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

**Re: PhRMA Comments on FDA's Proposed Modification of its Rule
on Citizen Petitions; Docket No. 99N-2497; 64 Fed. Reg. 66822
(November 30, 1999)**

Dear Sir or Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing over \$26 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures. PhRMA is pleased to submit these comments on FDA's proposed modification of its rule on citizen petitions.

In the 1970s, FDA stepped to the forefront of administrative reform by promulgating a series of procedural and programmatic regulations including the citizen petition regulations. FDA's regulations, 21 C.F.R. sections 10.25 and 10.30, have three key features. First, they allow any interested person to request that the Agency take any action – whether to issue, amend, or revoke a regulation; to issue, amend, or revoke an order; or to take or refrain from taking any other form of administrative action. Second, they require FDA to respond within 180 days of receipt of a petition, and ultimately to rule upon each petition filed. Third, they define and create an administrative record for judicial review.

FDA has now proposed to eliminate important parts of the citizen petition process. Under the proposed regulations, FDA will no longer consider petitions to issue an order or to amend a pending order. Requests for issuance, amendment, or repeal of a rule would have to pertain to "a subject that is appropriately and ordinarily addressed by regulation." FDA also proposes to eliminate the provision that a petitioner may

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request any administrative action, requiring instead that another FDA regulation authorize citizen petitions on the topic in question. The proposed regulations would also permit FDA to treat many petitions as correspondence – for instance, those pertaining to something other than public health or consumer protection, and those raising issues particular to a product or class of products.

PhRMA opposes the proposed revisions to FDA's regulations. They would cut off dialogue about important health, safety, and public policy issues. They would be a significant retreat from the open government philosophy embraced by the agency a generation ago, and comes at a time when access to the agency needs to be safeguarded. PhRMA notes that FDA has offered no evidence to support this radical change in its policy.

PhRMA notes that the citizen petition regulations have played an important role at FDA since they were adopted in the 1970s. They have initiated important dialogues about health, safety, and public policy issues, and they have been the catalyst for many important FDA decisions. They also provide a vehicle for members of the public to advise FDA of important issues and to present FDA with important data and feedback. The regulated industry, consumers, medical organizations, and FDA all stand to lose if the proposed regulations are adopted.

PhRMA urges that FDA suspend the rulemaking and convene a series of stakeholder meetings, so that all interested parties can discuss ways to address FDA's concerns without truncating the Agency's citizen petition process without curtailing public access, or eliminating important public dialogue. In Part III of the enclosed comments PhRMA explains its recommendation in more detail. PhRMA would be pleased to work with the Agency to draw up a model for the stakeholder or task force meeting and to compose a working list of options the group might consider.

Sincerely,



Marjorie E. Powell

Enclosure

PhRMA Comments on FDA's Proposed Modification of its Rule on Citizen
Petitions; Docket No. 99N-2497

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**Re: PhRMA Comments on FDA's Proposed Modification of its Rule on
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The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing over \$26 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures. PhRMA is pleased to submit these comments on the proposal published by the Food and Drug Administration (FDA) in 64 Fed. Reg. 66822 (November 30, 1999), to revise its citizen petition regulations, 21 C.F.R. § 10.25 and 21 C.F.R. § 10.30.

SUMMARY

In the 1970s, FDA stepped to the forefront of administrative reform by promulgating a series of procedural and programmatic regulations including the citizen petition regulations. Sections 10.25 and 10.30 of the Agency's regulations have three key features. First, they allow any interested person to request that the Agency take any action – whether to issue, amend, or revoke a regulation; to issue, amend, or revoke an order; or to take or refrain from taking any other form of administrative action. Second, they require FDA to respond within 180 days of receipt of a petition, and ultimately to rule upon each petition filed. Third, they define and create an administrative record for judicial review.

FDA has now proposed to eliminate the first and second parts of the citizen petition process. Under the proposed regulations, FDA will no longer consider petitions to issue an order or to amend a pending order. Requests for issuance, amendment, or repeal of a rule would have to pertain to “a subject that is appropriately and ordinarily addressed by regulation.” FDA would also eliminate the provision that a petitioner may request any administrative action, requiring instead that another FDA regulation authorize citizen petitions on the topic in question. The proposed regulations would also permit FDA to treat many petitions as correspondence – for instance, those pertaining to something other than public health or consumer protection, and those raising issues particular to a product or class of products.

PhRMA represents the nation's research-based pharmaceutical and biopharmaceutical companies. PhRMA and PhRMA members have often used the citizen petition process to bring issues pertaining to health, safety, and public policy before FDA. Moreover, PhRMA members' products are often the subject of citizen petitions filed by others.

PhRMA participates in the public debates that other parties initiate through the citizen petition process and believes the process is important to the agency's work.

PhRMA opposes the proposed revisions to FDA's regulations. They would cut off dialogue about important health, safety, and public policy issues. They would be a significant retreat from the open government philosophy embraced by the agency a generation ago, and come at a time when access to the agency needs to be safeguarded. FDA has offered no evidence to support this radical change in its policy.

The citizen petition regulations have played an important role at FDA since they were adopted in the 1970s. They have initiated important dialogues about health, safety, and public policy issues, and they have been the catalyst for many important FDA decisions. They also provide a vehicle for members of the public to advise FDA of important issues and to present FDA with important data and feedback. The regulated industry, consumers, medical organizations, and FDA all stand to lose if the proposed regulations are adopted. PhRMA urges that FDA suspend the rulemaking and convene a series of stakeholder meetings, so that all interested parties can discuss ways to address FDA's concerns without truncating the Agency's citizen petition process. In Part III of these comments (page 25, below) PhRMA explains its recommendation in more detail.

I. BACKGROUND

A. The Citizen Petition Provisions are Emblematic of FDA's Leadership in Open Government in the 1970s.

1. In the 1970s, Congress Sought to Make the Administrative Agencies Open to the Public.

In the 1970s, responding to complaints that national policy was set by administrative agencies without public knowledge or participation, Congress over several years undertook a re-examination of the way that administrative agencies did their work. The legislation resulting from this effort took two forms. The first was a series of general laws applicable to all administrative agencies, and the second was reflected in amendments to statutes governing specific agencies. Congress' goal was to make the administrative agencies more accessible to the public, to make their decisionmaking more transparent, and to make them publicly accountable.

Among the general laws were strengthening amendments to the Freedom of Information Act (FOI Act) of 1966,¹ the Government in the Sunshine Act,² and the Federal

¹ Pub. L. No. 89-487, 80 Stat. 250 (1966), codified as amended at 5 U.S.C. § 552.

Advisory Committee Act.³ Agency-specific reforms included the 1970 and 1977 amendments to the Clean Air Act,⁴ the Resource Conservation and Recovery Act (RCRA) of 1976,⁵ the Clean Water Act,⁶ the Consumer Product Safety Act of 1972,⁷ and the Occupational Safety and Health Act of 1970.⁸ A number of the general laws – for instance the Clean Water Act – called for public participation in the agency’s policy development. Others – for instance the RCRA, the Clean Water Act, and Clean Air Act – included generous provisions for judicial review.⁹

The theme of both the government-wide statutes and the agency-specific amendments was that members of the public should be informed about an agency’s work, should have some voice in the process, and should have legal recourse if they believe the agency has been wrong.

2. FDA was at the Forefront of the Open Government Movement.

a) FDA Undertook Reform of its Regulatory Procedures on its Own Initiative.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) was not amended during this process. Instead, FDA embraced the open government philosophy on its own initiative.¹⁰

² Pub. L. No. 94-409, § 5(b), 90 Stat. 1247 (1976), codified at 5 U.S.C. § 552b.

³ Pub. L. No. 92-463, § 1, 86 Stat. 770 (1972), codified at 5 U.S.C. App. 2.

⁴ Clean Air Act Amendments of 1970, Pub. L. No. 91-604, 84 Stat. 1676 (1970) and Clean Air Act Amendments of 1977, Pub. L. No. 95-95, 91 Stat. 685 (1977), amending Clean Air Act, Pub. L. No. 88-206, 77 Stat. 392 (1963), codified as amended in scattered sections of 42 U.S.C.

