



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
FAX: 504-253-4568

July 10, 2000

WARNING LETTER NO. 2000-NOL-27

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. John Tesvich, Owner
AmeriPure Oyster Companies
803 Willow Street
Franklin, Louisiana 70538

Dear Mr. Tesvich:

On November 11, 1999, the U.S. Food and Drug Administration (FDA) collected labels and labeling of AmeriPure Oyster Companies products from your firm, located at 803 Willow Street, Franklin, Louisiana, 70538.

The FDA reviewed the labels and labeling of your oyster products and found them misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the Act). The name "oysters" implies that your firm's products are prepared in accordance with Title 21, Code of Federal Regulations (CFR), Part 161.130(b), of the oyster standard while, in fact, the products are treated with the [REDACTED] process. The name of the oyster product must be sufficiently descriptive to distinguish these products from raw, untreated oysters. We suggest using the name "raw in-shell oysters pasteurized to reduce *V. vulnificus*" or "raw in-shell oysters temperature treated to reduce *V. vulnificus*" as appropriate statements of identity.

In addition, the AmeriPure oyster products are misbranded under section 403(e)(2) of the Act in that they fail to bear a net quantity of contents declaration as required by Title 21, CFR, Part 101.105. The net quantity of contents declaration must appear as a distinct item in the bottom 30 percent of the principal display panel, in lines generally parallel to the base of the container. The net quantity of contents statement must appear in both metric and the U.S. customary inch-pound system.

FDA also considers the phrase "Oysters have undergone AmeriPure's all-natural process to eliminate harmful bacterium such as . . ." to be misleading under section 403(a) of the Act in that the term "eliminate" means that the process has destroyed all pertinent microorganisms. However, absolute elimination cannot be guaranteed because of the limitations associated with detection methods. Therefore, use of the term "eliminate" is misleading.

FDA objects to use of the phrase “safest oysters in the world” and terms such as “safer” or “superior” to characterize this product. FDA has not sanctioned the use of terms that reference improved safety because of the potential for such terms to be misleading. These terms imply that the product is safer to consume than similar products (raw oysters), even though no attempt has been made to address, among other things, the virulence of the pathogen, or the consumer’s predisposed medical condition. The terms “safer” and “superior” also imply that oysters that have not undergone the *AmeriPure* process are not safe. For these reasons, we object to the phrase “safest oysters in the world” and to the terms “safer” and “superior” on the labels of oysters that have been treated with the *AmeriPure* process.

Your current labels state that the *AmeriPure* process is used to eliminate *V. parahaemolyticus* and other *Vibrio* species. Although we object to the term “eliminate” for the reasons stated above, if your firm can provide sufficient scientific data to substantiate that the process also reduces the levels of *V. parahaemolyticus* and other *Vibrio* species, then FDA would not object to the use of the statement “reduces potentially harmful bacterium . . .” on the labels of oysters that have undergone the *AmeriPure* process.

Your brochure used to promote the oyster products states that AmeriPure “. . . received unique one-of-a-kind labeling guidelines from FDA that do not require warning signs on control tags for raw oysters shipped out of state.” Although FDA gave labeling guidance to AmeriPure regarding their oysters (and did not state that a warning statement was required), FDA objects to this language in the brochure because it may be misleading.

We have also included the following labeling deviations that should also be brought to your attention for correction. These are:

- The nutrition information and the name and address of the manufacturer, packer or distributor do not appear together without intervening information as required by Title 21, CFR, Part 101.2; and,
- The statements, such as, “Oysters harvested from clean, government approved waters” and “All Naturally Cooled Pasteur-Iced . . .” should either be clarified or deleted. We object to the use of these statements on the labels of AmeriPure Oysters, as they imply that the government approves oysters, and other pasteurization processes are unnatural.

These comments are not an all-inclusive listing of AmeriPure's labeling deviations. It is your responsibility to assure that AmeriPure's labels are in full compliance with the food labeling laws and regulations that FDA enforces. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and /or injunction.

You should notify this office, within 15 days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 days, please state the reason for the delay and the time by which the corrections will be completed.

Your response should be directed to Patricia K. Schafer, Compliance Officer, U.S. Food and Drug Administration, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. Should you have any

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questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Ms. Schafer at (504) 253-4519.

Sincerely,

Nicole F. Hardin
for Carl E. Draper
District Director
New Orleans District