6. Information that illustrates the effect of foreign policy controls on the trade or acquisitions by intended targets of the controls.

7. Data or other information as to the effect of foreign policy controls on overall trade, either for individual firms or for individual industrial sectors.

8. Suggestions as to how to measure the effect of foreign policy controls on trade.

9. Information on the use of foreign policy controls on targeted countries, entities, or individuals.

BXA is also interested in comments relating generally to the extension or revision of existing foreign policy controls.

Parties submitting comments are asked to be as specific as possible. All comments received before the close of the comment period will be considered by BXA in reviewing the controls and developing the report to Congress.

All information relating to the notice will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, BXA requires written comments. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying.

The public record concerning these comments will be maintained in the Freedom of Information Records Inspection Facility, Room 6883, U.S. Department of Commerce, 14th Street and Pennsylvania Avenue, NW, Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in Part 4 of Title 15 of the Code of Federal Regulations. Information about inspection and copying of records at this facility may be obtained from the BXA Freedom of Information Officer at the above address or by calling (202) 482–0500.

Dated: November 23, 1999.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 99–31061 Filed 11–29–99; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. 99N–2497]

Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations pertaining to citizen petitions. The proposal would cover citizen petition requests to issue, amend, or revoke a regulation; requests to amend or revoke an order that FDA has issued or published; or any other action specifically authorized by another FDA regulation. The document further clarifies that persons who wish to contact the agency on matters outside these three types of actions would still be able to do so through informal means, such as letters and telephone calls. In addition the proposal would also revise certain content requirements for citizen petitions and would permit FDA to refer petitions for other administrative action, seek clarification of a petitioner's requests, withdraw certain petitions, and combine petitions. These changes are intended to improve the citizen petition mechanism.

DATES: Submit written comments by February 28, 2000. Submit written comments on the information collection provisions by December 30, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, ATTN: Wendy Taylor, Desk Officer for FDA

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

There are several mechanisms which can be used to contact FDA on a particular matter or issue. These mechanisms can be informal, such as calling the agency, sending a fax or electronic mail, writing a letter (see § 10.65(a) (21 CFR 10.65(a))), or requesting a meeting (see, e.g., § 10.65(b) and (c)). They may also be more formal, such as requesting a public hearing (see, e.g., 21 CFR 12.20) or submitting a citizen petition (see § 10.30 (21 CFR 10.30)).

Many persons use citizen petitions under § 10.30 to contact FDA on a diverse range of issues. The issues can be very specific, such as detailed scientific concerns about a particular product's safety or bioequivalence, but occasionally pertain to matters outside FDA's jurisdiction or to matters that would require legislative, rather than regulatory, relief. This results in a large number of citizen petitions filed at FDA. As of April 1999, several hundred citizen petitions have been filed and remain pending.

In many instances, it is readily apparent that citizen petitions may not be the best or most efficient mechanism for addressing the underlying subject or issue. For example, FDA often receives petitions requesting prompt or immediate action, yet each petition, after being filed and assigned to the appropriate office or center, must compete against other agency priorities, including other citizen petitions filed earlier. In contrast, a telephone call, letter, or a request for a meeting, while lacking the formal processing associated with citizen petitions, is usually an easier, faster, and more efficient way to discuss the same issue with the agency.

Reviewing and responding to these petitions can also be, and often is, a resource-intensive and time-consuming task because FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. In many instances, FDA must issue a tentative response stating that the agency is unable to reach a decision on the petition within the 180-day response period established in FDA's regulations.

Questions have also arisen whether a citizen petition can be used for improper purposes, such as delaying competition (see, e.g., Noah, L., ''Sham Petitioning as a Threat to the Integrity of the Regulatory Process,'' 74 N. *Carolina L. Rev.* 1 (1995) (also noting that the Federal Trade Commission, in 1993, had concerns that petitions were being submitted to FDA for anticompetitive reasons)) or delaying agency action. Some petitioners have submitted multiple citizen petitions concerning the same subject or product

with each petition containing one or few requests, while others have submitted several citizen petitions on the same subject or product over an extended time period. These petitions drain FDA resources both repeatedly and inefficiently because they commit FDA to multiple reviews and responses rather than having FDA consider and respond to all issues at one time.