⁵ Pub. L. No. 94-580, 90 Stat. 2795 (1976).

⁶ Pub. L. No. 92-500, 86 Stat. 816 (1972).

⁷ Pub. L. No. 92-573, 86 Stat. 1207 (1972).

⁸ Pub. L. No. 91-596, 84 Stat. 1590 (1970).

⁹ For instance, Section 505 of the Clean Water Act allows any citizen to commence a civil action on his own behalf against any person alleged to be in violation of an effluent standard or an EPA order, or against the EPA for failure to perform a non- discretionary act or duty. 33 U.S.C. § 1365(a).

¹⁰ FDA was not immune to Congressional scrutiny at the time. Congress held a number of hearings at which it examined the workings of the Agency. *E.g.*, “Preclinical and Clinical Testing by the Pharmaceutical Industry,” *Joint Hearings before the Subcomm. on Health of the Comm. on Labor and Public Welfare & the Subcomm. on Admin. Practice and Procedure of the Comm. on the Judiciary*, 94th Cong., 2nd Sess. (January 20 & 22, 1976); “Congressional Oversight of Administrative Agencies (Food and Drug Administration and Environmental

By the early 1970s, FDA officials had noted confusion about Agency requirements, inconsistent practices of information dissemination, uncertainty about the weight to be given to staff pronouncements, and confusion about how and where to direct inquiries.¹¹ The Commissioner's office decided, accordingly, that "comprehensive regulations should be adopted to codify existing requirements, establish new requirements where none currently exist, and conform present regulations so that practices and procedures will be applied consistently throughout the agency."¹²

Protection Agency)," *Hearings before the Subcomm. on Separation of Powers of the Comm. on the Judiciary*, 94th Cong., 1st Sess. (July 21 & 23, 1975); "Preclinical and Clinical Testing by the Pharmaceutical Industry," *Joint Hearings before the Subcomm. on Health of the Comm. on Labor and Public Welfare & the Subcomm. on Admin. Practice and Procedure of the Comm. on the Judiciary*, 94th Cong., 1st Sess. (July 10 & 11, 1975); "Regulation of New Research and Development by the Food and Drug Administration," *Joint Hearings before the Subcomm. on Health of the Comm. on Labor and Public Welfare & the Subcomm. on Admin. Practice and Procedure of the Comm. on the Judiciary*, 93rd Cong., 2nd Sess. (September 25 & 27, 1974); "Examination of the Pharmaceutical Industry (FDA Regulation & Drug Lag)," *Hearing before the Subcomm. on Health of the Comm. on Labor and Public Welfare*, 94th Cong., 1st Sess. (September 25 & 27, 1974); "Examination of the Pharmaceutical Industry (FDA Regulation)," *Hearing before the Subcomm. on Health of the Comm. on Labor and Public Welfare*, 94th Cong., 1st Sess. (August 15 & 16, 1974).

¹¹ 40 Fed. Reg. 40682, 40693 (September 3, 1975) ("Many Food and Drug Administration decisions vitally affect interested persons and groups outside the agency. Inquiries are constantly received, throughout the agency, from individual consumers, manufacturers, and affected professionals, as well as organizations representing these interests. Few people outside the agency understand where their questions and complaints should be directed."); *id.* ("Until relatively recently, there has been no Food and Drug Administration policy or regulations governing the dissemination [of draft federal register notices and regulations]. . . . As a result, such documents have at times been given to some persons and not to others."); *id.*, at 40694 ("Prior Food and Drug Administration policy has not distinguished between formal advisory opinions and informal oral advice and correspondence. As a result, confusion and uncertainty has been engendered both within the agency and outside as to whether opinions expressed in correspondence or orally carry the weight of the agency or only of the individual agency employee involved."); *id.* ("In many instances, important agency correspondence relating to the legal status of ingredients and products has not been compiled or reviewed in any comprehensive or systematic way."); *id.* ("The Commissioner would resolve the present uncertainty by the proposal of regulations that would clearly and explicitly recognize the difference between the informal opinion of an individual in the agency . . . and the formal opinion of the agency.").

¹² 40 Fed. Reg. 22950 (May 27, 1995).

The procedural reforms, which were released for public comment in 1975,¹³ included:

- methods for petitioning FDA to take or stop action;¹⁴
- preambles to proposed and final regulations;¹⁵
- rules for seeking reconsideration or gaining stays;¹⁶
- procedures for instituting court review;¹⁷
- methods for issuance of formal advisory opinions;¹⁸
- guidelines for dissemination of drafts of notices and regulations;¹⁹
- rules for separation of functions to split Agency decisionmaking roles from Agency litigating roles;²⁰
- defining the administrative record for decision and judicial review;²¹
- new procedures for Section 701(e) hearings;²² and
- institution of several new types of informal hearings.²³

Programmatic changes implemented by FDA as part of this regulatory overhaul included:

¹³ 40 Fed. Reg. 40682 (September 3, 1975); 42 Fed. Reg. 4680 (January 25, 1977) (final rule for most of the procedural regulations).

¹⁴ 42 Fed. Reg. at 4700-4701.

¹⁵ *Id.*, at 4702-4703.

¹⁶ *Id.*, at 4701-4702.

¹⁷ *Id.*, at 4704-4705.

¹⁸ *Id.*, at 4708-4709.

¹⁹ *Id.*, at 4708.

²⁰ *Id.*, at 4705-4706.

²¹ *Id.*, at 4703-4704.

²² 41 Fed. Reg. 51706 (November 23, 1976).

²³ *E.g.*, 41 Fed. Reg. 26636 (June 28, 1976).

- procedures for use of advisory committees;²⁴
- FOI Act regulations;²⁵
- procedures for systematic review of over-the-counter drugs;²⁶
- procedures for systematic review of GRAS food ingredients;²⁷
- procedures for establishing tolerances and action levels for food contaminants;²⁸
- public release of action levels;²⁹
- procedures for device reclassification;³⁰ and
- procedures for systematic review of biological drug products.³¹

b) FDA's Procedural Regulations Embodied the Agency's Commitment to Open Government.

The new FDA regulations embraced, in common with Congress' legislation, the themes central to the open government philosophy: information, access, and accountability. The Agency's Chief Counsel explained that FDA was engaged in "a determined effort, in a wide variety of ways, to keep all segments of the public informed, to permit reasonable participation in [its] decisions, and to allow formal legal challenge to [its] actions."³² Commissioner Alexander Schmidt told Congress in 1975 that he was "convinced" that the new policies – "stressing

²⁴ 41 Fed. Reg. 52148 (November 26, 1976).

²⁵ 39 Fed. Reg. 44602, 44634 (December 24, 1974).

²⁶ 37 Fed. Reg. 9464 (May 11, 1972).

²⁷ 37 Fed. Reg. 25705 (December 2, 1972).

²⁸ 42 Fed. Reg. 52814 (September 30, 1977).

²⁹ 38 Fed. Reg. 854 (January 5, 1972).

³⁰ 43 Fed. Reg. 32988 (July 28, 1978).

³¹ 38 Fed. Reg. 4319 (February 13, 1973).

