

(1) A bottler shall [submit an annual report to the Department that demonstrates continued compliance of the source and the product with the Codex Alimentarius standards by:

(i) Testing and approval of the source and product at least once every 2 months by the appropriate authority;

(ii) Microbiological testing:

1. On a weekly basis, as described in the Code of Hygienic Practices of the Codex Alimentarius, Alinorm 85/13A, for the collection, processing, and marketing of natural mineral water; and

2. In accordance with the standards described in 21 CFR 103.35; and

(iii) An annual inspection by an independent organization acceptable to the Department that demonstrates compliance with the Code of Hygienic Practices of the Codex Alimentarius, Alinorm 85/13A, and with the requirements of 21 CFR Part 129 for the collection, processing, and marketing of natural mineral water; and] **RENEW THE WAIVER OF THE FILTRATION AND DISINFECTION TREATMENT PROVIDED UNDER SUBSECTION (B) OF THIS SECTION ON AN ANNUAL BASIS IF A CONTINUATION OF OPERATIONS IS DESIRED BY SUBMITTING A LETTER OF COMPLIANCE WITH SUBSECTION (C) OF THIS SECTION FROM A REPRESENTATIVE OF THE BOTTLER TO THE DEPARTMENT.**

(2) THE REPRESENTATIVE OF THE BOTTLER SHALL CERTIFY UNDER PERSONAL KNOWLEDGE AND PENALTY OF PERJURY THAT THE CONDITIONS UNDER SUBSECTION (C) OF THIS SECTION ON WHICH THE WAIVER WAS GRANTED HAVE NOT CHANGED.

(3) THE REPRESENTATIVE OF THE BOTTLER SHALL HAVE A CONTINUING OBLIGATION TO NOTIFY THE DEPARTMENT OF ANY CHANGE OF A CONDITION UNDER SUBSECTION (C) OF THIS SECTION NOT LATER THAN 5 DAYS FROM THE DATE OF THE CHANGE.

[(2)] (4) The product shall be bottled:

(i) In an enclosed filling room or chamber that is under positive pressure of filtered purified air; and

(ii) At a facility and with good manufacturing practices that comply with the requirements of 21 CFR Part 129.