Recently, the Office of the Inspector General (OIG) in the Department of Health and Human Services reviewed FDA's citizen petitions process to assess the agency's effectiveness in handling citizen petitions and to identify ways that the process can be improved. The OIG noted that FDA had examined various options for reducing the citizen petition backlog and suggested that those options be thoroughly discussed within the agency and ''implemented where practical.''

This proposed rule contains several of those options and is intended to facilitate and to improve interactions between FDA and interested persons. The proposed rule would clarify the types of requests that may be the subject of a citizen petition and increase FDA's flexibility in responding to or taking action in response to a citizen petition.

FDA emphasizes that the proposed rule is not intended to and does not reduce or curtail access to or discussions with the agency. For example, FDA's regulations provide for meetings and correspondence (see, e.g., § 10.65), and other FDA regulations provide for meetings under certain situations (see, e.g., 21 CFR 314.102 (communication between FDA and persons who have submitted new drug application or abbreviated new drug application (ANDA))). Informal avenues of communication, such as telephone calls, faxes, and electronic mail, also exist. These avenues of communication can be faster and more efficient methods for discussing issues or addressing concerns than citizen petitions.

In addition to this rule, FDA has taken, or is exploring, various administrative approaches to reduce its citizen petition backlog and improve its handling of citizen petitions. These actions have included contacting petitioners whose requests are of long standing to determine whether they still want FDA to take action on their petitions and revising delegations of authority so that certain FDA centers may issue a greater range of petition responses. FDA is also considering options for improving managerial and oversight responsibility for citizen petitions to ensure that the citizen petition process is efficient and effective.

II. Description of the Proposed Rule

Under FDA's existing regulations, any person may submit a citizen petition to the agency requesting that the Commissioner of Food and Drugs (the Commissioner): (1) Issue, amend, or revoke a regulation; (2) issue, amend, or revoke an order; or (3) take or refrain from taking any other form of administrative action (§ 10.30(a) and (b)). The regulations also direct the agency to issue a response to a citizen petition within 180 days after receiving a petition (§ 10.30(e)(2)). (For petitions requesting permission to submit an ANDA for certain drugs, the response period is 90 days (see § 10.30(e)(4)).) The response can either approve the petition, deny the petition, or provide a tentative response, indicating why the agency has been unable to reach a decision on the petition (§ 10.30(e)(2)).

A. Proposed § 10.30(b)

1. Actions That May be Requested in a Citizen Petition

The proposed rule would amend the citizen petition requirements at § 10.30(b) and its description of the actions that may be requested in a citizen petition. Under the proposal, a citizen petition could request that the agency: (1) Issue, amend, or revoke a regulation; (2) amend or revoke an order that the agency has issued or published; or (3) take an action as specifically authorized by another FDA regulation.

The proposal would not alter a person's ability to petition the agency for the issuance, amendment, or revocation of a regulation. The Administrative Procedure Act (5 U.S.C. 553(e)) expressly provides for such petitions, and the proposal would preserve a person's ability to petition for rulemaking.

The proposal would, however, require that the requested regulation pertain to a subject that is appropriately and ordinarily addressed by regulation rather than other administrative action. For example, a petition that sought to amend the format and content requirements for an ANDA may be within the proposed rule because the requested change would be applicable to all ANDA's. However, a petition that sought a regulation directly or indirectly prohibiting the approval of a particular generic drug product, declaring a particular generic product to be unsafe, ineffective, or not bioequivalent, or prohibiting a class of generic drug products would, in most cases, not fall within the proposed rule because FDA generally does not issue regulations to prohibit the approval of individual generic drug products.