³² Peter Barton Hutt, "Philosophy of Regulation under the Federal Food, Drug and Cosmetic Act," 37 *Q. Bull. of the Ass'n of Food & Drug Officials of the U.S.* 175, 178 (July 1973).

openness and public participation” – would “strengthen the agency, and increase public confidence in the integrity of [its] decisions.”³³

First, FDA would ensure that members of the public were fully informed of its practices, procedures, and requirements. For instance, summaries of FDA procedures would be disseminated broadly, on the theory that “public understanding of agency procedures is essential to encourage and facilitate public participation in all agency activities.”³⁴ Moreover, these summaries would be prepared “in terms that will be readily understood and usable by the lay public.”³⁵ Commissioner Schmidt reported to Congress in 1975 that the new regulations “explain in clear, detailed fashion how new segments of the public can participate effectively in our activities.”³⁶ In addition, “public proceedings of any type [would] be held on the basis of publicly available data and information wherever possible.”³⁷ Unless this is true, FDA wrote, “participants in the proceeding may not be in a position to review and evaluate all relevant information, and thus to participate in such proceedings in a meaningful way.”³⁸ Furthermore, FDA realized “the government has a duty to inform those it regulates of the precise requirements that they are expected to fulfill under the law.”³⁹ Thus, FDA would “promulgate regulations and provide guidance with the purpose of spelling out the responsibilities of industry.”⁴⁰ In short, the agency would “set out, in detailed regulations, all legal requirements of which [it was] aware, so that no one can be mistaken about them.”⁴¹

Second, FDA would permit broad public participation in Agency proceedings. Commissioner Schmidt told Congress the Agency had “come to recognize the benefits of opening up [its] decisionmaking to public scrutiny and of broadened involvement by interested

³³ “Congressional Oversight of Administrative Agencies (Food and Drug Administration and Environmental Protection Agency),” *supra* note 10, at 9.

³⁴ 40 Fed. Reg. at 40683.

³⁵ *Id.*

³⁶ “Congressional Oversight of Administrative Agencies (Food and Drug Administration and Environmental Protection Agency),” *supra* note 10, at 8.

³⁷ 40 Fed. Reg. at 40684.

³⁸ *Id.*, at 40684-40685.

³⁹ Hutt, “Philosophy of Regulation,” *supra* note 32, at 179.

⁴⁰ “Congressional Oversight of Administrative Agencies (Food and Drug Administration and Environmental Protection Agency),” *supra* note 10, at 5.

⁴¹ Hutt, “Philosophy of Regulation,” *supra* note 32, at 180.

persons and experts outside the agency.”⁴² Thus, the new regulations defined “interested person” and “any person who will be adversely affected” as “any person who wishes to participate in any proceeding of the Food and Drug Administration.”⁴³ There would be no requirement that an aspiring participant “exhibit any particular interest, or show any specific economic harm or other indicia of ‘standing.’”⁴⁴ On the contrary, FDA noted that its activities “directly affect all members of the public,” and thus that “all members of the public who wish to participate are ‘interested persons’ and ‘adversely affected’ by definition.”⁴⁵ Agency employees “have a responsibility to meet with all segments of the public in order to promote the objectives of the act and the agency.”⁴⁶ The interested public is composed of different groups with different interests and needs. A genuinely open Agency would listen to them all.

Third, FDA defined and would create an administrative record of its decision for any subsequent judicial review. The Agency recognized that successful defense of its actions “ultimately depends upon showing the court that the Agency has conscientiously evaluated all views and data offered by interested persons and that its final regulation is supported by data and sound reasoning.”⁴⁷ Accordingly, the new regulation would “guarantee . . . adequate documentation of the manner in which, and the reasons for which, decisions are made within the agency.”⁴⁸ The Chief Counsel emphasized to staff that judicial review required the administrative record to demonstrate clearly the agency’s reasonableness.⁴⁹

Fourth, FDA would not interpose technical objections and procedural barriers when its decisions were challenged in court. Thus, the Agency wrote in 1975, “[o]nce a final agency decision has been made, it is the policy of the Food and Drug Administration not to interpose technical objections, such as a lack of standing, to the right of any interested person to

⁴² “Congressional Oversight of Administrative Agencies (Food and Drug Administration and Environmental Protection Agency),” *supra* note 10, at 5.

⁴³ 40 Fed. Reg. at 40683.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*, at 40692.

⁴⁷ Stephen Hull McNamara, “The ‘New Age’ of FDA Rulemaking: Section 701(a) Regulations,” speech prepared for delivery at the Symposium on “Food Regulations – Present and Future” at the University of Wisconsin (May 6, 1976), at 19.

⁴⁸ 40 Fed. Reg. at 40693.

⁴⁹ “Merrill Says Administrative Record Must Show FDA Rule is Reasonable,” *Food Chemical News* 1 (May 10, 1976).

seek court review.”⁵⁰ The regulations “would encourage any person who believes that the agency has acted improperly to seek judicial review, and guarantees that the Food and Drug Administration will not interpose technical procedural issues but rather will meet the substantive issue on its merits.”⁵¹

3. The Citizen Petition Regulations Were Emblematic of FDA’s Open Government Philosophy.

The citizen petition regulations exemplified FDA’s commitment to open government. They allow any interested person to request that the Agency take any action – whether to issue, amend, or revoke a regulation; to issue, amend, or revoke an order; or to take or refrain from taking any other form of administrative action.⁵² By specifying a mandatory format for citizen petitions,⁵³ the regulations enable members of the public to indicate to FDA which issues require formal Agency attention and which do not. The regulations require FDA to respond within 180 days of receipt of a petition, and ultimately to rule upon each petition filed.⁵⁴ And they define and create an administrative record for purposes of judicial review.⁵⁵ Commissioner Schmidt told Congress that “the new regulations describe clearly how citizens can petition the agency. We have provided a standard form petition to make it easier for individuals to take advantage of this right. Under our regulations, we must respond to any request for action within a reasonable period, and explain why we have or have not taken the action requested.”⁵⁶ The Agency had “accepted the fact that petitions constitute a legitimate method of raising issues before the agency and deserve serious review and disposition.”⁵⁷

The citizen petition regulations placed FDA at the vanguard of procedural reform. The Administrative Procedure Act (APA) only requires an agency to give interested persons the right to petition for “the issuance, amendment, or repeal of a rule.”⁵⁸ The term “rule,” as used in

⁵⁰ 40 Fed. Reg. at 40689.

⁵¹ *Id.*, at 40690.

⁵² 21 C.F.R. § 10.25.

⁵³ 21 C.F.R. § 10.30(b).

⁵⁴ 21 C.F.R. § 10.30(e).

⁵⁵ 21 C.F.R. § 10.30(i).

⁵⁶ “Congressional Oversight of Administrative Agencies (Food and Drug Administration and Environmental Protection Agency),” *supra* note 10, at 8.

⁵⁷ “Food Industry Use of Citizen Petitions Urged by Hutt,” *Food Chemical News* 12-13 (June 13, 1977).

⁵⁸ 5 U.S.C. § 553(e).

the APA, encompasses regulations promulgated pursuant to notice-and-comment procedure and certain other regulations expressly exempt from the notice-and-comment process (interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice) – but not an “order” or “any other form of administrative action.” FDA, however, permits petitioners to request any agency action. Nor does the APA require agencies to guarantee a response, let alone within a specific period of time. It requires merely that “prompt notice” be given of the denial of a petition, along with a statement of the grounds for denial.⁵⁹ It does not address the granting of petitions, nor does it define “prompt.” FDA, however, chose to guarantee a ruling, and a response within 180 days. In short, FDA chose to offer more than the APA required it to offer.

B. FDA Now Proposes to Truncate the Citizen Petition Process.

FDA now proposes to strip the citizen petition process to a bare minimum.⁶⁰ Under the proposed regulations, FDA would not consider a petition to amend a pending order or to issue a new order.⁶¹ Any request that the Agency issue, amend, or repeal a rule, would have to pertain to “a subject that is appropriately and ordinarily addressed by regulation.”⁶² Requests for administrative action would be limited to instances where an existing regulation authorizes citizen petitions on the topic.⁶³ Thus a petition could only be filed if (a) it requested the issuance, amendment, or repeal of a regulation; (b) an existing regulation authorized petitions on the topic; or (c) the petition pertained to an already-issued order. Even for petitions that fall within these three narrow categories, the proposed regulations would allow FDA to treat many citizen petitions as correspondence – for instance, petitions that pertain to issues other than public health and consumer protection, and petitions that pertain to a particular product or class of products.⁶⁴

FDA justifies the proposal by pointing to a backlog of several hundred petitions. The backlog, FDA suggests, is the result of frivolous petitions, repetitive petitions, petitions that request action beyond the Agency’s jurisdiction, and petitions that pertain to matters that require legislative relief.⁶⁵ FDA also suggests that petitions are filed for “improper purposes” such as

⁵⁹ 5 U.S.C. § 555(e).

