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; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing a proposed rule that appeared in the **Federal Register** of November 30, 1999 (64 FR 66822). The proposal would have modified the types of actions that can be requested through a citizen petition; revised certain content requirements for citizen petitions; and permitted the agency to refer citizen petitions for other administrative action, seek clarification of a petitioner's request, withdraw certain petitions, and combine petitions. We proposed these changes to improve the citizen petition process by making it more efficient and reducing the backlog of pending requests. We believe the proposed rule is no longer needed because we have made other improvements to our process for responding to citizen petitions.

DATES: The proposed rule is withdrawn on April 4, 2003.

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

SUPPLEMENTARY INFORMATION: FDA's citizen petition regulations at 21 CFR 10.30 provide a formal means for the public to contact FDA and seek its action or response on a particular matter. For example, the petition process can be used by a drug company to request a change in the approval standards for a generic competitor, a food trade association can request that we establish exemptions from certain package labeling requirements, or a consumer group can petition us to tighten regulation of a particular product. Citizen petitions are submitted to our Dockets Management Branch for processing and referral to the appropriate office, and our regulations require us to issue a tentative or final response within 180 days after receiving the citizen petition.

While the citizen petition process has benefited both FDA and the public, reviewing and responding to citizen petitions is often resource intensive and time consuming. We must research the petition, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the response. Petitioners occasionally sue over unfavorable responses or delays in issuing a response. This litigation consumes additional resources and time.

Historically, we have received more citizen petitions than we have been able to answer. We receive nearly 290 citizen petitions annually, and, in most years, the number of incoming citizen petitions exceeded the number of responses that we would issue. In the past, the response rate was approximately 100 responses per year. This resulted in a steadily growing backlog of citizen petitions.

Faced with a growing backlog of petitions and increasing demands on our resources, on November 30, 1999, we proposed to amend our citizen petition regulations to make the citizen petition system more efficient and responsive (64 FR 66822). The major changes under the proposal would:

- Limit the types of actions that could be requested through a citizen petition to: (1) Requests to issue, amend, or revoke a regulation; (2) requests to amend or revoke an order that FDA had issued or published; and (3) requests for any other action specifically authorized by another FDA regulation.
- Revise the content requirements to include a certification 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.''
- Allow us to refer petitions for other administrative action, seek clarification of a petitioner's requests, withdraw certain petitions, and combine petitions.

The preamble to the proposed rule emphasized that, while we were redefining the types of actions that could be the subject of a citizen petition, interested parties would still have other means of contacting or communicating with us.

We received nearly 20 comments on the proposed rule, with most comments opposing the rule in whole or in part. The comments opposed to the rule came from industry and public interest groups and stated that citizen petitions are a valuable means for communicating with us or for allowing public participation in agency actions. They expressed concern that the changes would unduly restrict the use of citizen petitions. Nonetheless, several comments supported the underlying goal of the proposal, and some of its relatively minor changes, pointing to the still-unanswered petitions they had submitted earlier as evidence that improvements were needed.

Two comments supported the proposal. These comments agreed with us that the proposal would prevent misuse of the citizen petition process (particularly with respect to approvals of generic drugs), and they suggested additional changes to strengthen the citizen petition process.

As we evaluated the comments, we continued efforts to improve our handling of citizen petitions. These efforts have led to a marked increase in the number of citizen petition responses, and our current annual response rate is equal to, and sometimes even exceeds, the number of citizen petitions that we receive. Given this progress, we believe that a revision of the citizen petition regulations is not warranted at this time. Consequently, we are withdrawing the proposed rule.

Dated: March 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–8165 Filed 4–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 902

[Docket No. FR–4707–N–07]

Public Housing Assessment System (PHAS) Proposed Rule: Notice of Extension of Public Comment Period

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of extension of public comment period.

SUMMARY: This notice extends, for an additional sixty days, the public comment period for the proposed rule that would amend the regulations for the Public Housing Assessment System (PHAS).

DATES: Comment Due Date: June 8, 2003.

FOR FURTHER INFORMATION CONTACT: For further information contact the Office of Public and Indian Housing Real Estate