FDA considered, but did not include in this proposed rule, a requirement that petitioners show why the requested rulemaking or action is within FDA's legal authority. The existing regulations require a petitioner to provide the factual and legal grounds on which the petitioner relies, but despite this requirement, the agency sometimes receives petitions requesting actions that are beyond FDA's legal authority or actions that are a matter of State law. For example, a petition requesting that FDA, under its existing statutory authority for drug products, regulate a particular class of drugs products would be appropriate, whereas a petition requesting that FDA require firms to observe certain employment practices (a matter that is generally not within FDA's legal authority) would not. Consequently, the agency contemplated various ways to have would-be petitioners request only those actions that fall under FDA's authority, but without requiring petitioners to provide a detailed or exhaustive legal analysis or to retain legal services to draft arguments on FDA's legal authority. The agency invites comments on how a rule might ask petitioners to ensure that their requested actions are within FDA's legal authority without making those petitioners do a detailed or exhaustive legal analysis.

For citizen petitions concerning agency orders, the proposal would amend § 10.30(b) to limit citizen petitions to requests that FDA amend or revoke an order that FDA has issued. In other words, a citizen petition could not be used to request that FDA amend pending FDA orders or issue future FDA orders. This change 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.

The proposal would also require the citizen petition to be based on more than unsupported claims, allegations, or general descriptions of positions or arguments. Although the existing regulation requires petitioners to provide a full statement of the factual grounds on which the petitioner relies, some petitions contain little or no evidence or support or rely on obsolete, irrelevant, or erroneous information. Thus, the proposal would deter the submission of frivolous or unsupported petitions and petitions which simply disagree with an agency decision regardless of the scientific evidence or legal authority supporting that decision, the importance of the public health

policies supporting that decision, or the petitioner's lack of sound scientific evidence or legal authority to support its request.

FDA is aware that the proposed change would remove a person's ability to petition FDA to issue an order or to affect a pending order and that some may object to this proposed change on the ground that persons should be able to present arguments and evidence to FDA before it makes a decision. Again, the agency emphasizes that the proposal does not prevent a person from contacting FDA nor does it curtail access to the agency. Persons who desire to present information to FDA would be able to do so through letters, electronic mail, meetings, discussions, and other avenues of communication. If FDA receives important information before it makes a decision, it will make appropriate use of that information. For example, if a person submitted information to FDA to argue that a particular test should be conducted before FDA approves a specific product, the agency may consider that information during its review of the product's application and consult the applicant and others on the issue. The fact that the information may not have been submitted in a citizen petition does not make the information any less persuasive or mean that it will receive less attention from FDA. In short, the citizen petition mechanism is not the sole mechanism for contacting FDA, especially with respect to persons who wish to provide information to FDA before the agency decides on or takes a specific course of action.

The proposal would also change the third category of citizen petitions — petitions requesting that the Commissioner ''take or refrain from taking any other form of administrative action''–to petitions requesting that the Commissioner take an action ''as specifically provided by regulation'' and would require the petitioner to cite the regulation at issue. The reference to actions ''specifically provided by regulation'' is intended to reflect over 20 FDA regulations which expressly provide for or instruct interested persons to submit citizen petitions in order to achieve a particular result. For example, under 21 CFR 60.30(b), a person may file a citizen petition if that person wishes to challenge the regulatory review period determination for a particular product which is being considered for patent term extension. FDA's regulations permit persons to submit a citizen petition if they seek an exemption from the pregnancy nursing warning (21 CFR 201.63(d)). Under 21 CFR 861.38(b)(2), an interested person may petition to establish, amend, or revoke a performance standard. The proposed rule would continue to allow petitions under these and other FDA regulations that expressly refer to the citizen petitions process, but the proposal would no longer provide an unqualified ability to use the citizen petition process for ''any other form of administrative action.''

FDA reiterates that persons who wish to contact FDA on matters outside the three types of actions described in proposed § 10.30(b) would still be able to do so through other means, such as correspondence, electronic mail, telephone calls, etc., and FDA will respond to such correspondence and other communications promptly. The agency is simply reorganizing its citizen petition mechanism to make it more focused and responsive.

2. Certification Statement for Citizen Petitions

Currently, § 10.30(b) requires a petitioner to certify, to its best knowledge and belief, that the petition includes all information and views on which the petitioner relies and includes ''representative data and information known to the petitioner which are unfavorable to the petition.'' To complement the other proposed changes to § 10.30(b), FDA is proposing to revise the certification statement. The proposed revision would have petitioners certify that, to the petitioner's best knowledge and belief, its citizen petition ''includes all information and views on which the petition relies, that it is well grounded in fact and is warranted by existing laws or regulations, that it is not submitted for any improper purpose, such as to harass or to cause unnecessary delay, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.''