⁶⁰ 64 Fed. Reg. 66822 (November 30, 1999).

⁶¹ *Id.*, at 66823.

⁶² *Id.*

⁶³ For instance, FDA states, 21 C.F.R. § 861.38(b)(2) expressly allows a person to file a citizen petition to establish, amend, or revoke a performance standard. 64 Fed. Reg. at 66824.

⁶⁴ 64 Fed. Reg. at 66828.

⁶⁵ *Id.*, at 66822.

“delaying competition” or “delaying agency action.”⁶⁶ The Office of the Inspector General (OIG) of the Department of Health and Human Services instead pointed to the absence of uniform policies and procedures to govern the handling of petitions; an inadequate process for screening and prioritizing of petitions; the tentative response option (which enables FDA to meet its 180 day requirement while allowing petitions to go unanswered for years); and the lack of central management and oversight of the citizen petition process at a high level within FDA.⁶⁷

II. FDA’S PROPOSAL IS MISGUIDED

The proposed rule would curtail public dialogue about important safety, health, and public policy issues. It would also eliminate an important guarantee of formal public access to FDA at a time when the Agency has dismantled much of the open government structure it built in the 1970s. FDA has not substantiated the factual basis for the proposal; the proposal is not supported by the publicly-available evidence; and in any event the Agency’s reasons are inadequate to justify the proposal.

A. The Proposed Regulations would Curtail Agency Dialogue with the Public about Important Safety, Health, and Public Policy Issues.

The citizen petition regulations have played an important role at FDA since they were adopted. Citizen petitions have raised important safety, health, and public policy issues. They have been catalysts for important decisions made by FDA, they have prompted important public debates, and they have provided members of the public with a voice at FDA. Many important petitions filed at FDA since 1975 would not have been accepted or could have been treated as informal correspondence if the proposed regulations had been in place.

1. The Citizen Petition Process has Played an Important Role at FDA.

FDA receives petitions from a wide variety of interested parties, requesting a wide variety of actions, and raising a wide variety of important issues. Members of Congress have submitted citizen petitions.⁶⁸ So have hospitals,⁶⁹ national professional organizations,⁷⁰

⁶⁶ *Id.*

⁶⁷ Department of Health and Human Services Office of Inspector General, “Review of the Food and Drug Administration’s Citizen Petition Process” (July 1998) (OIG Report), at 5.

⁶⁸ *E.g.*, FDA Docket No. 76P-0262 (citizen petition regarding common or usual name for equine (mule), submitted by Congressman John Melcher) (June 24, 1976).

government bodies,⁷¹ nonprofit advocacy groups,⁷² academics,⁷³ and students,⁷⁴ as well as companies regulated by FDA⁷⁵ and their trade associations.⁷⁶ In addition to requesting rulemakings, petitioners have requested other FDA action – for instance, that FDA revoke NDAs for all products containing a particular ingredient,⁷⁷ that FDA withdraw a warning letter,⁷⁸ that FDA amend the labeling of a particular product,⁷⁹ that FDA stay the effective date of a particular regulation,⁸⁰ and that FDA initiate an investigation.⁸¹

⁶⁹ *E.g.*, FDA Docket No. 77N-0094 (citizen petition regarding OTC internal analgesic, antipyretic and antirheumatic products, submitted by Brigham & Women’s Hospital) (January 6, 1993).

⁷⁰ *E.g.*, FDA Docket 90P-0180 (citizen petition regarding labeling of aerosol packages of food and cosmetic products, submitted by the National Conference on Weights and Measures) (May 11, 1990).

⁷¹ *E.g.*, FDA Docket No. 91P-0009 (citizen petition regarding exemption from lower federal milk standards, submitted by California Department of Food and Agriculture) (January 7, 1991); FDA Docket No. 85E-0310 (citizen petition requesting reconsideration of Lac-Hydrin patent extension application, submitted by U.S. Patent and Trademark Office) (March 13, 1990).

⁷² *E.g.*, FDA Docket No. 95P-0307 (citizen petition regarding request to expedite evaluation and approval of three vital AIDS drugs, submitted by Log Cabin Republicans) (September 13, 1995); FDA Docket No. 90P-0075 (citizen petition requesting a halt of all uses of human somatotropin in human subjects, submitted by Foundation on Economic Trends) (February 22, 1990).

⁷³ *E.g.*, 36 Fed. Reg. 20986 (November 2, 1971) (notice of petition filed by Georgetown law students and law professor regarding level of lead content in paint).

⁷⁴ *Id.*

⁷⁵ *E.g.*, FDA Docket No. 98P-0671 (citizen petition regarding user labeling for devices with natural rubber latex content, submitted by Acme United Corporation) (August 7, 1998).

⁷⁶ *E.g.*, FDA Docket No. 88P-0251 (citizen petition requesting amendment of the standard of identity for ice milk, submitted by the Calorie Control Council) (March 6, 1990).

⁷⁷ *E.g.*, FDA Docket No. 94P-0378 (citizen petition requesting revocation of NDAs for all products containing chlorzoxazone, submitted by Eaton, McClellan, & Allen) (October 17, 1994).

⁷⁸ *E.g.*, FDA Docket No. 94P-0370 (citizen petition requesting withdrawal of warning letter 94-75 regarding Healthstart 3000 defibrillator, submitted by Laerdal Manufacturing Corporation) (October 12, 1994).

⁷⁹ *E.g.*, FDA Docket No. 98P-0561 (citizen petition of Public Citizen regarding labeling of Viagra) (July 14, 1998).

⁸⁰ 63 Fed. Reg. 46174 (August 31, 1998) (staying effective date of new 21 C.F.R. §§ 801.437(f),(g) pertaining to labeling of medical devices whose packaging uses “cold seal”

The examples below illustrate just a few of the important safety, health, and public policy issues that have been raised by citizen petitions and that would be rejected under the proposed regulations or treated as mere correspondence.

- ***Use of legally approved drugs to effect the death penalty.*** In response to a 1980 citizen petition, FDA decided that it would not interfere with the use of approved drugs to effect capital punishment.⁸² This controversial decision ultimately led to a Supreme Court ruling establishing a foundational administrative law principle that an agency's decision not to take action is essentially unreviewable.⁸³ This petition would not be accepted under the proposed regulations.
- ***Child fatalities linked to ingestion of iron.*** Citizen petitions prompted FDA to respond to an increase in deaths and poisonings in small children due to accidental ingestion of iron-containing drugs. FDA opted to require label warning statements on products taken in solid oral dosage form to supplement dietary intake of iron or to provide iron for therapeutic purposes.⁸⁴ These petitions would not be accepted under the proposed regulations.
- ***Use of oral contraceptives as a morning-after pill.*** A citizen petition requested that FDA direct sponsors of certain oral contraceptives to amend the labeling and patient package inserts of their products to include information about the use of these products for postcoital emergency contraception. Although FDA denied the petition, it scheduled a meeting of the

adhesives, in response to citizen petition filed by the Health Industry Manufacturers Association) (FDA Docket No. 96N-0119) (citizen petition filed June 5, 1998).

⁸¹ *E.g.*, FDA Docket No. 94P-0400 (citizen petition requesting investigation of marketing of disposable dental syringe tips, submitted by Fish & Richardson) (November 3, 1994).

⁸² FDA Docket No. 80P-0513 (citizen petition filed by Larry Chaney *et al.*) (December 19, 1980).

⁸³ *Heckler v. Chaney*, 470 U.S. 821 (1985). The concurrence suggested, however, that Section 555(e) of the APA might have required the Agency's written denial. *Id.*, at 841 (Brennan, J., concurring).

⁸⁴ 62 Fed. Reg. 2218 (January 15, 1997).

Reproductive Health Drugs Advisory Committee to address the issue.⁸⁵ This petition would not be accepted under the proposed regulations.

