (D.C. Cir. 1982) (stating that a notice of proposed rulemaking should provide an accurate picture of the reasoning that has led the agency to the proposed rule).

The practical considerations FDA relies on to justify the proposed restriction of the citizen petition procedure are similarly unconvincing. First, FDA suggests that its proposed changes to the citizen petition process will save the agency time. They will not. Under FDA's existing regulations, for example, FDA can act swiftly upon those citizen petitions that do not warrant extensive consideration by the agency, but FDA has infrequently exercised this option. Conversely, under FDA's proposal, "requests" for future orders or other administrative action that raise serious public health issues will still have to be given appropriately in-depth consideration by the agency – even if not submitted as citizen petitions – because not addressing them properly would be contrary to the public interest and inconsistent with legal requirements. The only appreciable differences between the citizen petition mechanism and FDA's proposed changes to that mechanism, then, are that the changes will make FDA consideration of significant categories of requests less public and less predictable. Thus, FDA's proposed changes are not defensible on the ground of cost-effectiveness.

FDA implies that its proposal will save time by eliminating a large number of requests that are currently subject to the agency's thorough and comprehensive citizen petition review. FDA states that it must research and examine the scientific and medical issues raised by matters brought to the agency's attention in citizen petitions. 64 Fed. Reg. at 66822. FDA does not say, however, that these requests raise unmeritorious issues, or issues that do not require the agency to engage in substantive scientific review. FDA states that "it may be more appropriate for the agency to investigate the scientific issues or conduct a meeting to discuss those issues," *id.* at 66825, without explaining either how proceeding in this fashion will result in a significant reduction in its administrative burden or why the use of those procedures is incompatible with the issuance of a response to a citizen petition.

It is certainly possible that FDA could reduce its administrative burden by requiring persons to use alternative methods of raising issues, if the agency is operating on the assumption that such vehicles of communication as letters, phone calls, and meetings do not require it to give as much consideration to issues pursued in those ways as to issues submitted in citizen petitions. If that were FDA's reasoning, it would be improper. An administrative agency should conscientiously attempt to resolve all issues on their merits. The time and resources it applies to that process should be commensurate with the importance and difficulty of the issues, not with the procedural format in which the issues are raised.

FDA does not state that alternatives to the citizen petition will avoid the burden on the agency of providing a well thought-out response to a legitimate issue. However, FDA does suggest that alternative mechanisms may be a quicker and more efficient means than the citizen petition of obtaining the agency's position. See id. at 66822. This suggestion is belied by experience. Informal communications such as correspondence are subject to the same administrative delays as are citizen petitions. For example, letters are staffed and subject to a time-consuming decision-making process, and drafting responses has to compete with other agency priorities. Thus, FDA's proposed changes to the citizen petition process will not result in faster agency responses to matters submitted through informal mechanisms.

FDA's belief that issues relating to actions yet to be taken are not as important as issues relating to actions already taken is wrong. FDA proposes to "remove a person's ability to petition FDA to issue an order or to affect a pending order" and suggests that persons wishing to submit information to the agency regarding future or pending orders do so through letters, electronic mail, or other informal correspondence. Id. at 66824. FDA states that if it "receives important information before it makes a decision, it will make appropriate use of that information." Id. However, issues are no less important if they relate to an action yet to be taken than if they relate to an action already completed. For example, Berlex and 3M's citizen petition requests future agency action – the development of approval standards for generic transdermal estradiol patches – and this request is as important as any request relating to actions the agency has already taken. More importantly, the citizen petition procedure is currently used in some circumstances for the specific purpose of influencing an FDA action before the action is taken. This is done in recognition that the agency may be more open to considering counter proposals and alternatives before it takes an action than it is likely to be after it has reached a decision and issued a public position. See, e.g., National Tour Brokers Ass'n v. United States, 591 F.2d 896, 902 (D.C. Cir. 1978) ("People naturally tend to be more closed-minded and defensive once they have made a 'final' determination.") (footnote omitted). Moreover, many "future" FDA actions (e.g., the approval of an ANDA submitted by a third party) directly affect, but do not specifically relate to, persons who submit citizen petitions. For those persons, the citizen petition is an important administrative remedy. Although FDA says it will respond appropriately to information brought to its attention by informal means, 64 Fed. Reg. at 66826, the agency does not explain why such a response cannot be in the form of a response to a citizen petition.