B. Proposed § 10.30(e)(2)(ii)—Denial of Citizen Petitions

To facilitate responses to citizen petitions and to promote more efficient use of agency resources, the proposed rule would amend § 10.30(e)(2)(ii) to state that FDA's denial of a citizen petition may be ''brief, as appropriate.'' This is intended to conserve FDA's resources by eliminating the need to conduct exhaustive or comprehensive analyses and responses to requests or issues that the agency has already decided earlier in a different administrative proceeding or action and to give FDA the flexibility to act quickly on petitions where detailed responses are unnecessary. For example, under the proposal, if the citizen petition asked the agency to amend a regulation in a particular way, and FDA considered and rejected the same comment or a similar comment when the agency was drafting the final regulation, and the citizen petition contained no new evidence warranting a change in FDA's earlier decision, the agency's denial letter might simply state that the agency considered the same matter during the rulemaking and that the petition did not provide any new information that would change FDA's earlier decision.

Other examples of where a brief response denying a petitioner's request may be appropriate include, but are not limited to:

1. A citizen petition that makes a request that is outside FDA's legal authority or is based on unsupported claims or allegations. This would complement the changes in proposed § 10.30(b).

2. A citizen petition that is substantially similar or identical, in terms of its requests or issues, to an earlier administrative proceeding or action, and the citizen petition has not identified any significant change in evidence, laws, or regulations that affect the previous administrative proceeding or action. For example, in the past, some petitioners have submitted the same or similar petitions after receiving an unfavorable response. In these situations, when there has been no change in evidence, laws, or regulations since FDA's earlier response, the agency's denial letter might simply say that the agency has previously considered the same or similar request and that the petition has provided no new information that would change the agency's earlier decision.

3. A citizen petition where the agency has determined that the petition does not implicate a significant public health issue, and the agency lacks the resources to provide a more detailed response or to take the action requested by the petitioner. This may occur, for example, where the petitioner requests a change in FDA's regulations that has no significant public health implications, such as amending or establishing common or usual names regulations or standards of identity, quantity, and fill of container regulations for foods or allowing the use of a different test or method or a different manufacturing standard when the difference has no significant public health advantage over the existing test, method, or standard. In the absence of a significant public health issue, and considering the intense demand on FDA's resources, the agency must allocate its resources carefully and

wisely, so brief denial of these types of citizen petitions would be appropriate.

4. A citizen petition where changes in fact, science, or law since the date on which the citizen petition was submitted have made the petition moot. For example, if a citizen petition requested a change to a regulation that has been rescinded or withdrawn, drafting a detailed response to the petitioner's requested change would not be an efficient use of agency resources. Thus, a brief denial for these petitions would be appropriate.

C. Proposed § 10.30(e)(4)—Referral and Withdrawal of Citizen Petitions and Consolidation of Multiple Petitions

Proposed § 10.30(e)(4)(i) would authorize FDA to take administrative action other than preparing a formal response to a citizen petition. This would occur when a citizen petition involves a subject that is being addressed in another administrative proceeding (such as an ongoing or future rulemaking) or presents issues or involves requests that can be addressed through correspondence, meetings, or other agency action. Under such circumstances, the proposed rule would permit, but not require, the agency to refer the petitioner's information to the other administrative proceeding or to refer the petitioner's information to the relevant FDA center for its consideration and any appropriate action. If FDA refers a citizen petition to another administrative proceeding, the citizen petition would remain filed in FDA's Dockets Management Branch, but the agency would place a note in the citizen petition's docket stating that the petitioner's information has been referred to another administrative proceeding and that the petition's docket is closed.

For example, FDA sometimes receives petitions on topics that are the subject of a pending FDA regulation. Under the proposed rule, FDA could refer the petition to the docket for the rulemaking where it would be treated as if it were a comment on the rule, and the petition's docket would contain a note referring to the rulemaking. Referring information to the appropriate administrative proceeding would be an efficient and practical mechanism for reviewing scientific or technical issues because it would ensure that the relevant FDA office considers the petitioner's information in conjunction with the data and information contained in the administrative proceeding (as opposed to allocating separate resources to the administrative proceeding and to the citizen petition or completing the administrative proceeding and citizen petition at different times).