- ***Good Guidance Practices.*** The Good Guidance Practice regulations⁸⁶ resulted from a citizen petition requesting that FDA exert greater control over the initiation, development, and issuance of guidance documents, in order to ensure public participation in the process.⁸⁷ This petition could be treated as correspondence under the proposed regulations.
- ***The role of animal testing in nonclinical trials.*** A citizen petition initiated dialogue with the Agency about FDA regulations governing good laboratory practice for nonclinical labs and, in particular, the use of ear tags and ear punches for animal identification.⁸⁸ Another requested that all FDA centers revise their guideline test protocols for acute toxicity and clarify that the “classical” LD-50 test involving 60-120 animals per substance is not required by FDA.⁸⁹ These petitions could be treated as correspondence under the proposed regulations.
- ***Simplification of milk labeling.*** In response to a citizen petition, FDA simplified the labeling of milk products and provided that “skim” would be a synonym for “nonfat” when used to label milk products.⁹⁰ This petition could be treated as correspondence under the proposed regulations.

2. FDA’s Alternatives for Engaging the Agency are Inadequate.

FDA claims that “the proposed rule is not intended to and does not reduce or curtail access to or discussions with the agency.”⁹¹ But the alternative means of communicating

⁸⁵ FDA Docket No. 94P-0427 (citizen petition filed by the Center for Reproductive Law and Policy) (November 29, 1994); 61 Fed. Reg. 25682, 25683 (May 22, 1996) (announcing advisory committee meeting).

⁸⁶ 62 Fed. Reg. 8961 (February 27, 1997).

⁸⁷ FDA Docket No. 95P-0110 (citizen petition filed by Indiana Medical Device Manufacturers Council) (May 2, 1995).

⁸⁸ 56 Fed. Reg. 32087 (July 15, 1991).

⁸⁹ FDA Docket No. 86P-0224 (citizen petition filed by the American Society for the Prevention of Cruelty to Animals and 20 cosponsors) (May 15, 1986); *see also* 53 Fed. Reg. 39650 (October 11, 1988) (statement of policy in response).

⁹⁰ 61 Fed. Reg. 58991 (November 20, 1996).

⁹¹ 64 Fed. Reg. at 66823; *see also id.*, at 66824; *id.*, at 66826 (col. 1); *id.* (col. 2).

with the Agency that FDA lists – meetings, correspondence, telephone calls, electronic mail, and facsimiles – have always existed. They were available before the citizen petition regulations were promulgated. FDA officials themselves were convinced that they were insufficient, and the Agency responded by promulgating the citizen petition regulations. They have been viewed as insufficient by members of the public who – as noted above – have used the citizen petition process extensively.

It is hard to understand why FDA now claims these alternative methods of communicating will ensure adequate public access to the Agency. Informal contacts do not guarantee FDA involvement at the higher levels, nor do they guarantee FDA's engagement in the communication process. Without a recognized right of reply, the petitioner would not be assured of the Agency's attention. The petitioner's concerns might not be addressed for months or even years – if ever. Moreover, Agency regulations provide that the written or oral response of an FDA employee is an "informal communication" that represents only "the best judgment of that employee at that time" and "does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."⁹² Thus a statement that the Agency is receptive to any formal citizen petition about any topic within the Agency's jurisdiction, and a promise to respond to that petition, are fundamentally different from the reminder that an individual can always ring up Agency staff if he has a concern.

It is also hard to understand why FDA now thinks a system of informal contacts would be an effective way to run the Agency. Eliminating the citizen petition process would eviscerate the distinction between the important and the routine. Without a formal petitioning process, important safety, health, and public policy issues can be lost in the shuffle of the thousands of informal contacts that occur at FDA monthly. Moreover, an informal response to an informal query does not create an adequate administrative record for judicial review.⁹³ As recently as December 1997, the Director of the Center for Drug Evaluation and Research defended the citizen petition process, suggesting that external participation enhanced Agency

⁹² 21 C.F.R. § 10.85(k).

⁹³ The Agency is well aware of the problems that can result in court from an incomplete or inadequate administrative record. *E.g.*, *The Upjohn Company v. Kessler*, 938 F. Supp. 439, 442-43 (W.D. Mich. 1996) ("The Court is appalled by the gaps in the administrative record. The documents presented do not provide a clear decision making path for the Court's consideration. . . . The Court is astounded that an agency of the importance and resources of the FDA has not given more attention to the development of a clear record for review. . . . The parties and the public deserve a better decisional record.").

decisionmaking.⁹⁴ The Associate Chief Counsel for Drugs argued in May 1998 that citizen petitions are the best way to get information to the highest level at FDA, that they can raise important scientific issues, and that the process creates real benefits for the public.⁹⁵

FDA realized in the 1970s that these alternate means of communication were inadequate, and it has made no attempt to explain its reversal of position.

3. The Proposed Regulations would Curtail Agency Dialogue with the Public.

Under FDA's proposal, the public would be shut out of the bulk of the Agency's decisionmaking.

- Take, for instance, the Chaney petition, which requested boxed warnings on the drugs used for lethal injection, development of a policy for seizure of such drugs, and publicity on the "unapproved" use in question.⁹⁶ This petition would not be accepted by FDA under the proposed regulations.
- To give another example, a toothpaste manufacturer petitioned the Agency in 1996 requesting permission to use a nonanimal fluoride bioavailability test to show the effectiveness of its toothpaste.⁹⁷ This petition could be treated as correspondence under the proposed regulations.
- A law firm recently petitioned the Agency about the unfairness of its practice of posting warning letters on its web site without posting followup

⁹⁴ "Citizen Petition Process Enhancement by Increased External Participation," *The Tan Sheet* 5 (December 15, 1997) (quoting speech by Janet Woodcock at the Food and Drug Law Institute on December 9, 1997).

⁹⁵ "FDA Lukewarm to Generic Drug Firms' Idea to End Frivolous Petitions," *FDA Week* 12 (May 29, 1998) (discussing speech by Elizabeth Dickinson at the Food and Drug Law Institute on May 22, 1998).

⁹⁶ FDA Docket No. 80P-0513 (citizen petition filed by Larry Chaney *et al.*) (December 19, 1980), at 18-19.

⁹⁷ FDA Docket No. 80N-0042 (citizen petition filed by Tom's of Maine) (February 20, 1996).

information.⁹⁸ This petition could be treated as correspondence under the proposed regulations.

- When endorsing the current citizen petition provision in 1975, a representative of the Public Citizen Health Research Group told Congress of the product-specific petitions that organization had previously filed without response from the Agency – for instance, relating to FD&C Red No. 2 and metronidazole.⁹⁹ Under the proposed regulations, FDA could treat these as correspondence.

PhRMA is particularly concerned about the proposal to treat as correspondence any petition that “does not involve a significant public health or consumer protection issue.”¹⁰⁰ This exclusion could embrace economic issues that are vital to regulated industry and the resolution of which are part of the Agency’s mandate under the FD&C Act. Other important issues outside the scope of “significant public health or consumer protection” include Agency procedures, financial disclosure requirements, and good laboratory practices. These are within FDA’s statutory mandate and are appropriate subjects for citizen petitions.

B. The Proposed Regulations would Eliminate an Important Safeguard of Public Access to FDA, at a Time when the Agency is Increasingly Moving Away from Formal Decisionmaking.

Over the last fifteen years FDA has dismantled key parts of the procedural structure it built in the 1970s. Throughout this period, the citizen petition process has served to safeguard the public’s right of access to the Agency. FDA’s proposal to strip the citizen petition process to its bare essentials would eliminate this important guarantee.

⁹⁸ FDA Docket No. 99P-1656 (citizen petition filed by McKenna & Cuneo) (May 27, 1999).

