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June 9, 2010

Washington State Board of Health PO Box 47990 Olympia WA 98504-7990

Re: Petition for Rule Making, Chapter 246-290 WAC - Water Fluoridation - June 9 hearing

Chair and Members of the Board of Health:

I am submitting these comments on behalf of Clallam County Citizens for Safe Drinking Water ("SAFE"). We have reviewed the May 11, 2010 Petition to Improve and Protect the Public's Health with Rule-Making on Fluoridation (Fluoride Added to Public Drinking Water) ("Petition") that is scheduled for review as Item 16 on the Proposed Final Agenda for the Washington State Board of Health for June 9, 2010 ("Item 16").

We are strongly in support of the Petition and the changes proposed in the Petition for WAC 246-290-460 and WAC 246-290-220.

One of the items in your packet for Item 16 is the FDA & EPA MOU Number 225-79-2001, 1979. This MOU was issued to resolve a conflict in authority between the EPA and FDA regarding additives to drinking water. Subsection II.A of the MOU recognizes FDA authority to control "food additives." It is only this authority of the FDA to control "food additives" that is considered by the memo to be in conflict with EPA authority. There is no suggestion in the MOU that the FDA authority to regulate drugs is in conflict with any EPA authority. Therefore, this MOU may not be used to suggest that when drinking water is used to distribute drugs (such as fluoride to mitigate or prevent dental caries), it is validly done under the authority of the EPA.

Manufacture and distribution of drugs is controlled only by the FDA in interstate commerce and by the Board of Health and Board of Pharmacy in intrastate commerce. Because all fluoride compounds used to fluoridate water to mitigate or prevent dental disease are used in interstate commerce, they must be subject to FDA drug regulation.

SAFE was the Appellant in <u>Clallam County Citizens for Safe Drinking Water v. City of Port Angeles</u>, 137 Wn.App. 214, 151 P.3d 1079 (2007).

Washington State Board of Health June 9, 2010 Page 2

SAFE requests that this Board also amend WAC 246-290-220(3) when it responds to the Petition. This WAC currently allows drugs to be added to public drinking water if they are approved by the industry-generated "ANSI/NSF Standard 60" even if they do not comply with drug regulations of the FDA.

SAFE suggests the following amendment (underlining below) to WAC 246-290-220(3):

WAC 246-290-220(3): Any treatment chemicals, with the exception of commercially retailed hypochlorite compounds such as unscented Clorox, Purex, etc., added to water intended for potable use must comply with ANSI/NSF Standard 60. The maximum application dosage recommendation for the product certified by the ANSI/NSF Standard 60 shall not be exceeded in practice. Drugs to be added with the intent to treat, mitigate, diagnose, or prevent disease (including fluoride compounds added to mitigate or prevent dental caries) must be approved by the Food and Drug Administration Center for Drug Evaluation and Research in a New Drug Application.

The changes proposed in the Petition and the additional change proposed above are necessary to protect the health of the public.

Very truly yours,

Gerald Steel

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Attorney for SAFE