As another example, some petitions raise substantive scientific issues and request that the agency not approve or rescind approval of a specific product. In these cases, it may be more appropriate for the agency to investigate the scientific issues or conduct a meeting to discuss those issues before deciding what regulatory action, if any, to take against the product. Thus, the proposed rule would preserve FDA's flexibility to develop the appropriate administrative response. This flexibility may be particularly valuable when, after reviewing the petitioner's request, the agency determines that the best solution is different from the one suggested by the petitioner.

Proposed § 10.30(e)(4)(ii) would permit the agency to seek clarification of a petitioner's requests. Occasionally, FDA receives citizen petitions that make vague or conflicting requests, but the existing regulations do not expressly permit FDA to request clarification from the petitioner. The proposal would remedy this by permitting FDA to seek clarification. The request for clarification would include a time period for providing the clarifying information to FDA. If the petitioner fails to provide the requested clarification to FDA within that time period, proposed § 10.30(e)(4)(ii) would permit the agency to consider the petition to be withdrawn.

Proposed § 10.30(e)(4)(iii) would permit FDA to consider a citizen petition to be withdrawn where the agency is aware that the petitioner no longer exists or the petitioner cannot be located, or where the petitioner has expressly stated that it does not seek a response to its petition. For example, if a firm submitted a citizen petition and subsequently went out of business, the proposal would permit FDA to consider the petition to be withdrawn. As another example, in rare cases, persons have submitted citizen petitions to protest a particular FDA action. These petitions state that they are submitted as a protest or for symbolic reasons and that no response is sought or expected. Nevertheless, existing regulations do not give FDA express authority to withdraw these petitions even though it is both illogical and a waste of agency resources to require FDA to develop and to issue petition responses when the petitioner no longer exists or when the petitioner seeks no response. The agency does not contemplate using this authority often.

Proposed § 10.30(e)(4)(iv) would apply where FDA has received multiple citizen petitions on the same subject or involving the same product or has received similar or identical citizen petitions from different parties. These citizen petitions, which sometimes contain only a single request and are submitted over an extended period of time, divert FDA resources repeatedly and, from FDA's perspective, inefficiently when the petitioner or petitioners could have easily submitted all requests in the same petition or when the petitioner submits essentially the same petition repeatedly. The proposal, therefore, would enable FDA to combine multiple citizen petitions on the same issue or product. The agency encourages potential petitioners to combine petitions and requests to the greatest extent practicable.

D. Conforming or Miscellaneous Amendments

Section 10.25(a) (21 CFR 10.25(a)) currently states how petitions can be used to initiate an administrative proceeding. Because proposed § 10.30 would redefine the types of actions that may be the subject of a citizen petition, the agency is proposing to revise § 10.25(a) to enable interested persons to request (rather than ''petition'' for) the initiation of an administrative proceeding. Such requests would be made when the desired administrative proceeding falls outside the scope of proposed § 10.30.

Because the proposed rule would permit the agency to refer and to withdraw citizen petitions under certain conditions, two conforming amendments to § 10.30(e)(1) and (e)(2) would be necessary. Currently, § 10.30(e)(1) states that the Commissioner shall ''rule upon'' each petition. Arguably, because a decision to withdraw a citizen petition does not necessarily involve a decision directly on the citizen petition's merits, FDA is proposing to amend § 10.30(e)(1) to state that the Commissioner shall ''act upon'' each citizen petition.

Similarly, § 10.30(e)(2) states that the Commissioner shall furnish a response to each petitioner within 180 days (except to persons who submitted suitability petitions, in which case the response time period is 90 days). Arguably, a decision to refer or withdraw a citizen petition under the proposed rule might not be considered a ''response,'' so FDA is proposing to amend § 10.30(e)(2) to state that, ''Except as provided in paragraphs (e)(4) and (e)(5) of this section * * *.''

The proposal would also revise § 10.30(b) to update the address for the Dockets Management Branch.