⁹⁹ “Congressional Oversight of Administrative Agencies (Food and Drug Administration and Environmental Protection Agency),” *supra* note 10, at 71. Public Citizen continues to use the citizen petition process to raise issues pertaining to individual products. For instance, it requested in 1994 that FDA remove from the market all drug products containing piroxicam, a non-steroidal anti-inflammatory drug, stating that the drug presents a significantly higher risk of gastropathy than other drugs in its class. FDA Docket No. 94P-0458 (December 29, 1994). Although FDA denied the petition, it found the issue sufficiently meritorious to warrant scheduling a meeting of the Arthritis Advisory Committee. 60 Fed. Reg. 49616 (September 26, 1995).

¹⁰⁰ 64 Fed. Reg. at 66828.

1. The Citizen Petition Process is Important Because FDA Increasingly Announces and Promulgates Policies without Engaging in Rulemaking.

The Agency now formulates and announces important policies without rulemaking. Perhaps the best evidence of this is the list of 89 pre-1986 proposed rules that FDA withdrew in 1991 on the ground that, in view of its limited resources, further rulemaking was not warranted.¹⁰¹ This represented a decision to resolve many of the issues in question through informal administrative action rather than through rulemaking. The discussion below highlights some of the informal means by which the Agency now formulates and announces policy.

Substitution of Guidance for Rules. FDA increasingly relies on guidance documents to state its policies. Rather than initiating notice and comment rulemaking, and promulgating rules, FDA issues guidance documents – or sometimes only draft guidances – which set forth the agency’s expectations as to nearly every aspect of its work and its enforcement of the FD&C Act. CDER alone has posted more than 300 guidance documents on the FDA web site. In the first half of February 2000, alone, FDA issued twelve guidance documents, either in draft or final form.¹⁰²

“Rulemaking” by Press Statement. The Agency recently decided that application of cloning technology to human beings would require an investigational new drug (IND) application. This was announced to the public by way of a statement on a national radio show

¹⁰¹ 56 Fed. Reg. 42668 (August 28, 1991); 56 Fed. Reg. 67440 (December 30, 1991).

¹⁰² *Guidance for Reviewers: Potency Limits for Standardized Dust Mite and Grass Allergen Vaccines: A Revised Proposal*, 65 Fed. Reg. 7557 (February 15, 2000); *Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme*, 65 Fed. Reg. 7027 (February 11, 2000); *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, 65 Fed. Reg. 7027 (February 11, 2000); *M4 Common Technical Document*, 65 Fed. Reg. 7027 (February 11, 2000); *Special Protocol Assessment*, 65 Fed. Reg. 6377 (February 9, 2000); *Guidance for Industry: Development of Supplemental Applications for Approved New Drugs*, 65 Fed. Reg. 6214 (February 8, 2000); *IND Meetings for Human Drugs and Biologics; Chemistry, Manufacturing, and Controls Information*, 65 Fed. Reg. 5645 (February 4, 2000); *Stability Testing of Biotechnological/Biological Veterinary Medicinal Products*, 65 Fed. Reg. 5305 (February 3, 2000); *Guidance for the Content of Premarket Notifications for Penile Rigidity Implants*, 65 Fed. Reg. 4881 (February 2, 2000); *Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements*, 65 Fed. Reg. 4981 (February 2, 2000); *Seafood HACCP Transition Guidance*, 65 Fed. Reg. 4984 (February 2, 2000); *Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme*, 65 Fed. Reg. 4985 (February 2, 2000).

and then a letter to a member of the Senate.¹⁰³ The decision broke new ground insofar as it extended the applicability of INDs to a new medical technology. And yet the public was not given advance notice of, or invited to comment on, the Agency's conclusion. FDA has similarly made use of speeches to announce new policies regarding drug promotional practices. For example, an FDA spokesperson announced in a speech that the Agency had decided to limit help-seeking advertisements (those describing a disease and urging the consumer to consult his physician, but not identifying a product) to diseases for which there are other therapies in addition to drugs.¹⁰⁴

"Rulemaking" by Letter. The Agency sometimes announces important policy changes in letters. For instance, in a letter sent to gene therapy IND sponsors and principal investigators in November 1999, FDA announced that it would require all gene therapy IND sponsors to submit detailed information (including protocols and adverse events) to the National Institutes of Health prior to submission of an IND, and that it would wait for a decision from NIH as to whether "public review" was warranted, before permitting the protocol to proceed.¹⁰⁵ Prior to this statement, submission to NIH was required by NIH (not FDA) and only of entities receiving NIH funds. The letter provided no explanation of the Agency's reasoning and did not invite public comment. FDA has similarly used industry-wide letters to announce restrictions on drug promotion practices.¹⁰⁶

There may be legitimate reasons for the Agency to rely on less formal means of announcing new requirements. Both a need for expediency and a preference for less legalism could justify the Agency's reliance on informal procedures. But the irony is that FDA now proposes to deprive the public of the right to participate formally in anything *but* a rulemaking. In short, FDA would create a "Catch-22": the public would only be allowed to petition for rulemakings, but the Agency rarely uses rulemaking. If the Agency continues to favor informal means of announcing policy, the public should have the right to petition for and against actions other than rulemaking.

¹⁰³ Interview of Michael Friedman (FDA Deputy Commissioner) on National Public Radio's Diane Rehm Show (January 12, 1998); letter from Sharon Smith Holston (FDA) to Senator Edward Kennedy (February 10, 1998).

¹⁰⁴ FDA Docket No. 95P-0110 (citizen petition filed by Indiana Medical Device Manufacturers Council) (May 2, 1995), at 5.

¹⁰⁵ Letter From Kathryn Zoon (Director, CBER) to Gene Therapy IND Sponsors and Principal Investigators (November 5, 1999).

¹⁰⁶ *E.g.*, Letter from Janet Rose (FDA) to holders of new drug applications, abbreviated new drug applications, and abbreviated antibiotic drug applications (July 1993) (announcing policy of requiring that all direct-to-consumer advertisements be pre-cleared by FDA).

2. The Citizen Petition Process is Important Because FDA No Longer Treats Advisory Opinions, Preambles, and Compliance Policy Guides as Binding Statements of Agency Policy.

In the 1970s, FDA stated that advisory opinions issued in response to a petition, statements of policy or interpretation published in the *Federal Register*, trade correspondence, compliance policy guides, and other formal policy statements (including “guidelines”) issued by the Agency would constitute advisory opinions on which regulated parties and members of the public could rely, except in emergency situations.¹⁰⁷ In 1992, however, the Agency proposed to revoke that commitment,¹⁰⁸ largely because of a D.C. Circuit opinion holding that the action level for particular poisonous or deleterious substances in food was treated by the Agency as binding and thus required notice and comment.¹⁰⁹ FDA never issued a final rule. Nevertheless, since 1992 the Agency has adhered to the policy that members of the public cannot rely on preambles, compliance policy guides, or guidance documents as reliable predictions of FDA policy. (Although the regulations still provide that “guidelines” and “advisory opinions” are binding, the Agency uses other labels for the documents it issues.) In 1997, Congress stepped in and provided that Agency employees may not deviate from guidance documents without appropriate justification and supervisory concurrence.¹¹⁰ This provision does not, however, bind the Agency’s advisory committees, and FDA does not always tell the committees to honor informal Agency statements.

By taking these steps, the Agency may be able to avoid what it views as cumbersome rulemaking procedures. However, most of the time most of these documents are *de facto* binding on others. The high cost of disagreement with the Agency and the deference given to FDA by the courts serve as significant deterrents to the parties to whom these documents apply. Often those subject to these policies do not understand that the documents are not binding. Moreover, as a practical matter FDA staff look for deviations from the Agency’s statements of policy rather than for deviations from the FD&C Act or FDA regulations. If the bulk of the Agency’s work is set forth in “non-binding” statements which the Agency may argue are insufficiently “final” to permit judicial review, members of the public should be able to initiate dialogue about Agency policy through the petitioning process.

¹⁰⁷ 42 Fed. Reg. at 4709-4710; 21 C.F.R. §§ 2.19, 2.20 (1977). These regulations were later re-issued as 21 C.F.R. §§ 10.85 and 10.90.

¹⁰⁸ 57 Fed. Reg. 47314 (October 15, 1992).

¹⁰⁹ *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987).