Finally, FDA suggests that current § 10.30(b) is used for "improper purposes, such as delaying competition . . . or delaying agency action." Id. at 66822. However, FDA does not offer any evidence that it has received such petitions or that any agency action has ever been inappropriately delayed as a result. Furthermore, if a petition submitted for an "improper purpose" lacks merit, it should not take FDA a long time to dispose of it, because a meritless petition would not require the agency to address the

type of genuine, substantive issues that require a careful review. If the petition raises issues requiring a significant evaluation and response by the agency, on the other hand, it follows that the issues are meritorious. FDA does not explain why it would be proper for it to disregard meritorious issues based on the agency's belief that they were put before the agency for an ulterior purpose, or why it is "improper" to request the agency not to approve a competitor's product on the basis of scientific, medical, and technical considerations explained in the petition. Nor does FDA explain why channeling such efforts into "informal communications" will save time or improve FDA's administrative efficiency if, as FDA insists, it intends to provide a substantive scientific review and response to issues raised by informal mechanisms.

### **III. FDA SHOULD IMPLEMENT MANAGEMENT REFORMS TO MAKE THE CITIZEN PETITION PROCESS WORK BETTER**

In its 1998 report on FDA's citizen petition process, the Department of Health and Human Services' (HHS') Office of Inspector General (OIG) concluded that FDA "does not have an effective process for handling citizen petitions in a timely manner." See OIG, HHS, Review of the Food and Drug Administration's Citizen Petition Process, at 3 (July 1998) (hereinafter "OIG Report"). The OIG noted several factors that contribute to the problems FDA is experiencing with the process, including:

- (1) the absence of uniform policies and procedures;
- (2) an inadequate process for screening and prioritizing petitions;
- (3) the tentative response option that enables FDA to meet its 180-day requirement while allowing petitions to go unanswered for years;
- and (4) [the] lack of central management and oversight of the process at a high level within FDA . . . .

Id. at 5. The OIG noted that FDA had already studied the citizen petition process and that although FDA had "developed several options for reducing the citizen petition backlog," the agency had "not implemented most of them." Id. at 7. The OIG recommended that FDA "promptly" implement, "where practical," the options FDA developed to improve the citizen petition process and consider the additional approaches the OIG recommended to further improve the process.

FDA has begun to implement some of the options it developed as a means to improve the citizen petition process. This proposed rule is one of those options. See id. at 7. However, Berlex believes that FDA's proposal puts the cart before the horse. FDA should first try to improve the citizen petition process. Only if that effort proves inadequate should the agency consider eliminating the types of requests that can be made by citizen petition. FDA states that it "has taken, or is exploring, various administrative approaches to reduce its citizen petition backlog and improve its handling of citizen petitions." 64 Fed. Reg. at 66823. One administrative approach FDA is exploring is the improvement of its "managerial and oversight responsibility for citizen petitions," which

is what OIG recommended to FDA in its report. Id.; see OIG Report at 7. It makes no sense for FDA to take the drastic measure of proposing to eliminate certain types of requests from being addressed through the citizen petition mechanism before implementing the administrative approaches it and OIG have developed to improve FDA's handling of citizen petitions. The implementation of OIG's recommendations, in combination with some of FDA's proposed changes to the citizen petition process, will make the citizen petition process more efficient and effective and thus may make FDA's proposed changes unnecessary.<sup>4</sup>

For example, Berlex supports FDA's proposal to issue brief denials for those citizen petitions not warranting a lengthy response. See 64 Fed. Reg. at 66824 (proposed § 10.30(e)(2)(ii)). If a petition makes a meritless request, for instance, there is no reason why FDA should prepare a lengthy analysis of the technical basis for the request. Berlex also supports FDA's proposal to consolidate petitions involving the same product or subject matter. See 64 Fed. Reg. at 66825 (proposed § 10.30(e)(4)(iv)). It makes sense that the agency should be permitted to dispose of an issue once instead of having to address it multiple times. Finally, Berlex supports FDA's proposals to allow itself to seek clarification of a petitioner's request, see 64 Fed. Reg. at 66825 (proposed § 10.30(e)(4)(ii)), and to consider a citizen petition to be withdrawn when the petitioner no longer exists, cannot be located, or has stated that it no longer desires a response, see 64 Fed. Reg. at 66825 (proposed § 10.30(e)(4)(iii)). These two changes are practical and will help the agency become more efficient.