III. Legal Authority

When first issued over 20 years ago, FDA's citizen petition regulations were intended to reflect the right to petition the government and to reduce ''confusion and uncertainty on the part of those who wish to petition the agency on a particular matter, as well as on the part of those in the agency who have received various forms of requests and have been unable to determine how they should be handled'' (see 40 FR 40682 at 40686, September 3, 1975).

The right to petition, however, is not absolute; it does not include the right to speak to government officials (see *Welch* v. *Board of Education of Baltimore County*, 477 F. Supp. 959 (D. Md. 1979)), nor does it include the right to an oral hearing (see *Stengel* v. *City of Columbus, Ohio*, 737 F. Supp. 1457 (S.D. Ohio 1988)). Neither does the right to petition the government create an affirmative duty on the government to act or to investigate. See *Minnesota State Board for Community Colleges* v. *Knight*, 104 S. Ct. 1058, 1067 (1984); *Smith* v. *Arkansas State Highway Employees*, 441 U.S. 463, 465 (1979); *Gordon* v. *Heimann*, 514 F. Supp. 659 (N.D. Ga. 1980); *Town of Brookline* v. *Goldstein*, 447 N.E.2d 641, 646 (Mass. 1983).

In fact, court opinions indicate that agencies have broad discretion in establishing and applying rules for public participation in agency matters (see *Cities of Statesville, et al.* v. *Atomic Energy Commission*, 441 F. 2d 962 (D.C. Cir. 1969); *Pasco Terminals, Inc.* v. *United States*, 477 F. Supp. 201 (1979), aff'd 634 F. 2d 610)). Moreover, the Supreme Court has indicated that courts cannot require more than minimum procedural boundaries even if a proposed regulation would establish complex or technical factual issues or important public issues; in those instances, an agency is to decide whether additional procedures are needed. See *Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council, Inc.*, 98 S. Ct. 1197, 1202 (1978).

Here, the proposed rule does not restrict access to or contact with the agency; it simply redefines the types of actions that may be the subject of ''citizen petitions'' under § 10.30 in order to make that formal administrative mechanism more responsive and efficient. Indeed, given that other FDA's regulations provide other means for contacting the agency (see, e.g., § 10.65(a) (regarding correspondence)), the citizen petition regulation at § 10.30 cannot and should not be viewed as being the sole or exclusive mechanism for ''petitioning'' FDA or as an exclusive mechanism for exercising a right to petition FDA.

Certain aspects of the proposed rule, such as the proposed provisions concerning brief denials, withdrawals, and referrals to other administrative action, would affect how citizen petitions are handled. However, as stated earlier, agencies have broad discretion in establishing and applying rules for public participation in administrative matters. The proposal furthers an important government interest–permitting the agency to concentrate its resources on agency priorities and statutory obligations instead of diverting those resources to, for example, citizen petitions that request actions outside FDA's authority, that repeat requests that the agency has already addressed, or that are submitted for symbolic purposes.

Furthermore, as court decisions readily indicate, the right to petition does not impose any duty on the government to take any specific action. Given this case precedent, it would be illogical to conclude that the right to petition demands that FDA continue to receive citizen petitions under § 10.30 requesting actions which FDA cannot legally perform or to have FDA decide how it might act on a particular issue in the future. The proposed rule preserves an individual's ability to submit a citizen petition to FDA for actions that FDA has taken and for actions that are within FDA's legal authority, as well as other types of actions specified in proposed § 10.30.

Persons who wish to contact or ''petition'' FDA on issues that are outside the scope of proposed § 10.30 would still be able to contact the agency, through letters, calls, or other means of communication. FDA emphasizes, again, that the proposed rule would not reduce public access to FDA; instead, it is intended to make the formal citizen petition process more efficient and more responsive.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(a) and (h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize new benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize the impact of the rule on small entities.

The Unfunded Mandates Reform Act of 1995 requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation).

