

June 2, 2000

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

RE: Docket No. 00N-1060, Agency Information Collection Activities;  
Proposed Collection; Comment Request; Adoption of the FDA Food Code  
by Local, State, and Tribal Governments

Dear Sir or Madam:

I am writing as a private citizen.

This **Notice** solicits comments on the Food and Drug Administration's (FDA's) proposal to have the Association of Food and Drug Officials (AFDO) collect information, under contract, on adoption of the Food Code.

#### **Necessity for the Data Collection**

The Public Health Service Act (PHS Act) provides FDA with the authority to "...assist states and their political subdivisions..." and it is under this authority that the FDA Food Code is issued.

The PHS Act does not give the Agency authority to demand that states (or local subdivisions) accept the Federal recommendations found in the Food Code. In fact, the Tenth Amendment of the U.S. Constitution would seem clearly to permit states to accept in toto, reject in toto, or take whatever portions of the Food Code they like. While the FDA might like to know what each of the more than 3,000 State, local, Tribal, and other Federal Agencies are using as food safety requirements for the retail sector, there is no real need to actively search for such information.

Under the FDA's Draft Retail Program Standards (Standard #9), the Agency has suggested a self-reporting system, to include a section-by-section review of state (or other) laws, ordinances and regulations. FDA would then make the information available on its web site. Such a voluntary system is more in

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line with the normal relations between the FDA and the state, local, Tribal, and other Federal Agencies.

Currently, FDA lists on its web site those jurisdictions that have been reported to have adopted the Food Code or are in process of such adoption. Though this listing does not provide details on a section-by-section basis and, therefore, may be misleading to some degree, more definitive information is really neither helpful nor necessary.

The information that would be supplied under this contract does not help the Agency in any meaningful way and is therefore simply wasteful.

### **Sole-source Contract**

This is proposed to be a 5-year activity and has been sole-sourced at \$75,000 per year.

There are many organizations that could provide this service, assuming it was necessary. Yet, no opportunity was given for others to bid on this contract. One possible explanation for failure to advertise and seek less expensive bids is **conflict of interest**. A number of the FDA employees and contractors who were involved in suggesting or approving this data collection activity are AFDO members. Supplying a group of which you are a dues-paying member with \$375,000 of government contracting dollars seems to be an obvious conflict of interest.

For the two reasons delineated above, I feel strongly that this contract should not be approved and the Food Safety Initiative funds used to support initiatives that will directly benefit consumers.



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