¹¹⁰ Food and Drug Modernization Act of 1997, 111 Stat. 2296 (1997); 21 U.S.C. § 371(h).

3. The Citizen Petition Process is Important Because FDA No Longer Invites Comment Prior to Promulgating Interpretive Rules.

The Administrative Procedure Act requires an agency to follow notice and comment rulemaking for all “rules” except for interpretive rules, rules of agency organization, practice, and procedure, and general statements of policy. As part of its embrace of the open government philosophy, FDA waived this exception and announced that it would follow informal notice-and-comment rulemaking procedures for interpretive as well as substantive regulations, and for rules of Agency practice and procedure.¹¹¹ FDA stood at the forefront of reform; both the American Bar Association House of Delegates and the Administrative Conference of the United States would later recommend that agencies use informal rulemaking at least where interpretive rules and general statements of policy have a substantial impact on the public.¹¹²

In 1991, FDA rescinded the waiver.¹¹³ The Agency claimed the change was necessary because court decisions had expanded the definition of “rule” to include “a great number of other agency pronouncements that FDA does not consider rules but that reviewing courts may consider rules within the meaning of the . . . [APA]” and such widespread use of notice-and-comment procedures was “not feasible.”¹¹⁴ Ironically given the proposal now under consideration, FDA in its final rule *three times* cited the citizen petition process as a substitute means for interested persons to make their views known.¹¹⁵ In the absence of an opportunity to comment, citizen petitions should continue to serve as a way for members of the public to address the Agency’s interpretive regulations.

4. The Citizen Petition Process is Important because it Assures the Opportunity for Judicial Review of Agency Policies.

In 1975, FDA stated that it would not interpose technical or procedural objections – standing, ripeness, and the like – when an interested person challenged its final Agency actions

¹¹¹ 42 Fed. Reg. at 4703; 21 C.F.R. § 2.10(d)(1977).

¹¹² ABA Section of Administrative Law and Regulatory Practice, Comments in Response to 55 Fed. Reg. 31080 (July 31, 1990) (October 1, 1990); ACUS Conference Recommendation 76-5, Interpretive Rules of General Applicability and Statement of General Policy, 1 C.F.R. § 305.76-5 (1977).

¹¹³ 55 Fed. Reg. 31080 (July 31, 1990); 56 Fed. Reg. 13757 (April 4, 1991).

¹¹⁴ 55 Fed. Reg. at 31080; 56 Fed. Reg. at 13757.

¹¹⁵ 56 Fed. Reg. at 13757, 13758 (twice).

in court.¹¹⁶ It also stated that a Regulatory Letter – now a Warning Letter – would be considered a final action, which the recipient could challenge in court and which the FDA would defend on the merits.¹¹⁷ It has since reversed this position. In 1987, FDA proposed to amend Section 10.45 of its regulations and oppose judicial review of policy pronouncements like advisory opinions, preambles, and guidelines. Although this proposal was never finalized, in fact now FDA claims Warning Letters are *not* final, and it invariably interposes procedural and technical objections in litigation.¹¹⁸

When FDA began interposing technical objections to litigation on the merits, the citizen petition regulations served as a means to force a substantive discussion on the issue in question. They also created an administrative record and culminated in final Agency action, for purposes of judicial review. If the current proposal is implemented, the Agency will be able to avoid substantive discussion and may insulate itself from judicial review.

5. The Proposed Regulations may Create the Problems FDA Avoided by Embracing Open Government.

Narrowing the citizen petition process may also create some of the problems the Agency hoped to avoid with the open door policy. For instance, the proposal may channel important issues into obscure channels of communication. Replacing formal petitions with informal meetings and phone contacts would force exchanges that are now recorded on the public docket into private meetings and exchanges. Under a regime of informal queries and responses, Agency decisions will be made without any supporting administrative record for judicial review. The proposed regulations will also increase the Agency's litigation burden. A citizen petition requesting that the Agency stay the effective date of a new regulation is, today, often filed and not infrequently granted.¹¹⁹ Under the new regime, these petitions would be turned away at the door. These are the kind of problems that the Agency's open government philosophy helped to avoid.

¹¹⁶ 40 Fed. Reg. at 40683.

¹¹⁷ *Cf.* Compliance Policy Guide 7153.04 (1974).

¹¹⁸ *E.g.*, *Schering Corp. v. Food and Drug Admin.*, 51 F.3d 390 (3d Cir. 1995) (standing); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993) (mootness).

¹¹⁹ *E.g.*, 63 Fed. Reg. 46174 (August 31, 1998) (staying effective date of new 21 C.F.R. § 801.437(f),(g) pertaining to labeling of medical devices whose packaging uses "cold seal" adhesives, in response to citizen petition filed by the Health Industry Manufacturers Association) (FDA Docket No. 96N-0119) (citizen petition filed June 5, 1998).

C. FDA Lacks Evidence to Support the Proposed Change.

FDA suggests that the change is justified because the Agency receives frivolous petitions, repetitive petitions, petitions that pertain to matters that require legislative relief, and petitions that request action beyond its jurisdiction.¹²⁰ FDA also suggests it receives petitions filed for “improper purposes,” such as delaying Agency action or delaying competition.¹²¹ This, the Agency suggests, combined with its commitment to respond to every petition received, is responsible for the backlog of petitions and creates a drain on Agency resources. However, FDA has offered no evidence to support these claims and the publicly-available evidence does not support FDA. Moreover, this explanation is insufficient to justify curtailing public access to the Agency.

First, FDA offers no evidence to support its assertions. It cites one example of a petition pertaining to a matter outside its jurisdiction, and no examples of petitions that pertain to matters requiring legislative relief. It cites no examples of petitions filed for “improper purposes, such as delaying competition,” and no examples of repetitive petitions. It has not indicated what percentage of filed petitions fall into these various categories, nor has it provided any quantitative support for the assertion that “these petitions drain FDA resources.”¹²² Indeed, OIG noted that “the agency does not keep statistics on the amount of time it actually spends, or needs to spend, to perform its various activities” and that none of FDA’s centers “could accurately estimate the time allocated to handling petitions.”¹²³ Before denying petitions on resource grounds, OIG wrote, “the agency should have quantitative data to specifically show why it lacks resources to respond to the petitions.”¹²⁴ The proposal contains no such data.

Second, publicly-available evidence rebuts the claim that FDA is burdened by frivolous petitions. FDA makes clear in its proposal that its major objective is to curtail petitions filed by innovator companies that could affect generic competition. These petitions, however, are not frivolous. They raise important issues relating to the approval of generic substitutes through the ANDA process – issues including bioequivalence testing requirements, the appropriateness of a generic dosage form or formulation for an ANDA, the use of innovator company data, and therapeutic equivalence determinations.¹²⁵ The Agency’s decision to require

¹²⁰ 64 Fed. Reg. at 66822.

¹²¹ *Id.*

¹²² 64 Fed. Reg. at 66823.

¹²³ OIG Report, *supra* note 67, at 5.

¹²⁴ *Id.*, at 8.

¹²⁵ Other subjects of these could include requirements for approval of an ANDA, such as having the same active ingredient; labeling differences; patent issues, such as the appropriate

an additional bioequivalence study for generic Verelan, for instance, and its refusal to approve ANDAs for conjugated estrogen products, can both be traced to citizen petitions.¹²⁶ The *Serono Laboratories* litigation further supports the fact that innovator company petitions on ANDA issues are far from frivolous.¹²⁷

Drug-related citizen petitions filed by innovator companies do not significantly outnumber drug-related citizen petitions filed by generic companies and consumers.¹²⁸ Between January 1985 and early 1998, innovator companies filed approximately 69 citizen petitions concerning human drugs that could affect generic competition. In the same time period, generic companies filed approximately 50 petitions on a variety of subjects affecting competitive issues (for instance, seeking denial of market exclusivity for an innovator company, or relating to bioequivalence or other testing issues).¹²⁹ Consumer petitions on such topics are even more numerous. Between January 1990 and April 1998, consumers filed approximately 75 petitions concerning human drugs and biologics. In that same time period, the generic industry filed approximately 45 and the brand name industry filed approximately 48.