The agency has reviewed this proposed rule and determined that it is consistent with the regulatory philosophy and the principles identified in the Executive Order 12866 and these two statutes. Though this proposed rule is not economically significant, it has been determined by OMB that this proposed rule is a significant regulatory action.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant economic impact on small entities. The proposed rule would define the actions that may be the subject of a citizen petition and facilitate efficient resolution of citizen petitions. It would not preclude persons from using less formal means (such as letters) to contact the agency. In fact, because less formal means of communication lack the format and procedures associated with citizen petitions, the economic impact on small businesses should be reduced when compared against the existing citizen petition mechanism. Thus, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given

below in this section of the document with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action

Description: The proposed rule would specify the types of actions that could be requested through a citizen petition. The proposal would also revise the content requirements for citizen petitions and provide authority for the agency to refer petitions for other administrative action, seek clarification of a petitioner's requests, withdraw certain petitions, and combine petitions.

Description of Respondents: Businesses, trade organizations, public interest groups, and individuals.

The proposed rule would increase the estimated burden associated with the information collection requirements from 1,440 hours to 2,646 hours. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	189	1	189	14	2,646

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in Table 1 reflect the reporting burden that would be attributable solely to the rule. FDA derived these estimates by examining its records to determine the average number of citizen petitions submitted to FDA and by decreasing the number of respondents by 30 percent. The agency calculated the percentage reduction in citizen petitions by reviewing all citizen petitions filed in a 6-month period in 1997 against the proposed rule's citizen petition criteria. The review suggested that the proposed rule would reduce the number of citizen petitions by over 30 percent, but the agency is adopting the 30 percent estimate as an initial estimate.

Additionally, FDA has revised the hours per response from 12 hours to 14 hours. The additional two hours reflect the proposed rule's changes to the content requirements for a citizen petition and the change to the certification statement. This additional amount of time may be overestimated because, under the existing citizen petition regulation, petitioners are already required to provide all relevant information and views and a certification as part of their petitions.

The agency has submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to send comments regarding information collection by December 30, 1999, to the Office of Information and Regulatory Affairs, OMB (address above).

Interested persons may, on or before February 28, 2000, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 10 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558; 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 236b, 264.

2. Section 10.25 is amended by revising paragraph (a) to read as follows:

§ 10.25 Initiation of administrative proceedings.

* * * * *

(a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or request that the Commissioner take or refrain from taking any other form of administrative action. For petitions involving a regulation or order, the petition must be either:

(1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1 of this chapter, for a food additive petition in § 171.1 of this chapter, for a new drug application in § 314.50 of this chapter, for a new animal drug application in § 514.1 of this chapter, or

(2) In the form for a citizen petition in § 10.30. For requests involving administrative action, the request may be made in any written form (e.g., letter, facsimile).

* * * * *

3. Section 10.30 is amended by revising paragraphs (b), (e)(1), the introductory text of paragraph (e)(2), paragraph (e)(2)(ii), by redesignating paragraph (e)(4) as (e)(5), and by adding a new paragraph (e)(4) to read as follows:

§ 10.30 Citizen petition.

* * * * *

(b) A petition (including attachments) shall be submitted in accordance with § 10.20 and in the following form:

(Date) _____

Dockets Management Branch (HFA–305), Food and Drug Administration, Department of Health and Human Services, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

CITIZEN PETITION

The undersigned submits this petition under ____ (relevant statutory sections, if known) of the ____ (Federal Food, Drug, and Cosmetic Act or the Public Health Service Act or any other statutory provision for which authority has been delegated to the

Commissioner of Food and Drugs under 21 CFR 5.10) to request that the Commissioner of Food and Drugs ____ (issue, amend, or revoke a regulation or amend or revoke an order that the agency has issued or published or take an action as specifically provided by regulation).

A. Action requested

((1) If the petition requests that the Commissioner issue, amend, or revoke a regulation, the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.)

((2) If the petition requests that the Commissioner amend or revoke an order, the date on which the order was issued or published, the exact wording and the citation for the existing order and, if the request is to amend an order, the exact wording requested for the amended order.)

((3) If the petition requests that the Commissioner take an action, and a petition is specifically required by regulation, a citation of the regulation and the specific action requested.)

