

The United States Department of Health and Human Services
Food and Drug Administration

1700 '00 FEB 29 P1:34

Citizen Petitions; Actions That Can be Requested by Petition;) Docket No. 99N-2497
Denials, Withdrawals, and Referrals for Other Administrative Action)

Comments of

Center for Science in the Public Interest

Michael F. Jacobson, Ph.D.
Executive Director
1875 Connecticut Avenue, N.W.
Washington, D.C. 20009
(202) 332-9110

99N-2497

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February 28, 2000

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

Re: Docket No. 99N-2497
Citizen Petitions; Actions That Can be Requested by Petition; Denials,
Withdrawals, and Referrals for Other Administrative Action.

The Center for Science in the Public Interest (CSPI)¹ appreciates this opportunity to comment on the Food and Drug Administration's (FDA) proposal regarding citizen petitions. Since we were founded in 1971, CSPI has filed dozens of petitions with the Agency, seeking adoption of regulations or requesting specific enforcement actions. The ability of organizations like ours, as well as individual citizens, to petition the agency is a fundamental component of an open, responsive government. Any attempts to unduly hamper this ability should be opposed.

While the goal of this proposed rule is to improve the citizen petition mechanism, we are concerned that the result may be just the opposite. One of the major proposed changes would prohibit citizens from using petitions to request that FDA amend pending orders or issue future orders. It is unclear how this change will effect our ability to request that the agency take specific enforcement actions, such as prohibiting misleading labeling on food products. We are concerned that our ability to prompt agency action may be impaired.

The agency indicates in the preamble to the proposed rule that, while the petition process may no longer be available, any person who wants to present information to the FDA or to

¹ CSPI, a non-profit consumer organization supported by almost 1,000,000 members, has worked since 1971 to improve national health policies. We have been especially concerned about food labeling and food safety.

request that particular actions be taken – requests that are not necessarily “speculative” or “insignificant” as alleged by the Agency -- would still be able to do so through letters, electronic mail, meetings, and discussions. These other avenues of communications, however, may not be legally equivalent to a petition. For example, FDA rules require that the Commissioner respond to each petitioner within 180 days of receipt of a petition, 21 C.F.R. §10.30(e)(2), but provide no such deadline for requests made in letters, meetings, and other forms of communication. We are concerned that this discrepancy will have a negative impact on public input regarding FDA activities.

CSPI would also like to take this opportunity to comment on 21 C.F.R. §10.30(e)(2). We urge the agency, in particular the Center for Food Safety and Applied Nutrition, to comply with the 180-day deadline for responding to citizen petitions provided in this regulation. Many of the petitions that CSPI has filed with the Agency have been languishing in the Dockets Room for years; some others have been put out for comment, but often only after a number of years, not months, as is required by law. For example, FDA recently put out for comment a CSPI petition regarding trans fat labeling that was filed in February 1994. It should not take more than 5 years for the Agency to take action on a petition. We urge the agency and CFSAN to develop expeditious review procedures for petitions, which may involve not only structural reorganization, but also some reallocation of resources.

Sincerely,


Bruce Silverglade
Director of Legal Affairs

Of Counsel
Sandra B. Eskin, Esq.

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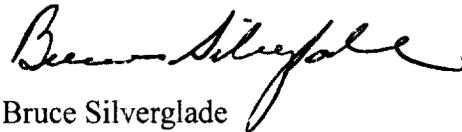
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To Whom it May Concern:

Please find enclosed two copies of the Comments of the Center for Science in the Public Interest on the above Docket No. 99N-2497. Thank you for your attention to this matter.

Sincerely,



Bruce Silverglade
Director of Legal Affairs