FDA has granted, at least in part, many drug-related citizen petitions filed by innovator companies, just as it has granted, at least in part, such petitions when filed by generic companies. For instance, FDA has granted at least in part approximately 26 percent of the petitions relating to human drugs or biologics filed by innovator companies since January 1998, and 31 percent of those filed by the generic industry. (41 percent of the innovator petitions are still pending, and 31 percent of the generic petitions are still pending.) Petitions that are meritless or seek action beyond FDA's jurisdiction are easily recognized. FDA itself cites the

expiration of a patent; market exclusivity; or lack of evidence of effectiveness of a proposed generic product.

¹²⁶ FDA Docket No. 97P-0386 (citizen petition filed by Wyeth-Ayerst Research regarding bioequivalence study for ANDAs for once-daily verapamil HCl pharmaceutical formulations) (September 10, 1997) (granted); FDA Docket No. 94P-0429, 94P-0430 (citizen petitions filed by Wyeth-Ayerst regarding generic equivalents for Premarin) (December 1, 1994); FDA Press Release P97-12 (May 5, 1997) ("FDA's Center for Drug Evaluation and Research (CDER) announced today that at this time it will not approve synthetic generic forms of the estrogen-replacement drug Premarin.").

¹²⁷ *Serono Laboratories v. Shalala*, 974 F. Supp. 29 (D.D.C. 1997) (reversing FDA's denial of innovator company petition), *rev'd*, 159 F.3d 1313 (D.C. Cir. 1998).

¹²⁸ The numbers that follow are the result of work commissioned by a PhRMA member in 1998 and supplemented by PhRMA in 2000. They can be independently verified at the Dockets Management Branch of FDA.

¹²⁹ This does not include ANDA suitability petitions or petitions filed in the OTC Drug Review.

example of a petition requesting that FDA require certain employment practices at a firm.¹³⁰ The existing rule permits summary rejection of such petitions.

The Agency's claim that it is overburdened by frivolous petitions, repetitive petitions, petitions that pertain to matters that require legislative relief, and petitions that request action beyond its jurisdiction is simply not credible.

Third, the filing of such petitions would not justify a change in Agency rules. When the petition provision was drafted, the Agency anticipated both frivolous petitioning and resource problems. The Agency's Chief Counsel wrote in 1972 that petitions would "increase in number and in complexity" and "undoubtedly result in a substantial drain on our resources." Indeed, "Some will make very good sense, and some will be frivolous."¹³¹ The preamble to the final regulation admitted the resource scarcity problem – "Perhaps the greatest problem facing the Food and Drug Administration today is the scarcity of resources to deal with petitions and other similar requests. . . . [T]he Commissioner anticipates that, in a significant number of instances, petitions with a relatively low priority would not be acted upon promptly."¹³² In 1972, FDA decided that the need for open government, public access, and accountability were worth a higher volume of incoming petitions, the frivolousness of some, the burden of responding to every one of them, and the likely fact of delay as to some. FDA has articulated no reason to revisit this conclusion.

III. PhRMA PROPOSAL

As noted above, PhRMA participates in the public debate that the citizen petition process initiates, and believes the process is important to the Agency's work. Citizen petitions have played an important role at FDA: they have prompted significant dialogues, they have been the catalyst for important decisions, and they have enabled FDA to make more informed decisions. Although PhRMA believes the Agency's concerns about frivolous petitioning are not supported by the evidence, PhRMA recognizes that the Agency is frustrated by its seeming lack of resources to handle citizen petitions. The proposed regulations will, however, significantly curtail public dialogue and access to the Agency, and everyone – including the Agency – stands to lose if the proposal is adopted. PhRMA therefore proposes that FDA suspend the rulemaking

¹³⁰ 64 Fed. Reg. at 66823.

¹³¹ Peter Barton Hutt, "Public Information and Public Participation in the Food and Drug Administration," 36 *Q. Bull. of the Ass'n of Food and Drug Officials of the U.S.* 212, 218 (October 1972).

¹³² 40 Fed. Reg. at 40686.

and invite all interested parties to discuss the Agency's concerns and to negotiate a solution that protects the interests of all affected constituencies.

The Agency could look to several models for these meetings. For instance, the Agency might consider negotiated rulemaking, which involves establishment of a committee of stakeholders which then deliberates until it reaches consensus.¹³³ This process allows the Agency and all affected parties to jointly frame the issues and search for mutually agreeable solutions. In addition to increasing citizen participation, the process is thought to improve the substance of the proposed rule, shorten the length of time necessary for implementation of the rule, and reduce litigation.

Another possibility would be a stakeholder meeting in the form of a "legislative hearing" under Part 15 of FDA's regulations. The Agency has convened such meetings to consider issues such as the safety of food products derived from bioengineered food¹³⁴ and strategies for effective regulation of dietary supplements.¹³⁵ Typically in these meetings FDA shares its experiences, solicits the views of stakeholders, and gathers information. Interested parties may file written comments and make oral presentations to Agency officials.

FDA could also look to the Drug Enforcement Administration (DEA) for precedent. The DEA convened a "Suspicious Orders Task Force" in August 1997, under the auspices of the Federal Advisory Committee Act.¹³⁶ The task force, which was composed of members of trade associations and law enforcement, met regularly for a year for the purpose of developing a proposal to define "suspicious orders" of listed chemicals which must be reported to DEA.¹³⁷ Its final report was issued in February 1999.¹³⁸

The stakeholder meeting or task force should investigate the scope of the problem at FDA, building on the work of the OIG task force. It should also be creative in its

¹³³ 5 U.S.C. §§ 561-570; EO 12866 (Executive Order on Regulatory Planning and Review), 58 Fed. Reg. 392917 (September 30, 1993).

¹³⁴ *E.g.*, 64 Fed. Reg. 57470 (October 25, 1999).

¹³⁵ *E.g.*, 64 Fed. Reg. 32880 (June 18, 1999).

¹³⁶ 5 U.S.C. App. 2.

¹³⁷ 62 Fed. Reg. 61829 (November 19, 1991).

¹³⁸ *Report to the U.S. Attorney General by the Suspicious Orders Task Force (Comprehensive Methamphetamine Control Act of 1996) and Supplemental Report to the Attorney General* (February 1999), <www.usdoj.gov/dea/programs/diversion/sotf> (visited February 22, 2000).

consideration of solutions for the Agency to adopt. Although by no means an exhaustive list, PhRMA suggests by way of example that the group consider:

- encouragement of members of the public to attempt resolution of their concerns through informal means – meetings, correspondence, telephone calls, electronic mail, and facsimiles – before resorting to the citizen petition process.
- adoption of OIG's recommendations that the Agency (a) correspond with petitioners of long-standing petitions to determine whether they still desire action; (b) publish a statement in the Federal Register notifying non-responding petitioners that their petitions will be removed from Agency records; (c) handle first the oldest petitions with the most serious public health implications; (d) establish target dates for elimination of the backlog; and (e) establish management and oversight of the process in the Office of the Commissioner.
- review of backlogged petitions and issuance of a brief omnibus response to those which are moot or otherwise overtaken by events.
- negotiation of new procedures for processing any categories of petitions that in fact consume a significant amount of Agency resources.
- negotiation of a system of payment for use of FDA resources, in order to alleviate the burden on the Agency.

Ultimately, the group should propose, and the Agency should adopt, a solution that represents a compromise satisfying all constituencies.

PhRMA would be pleased to work with the Agency to draw up a model for the stakeholder or task force meeting and to compose a working list of options the group might consider.

IV. CONCLUSION

For the reasons discussed above, PhRMA opposes the proposed rule. PhRMA requests that FDA place the rulemaking in abeyance. PhRMA recommends that, instead, FDA should initiate a series of stakeholder meetings (or some other similar process) that will enable the public to work with the Agency to address its stated concerns without curtailing public access or eliminating important public dialogue.