



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 4 2000 9 881 '00 DEC -7 P1:28

The Honorable Susan M. Collins
United States Senate
Washington, D.C. 20510-1904

Dear Senator Collins:

Thank you for your letter of October 3, 2000, co-signed by Senator Olympia J. Snowe. You requested that the Food and Drug Administration (FDA or the Agency) complete action on a proposed microbiological quality standard for coliform bacteria in bottled water that was announced in the Federal Register (FR) of October 6, 1993 (58 FR 52042, the 1993 proposal). A similar response has been sent to Senator Snowe.

By way of background, it is important to note that the existing requirements of the Federal Food, Drug, and Cosmetic (FD&C) Act and regulations issued under that Act for bottled water address the safety of bottled water and are sufficiently protective of public health. FDA issued the 1993 proposal for purposes of consistency with the Environmental Protection Agency's (EPA) regulation for total coliform bacteria in public drinking water.

As you know, the 1993 proposal would change the existing FDA quality regulations for bottled water. In 1989, EPA published a final rule amending its National Primary Drinking Water Regulation for total coliform bacteria in public drinking water. At that time, section 410 of the FD&C Act required that within 180 days after EPA's promulgation of a national primary drinking water regulation, FDA was to consult with EPA and either promulgate amendments to FDA's regulations to bottled water or publish in the Federal Register reasons for not making such amendments. Although FDA determined the current regulations were protective of the public health, FDA proposed, in 1993, to change its microbiological quality standard for coliform bacteria in bottled water in order to make it consistent with EPA's 1989 final rule.

93N-0200

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In its 1989 rule, EPA set a maximum contaminant level goal of zero for coliform bacteria but made limited allowance for coliform bacteria to be present in public drinking water because coliforms are a persistent presence in some public water distribution systems. FDA tentatively concluded in the 1993 proposal that an allowance for the presence of coliforms in bottled water would not be appropriate since water bottlers do not use public water distribution systems to deliver finished bottled water products. Therefore, FDA proposed to revise its microbiological quality standard to provide that coliform bacteria not be present in bottled water. A number of comments were submitted to the 1993 proposal.

After carefully evaluating these comments, FDA has determined that concerns raised in the comments may not be satisfactorily addressed in a final rule. Therefore, we are considering whether to develop a new proposal to revise the microbiological quality standard for coliform bacteria in bottled water in conjunction with a withdrawal of the 1993 proposal.

Thanks again for contacting us concerning this matter. We have forwarded your correspondence to the Docket for the 1993 proposal (Docket No. 93N-0200) for inclusion in the record. If you have further questions, please let us know.

Sincerely,



Melinda Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch (HFA-305)

United States Senate
WASHINGTON, DC 20510

October 3, 2000

Jane E. Henney, M.D.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

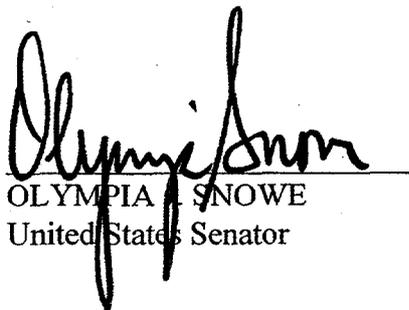
Dear Dr. Henney:

In 1993, the FDA established the need for a regulation for a standard of quality for coliform content in bottled water for the protection of the public's health. The proposed FDA regulation crafted seven years ago would bring the government's standard into consistency with the current stringent bottled water industry standard to compliment the FDA's ongoing food safety initiatives. We are writing to request that the Food and Drug Administration not only finalize the standard but to consider the inclusion of the EPA's repeat monitoring procedure and approved testing methodology model, for example, *colilert*.

As you may be aware, the bottled water industry has a quality standard for coliform that requires bottled water to be free of coliform bacteria, which is associated with the outbreak of disease. The level of total coliform bacteria in water is used to measure the microbiological quality of drinking water. Retesting for the presence of coliform bacteria should be required, and, to avoid needless recalls of products and to create consistency, the FDA should consider adopting the retesting procedures from EPA's model.

Thank you for your timely attention to this public health matter. We look forward to hearing from you as to what your decision may be for making this small but important change to your proposed rule and urge you to finalize the standard of quality as soon as possible.

Sincerely,


OLYMPIA SNOWE
United States Senator


SUSAN M. COLLINS
United States Senator

60-6618