In sum, FDA is ahead of itself in proposing to alter the citizen petition process instead of first trying to make the process work better. Berlex believes that OIG's recommendations and those changes to proposed § 10.30 that Berlex supports would significantly improve the citizen petition process without having to limit the types of requests that may be made in a citizen petition. At a minimum, these changes should be

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<sup>4</sup> Indeed, it was the very lack of FDA managerial and oversight responsibility for citizen petitions that required Berlex and 3M to file supplements to their June 12, 1998, citizen petition. In the January 8, 1999, supplement, Berlex and 3M brought to FDA's attention the absence of several letters submitted to the agency on the issue of Berlex and 3M's citizen petition that were not placed in the public docket as required by FDA regulations. See 21 C.F.R. §§ 10.30(d), 10.30(i). In the March 24, 1999 supplement, Berlex informed FDA that another letter sent to the agency on the subject of Berlex and 3M's citizen petition was also not added to the docket. These two supplements to Berlex and 3M's citizen petition would probably have been unnecessary had FDA had in place appropriate managerial and oversight responsibility for citizen petitions.

given a chance to work before a decision is made to limit the public's procedural options in seeking redress from the agency.

#### **IV. SHOULD FDA ADOPT THE PROPOSED RULE, FDA SHOULD NOT APPLY IT RETROACTIVELY**

Should FDA adopt the rule as proposed, it would be fundamentally unfair to apply the rule to those citizen petitions already filed with the agency. The filing of a citizen petition requires a considerable amount of time, effort, and expense. In many cases, those filing petitions have sought the advice of outside counsel and scientific and economic experts, and have expended an extensive amount of their own time and resources in putting a petition together. So much effort is placed into the drafting of a citizen petition because a petitioner submits a petition with the expectation that the petition's contents will be public and thoroughly reviewed by those high-level FDA officials having decision-making authority. In addition, FDA's decision on a citizen petition is subject to judicial review, so petitions are carefully drafted with this in mind. With all of the effort, time, and expense put forth in the filing of a citizen petition, applying proposed § 10.30 to those petitions already filed with FDA would be unfair.

Retroactive application of administrative rules is “not favored in the law.” Bowen, 488 U.S. at 208. In Bowen, the petitioners challenged the retroactive effect given by the Department of Health and Human Service (HHS) to a wage-index rule for calculating the limit on reimbursable wage costs under the federal health care reimbursement programs. Id. at 207. The Supreme Court held that HHS did not have the authority to promulgate a retroactive rule. Id. at 215. The Court stated that “[e]ven where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant.” Id. at 208-09; see also Motion Picture Ass'n of America, Inc. v. Oman, 969 F.2d 1154, 1156 (D.C. Cir. 1992) (“Agencies do not have authority to promulgate retroactive rules unless Congress gives them that authority in express terms.”).

FDA derives its rulemaking authority from § 553 of the APA and § 701 of the Federal Food, Drug, and Cosmetic Act (FDC Act). The APA defines a “rule,” in pertinent part, as “an agency statement of general or particular applicability and future effect.” 5 U.S.C. § 551(4) (emphasis added); see also Bowen, 488 U.S. at 216 (Scalia, J., concurring). Although rules of “agency organization, procedure, or practice” are exempt from specified requirements, 5 U.S.C. § 553(b), they are otherwise subject to the APA's rulemaking requirements. Neither the APA nor the FDC Act provide for the retroactive application of administrative rules. See 5 U.S.C. § 553; 21 U.S.C. § 371(a). Under Bowen, therefore, FDA lacks the authority to apply proposed § 10.30 retroactively.

## V. CONCLUSION

In sum, the citizen petition process was developed by FDA for important reasons, and now, in experiencing some difficulties with the process, the agency is proposing to change it. However, FDA lacks a basis for at least two of its proposed changes, and FDA has proposed these changes without having taken the first logical step to make the citizen petition process work better: establish management and oversight responsibility for the citizen petition process, as recommended by the OIG.

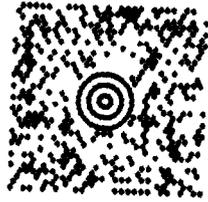
FDA should first implement management reform in order to make the citizen petition process work better. Only if this fails should FDA consider eliminating some of the types of requests that may be made by a citizen petition. However, if FDA adopts the rule as proposed, then FDA should apply the rule prospectively only. To apply the rule to those petitions already submitted to the agency would be fundamentally unfair, and the retroactive application of administrative rules is not favored in the law.

to address la'

BERLEX LABORATORIES  
(973)276-2204  
340 CHANGEBRIDGE ROAD  
PINEBROOK NJ 07058-9714

2 LBS 'e the addr

SHIP TO: DOCKETS MANAGEMENT BRANCH (HFA-305)  
FOOD AND DRUG ADMINISTRATION  
ROOM 1061  
5630 FISHERS LANE  
ROCKVILLE MD 20857



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