B. Statement of grounds

(A full statement, in a well organized format, of the factual and legal grounds on which the petitioner relies, including all relevant information and views on which the petitioner relies, as well as representative information known to the petitioner which is unfavorable to the petitioner's position. Additionally, for petitions requesting that FDA issue, amend, or revoke a regulation, the petition shall show why the requested regulation pertains to a subject that is appropriately addressed by regulation rather than other administrative action. For petitions requesting that FDA amend or revoke an order that was issued or published, the petition shall be based on more than unsupported claims, allegations, or general descriptions of positions or arguments.

C. Environmental impact

(A claim for categorical exclusion under §§ 25.30, 25.31, 25.32, 25.33, or § 25.34 of this chapter or an environmental assessment under § 25.40 of this chapter.)

D. Economic impact

(The following information is to be submitted only when requested by the Commissioner following review of the petition: A statement of the effect of the requested action on: (1) Cost (and price) increases to industry, government, and consumers; (2) productivity of wage earners, businesses, or government; (3) competition; (4) supplies of important materials, products, or services; (5) employment; and (6) energy supply or demand.)

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, that it is well grounded in fact and is warranted by existing laws or regulations, that it is not submitted for any improper purpose, such as to harass or to cause unnecessary delay, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number)_____

* * * * *

(e)(1) The Commissioner shall, in accordance with paragraph (e)(2) of this section, act upon each petition filed under paragraph (c) of this section, taking into consideration:

(i) Available agency resources for the category of subject matter;

(ii) The priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency; and

(iii) Time requirements established by statute.

(2) Except as provided in paragraphs (e)(4) and (e)(5) of this section, the Commissioner shall furnish a response to each petitioner within 180 days of receipt of the petition. The response will either:

* * * * *

(ii) Deny the petition; the denial may be brief, as appropriate; or

* * * * *

(4) The Commissioner may:

(i) Refer a petition for other administrative action instead of issuing a response. In such cases, the agency shall place a note in the docket for the petition stating that the petition has been referred for other administrative action and close the docket for the petition. FDA may refer a petition for other administrative action if the petition:

(A) Involves issues that are the subject of an ongoing or future administrative proceeding. In such cases, the agency may consider the issues raised by the petition as part of the administrative record for the administrative proceeding;

(B) Presents scientific or technical issues or data that are specific to a particular product or class of products;

(C) Requests a regulation on an issue that is not appropriately addressed by regulation;

(D) Does not involve a significant public health or consumer protection issue; or

(E) Involves a subject that is appropriately addressed by other administrative action.

(F) For petitions described in paragraphs (e)(4)(i)(B) through (e)(4)(i)(E) of this section, the agency may treat the petition as correspondence under § 10.65.

(ii) Request clarification if the petition presents vague or conflicting requests. If the petitioner does not respond to the request for clarification within a time specified by FDA, the petition may be considered withdrawn;

(iii) Consider the petition to be withdrawn if the petitioner no longer exists or cannot be located or the petitioner has stated that it does not seek a response from the agency; or

(iv) Combine petitions and supplements submitted by the same petitioner or by different petitioners if those petitions concern the same or similar subjects or products.

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Dated: August 10, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–30957 Filed 11–29–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

RIN 1076—AD90

Acquisition of Title to Land in Trust

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule; Reopening of comment period.

SUMMARY: This notice reopens the comment period for submission of electronic access and filing of comments only for the proposed rule published at 64 FR 17574–17588, April 12, 1999, Acquisition of Title to Land in Trust. Due to circumstances beyond our control, a malfunction in the computer system prevented receipt of comments via the Internet after August 1, 1999. Comments submitted via the Internet between August 1, 1999 and November 12, 1999 were not received. Please resubmit your Internet comments as an ASCII file avoiding the use of special characters and any form of encryption. Please also include ''Attn: 1076–AD90'' and your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact the Office of Trust Responsibilities directly at (202) 208–5831.

DATES: Comments must be received on or before December 29, 1999.

ADDRESSES: Please resubmit your e-mail comments to: landcomments@bia.gov.

FOR FURTHER INFORMATION CONTACT: Terry Virden, Director, Office of Trust Responsibilities, Bureau of Indian Affairs, MS–4513, Main Interior Building, 1849 C Street, NW,