



DEPARTMENT OF HEALTH & HUMAN SERVICES

John E. Kammer, C.O. 8-19-97
Public Health Service
SLS

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 19, 1997

WARNING LETTER
97-DT-14

Mr. Steven I. Cohen, Manager
City Smoked Fish Co.
14440 Wildemere
Detroit, MI 48238

Dear Mr. Cohen:

An inspection of your fish processing operation was conducted on September 19, 20 & 30, 1996 by Investigators Michael V. Owens, Flavia R. Bender and Steven A. Jarred. During the inspection, the Investigators obtained two labels for City Brand Nova Salmon-Lox (3 lb.) along with the shipping box which holds 8/3 lb. trays, and the label for vacuum packed King Nova Salmon Sliced Lox (3 oz.) along with the display box which holds 12/3 oz. packages. Review of these labels and labeling revealed that your products are in serious violation of the Federal Food, Drug and Cosmetic Act (the Act) in that they are misbranded within the meaning of Sections 403(a), 403(i), 403(k), and 403(q) of the Act and Title 21, Code of Federal Regulations, Part 101 (21 CFR 101).

CITY BRAND NOVA SALMON-LOX, 3 LB. (CURRENT LABEL)

1. The product is misbranded within the meaning of Section 403(a)(1) of the Act in that the label statement "Smoked...by City Smoked Fish Co." is false and misleading since the inspection revealed that the product is not smoked or heat processed, but that liquid smoke flavor is added. Products flavored with liquid smoke are not considered as smoked. Consequently, the product should be labeled "smoke flavored" as required by 21 CFR 101.22(i), and the term "Smoked" unqualified should be removed from the label.
2. The product is misbranded within the meaning of Section 403(i)(2) of the Act in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient as required by 21 CFR 101.4. The label declares "sodium nitrate" as an ingredient of the product, whereas, FDA's inspection revealed that sodium nitrate is not added. Inspection found the added ingredients which are not declared in the ingredients listing are water, salt and sorbic acid.

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3. The product is misbranded within the meaning of Section 403(k) of the Act in that sodium nitrite is added to the product however, the ingredients listing does not identify this ingredient as a preservative as required by 21 CFR 101.22(j).

4. The product is misbranded within the meaning of Section 403(q)(1) of the Act because it fails to bear nutritional labeling in the formats required under 21 CFR 101.9.

In addition to the above violations, we note that the label statement of the place of business fails to include the ZIP code as required by 21 CFR 101.5(d) and that the ingredient designated as "vegetable oil" fails to be declared by its specific common or usual name as required by 21 CFR 101.4(b)(14).

CITY BRAND NOVA SALMON-LOX, 3 LB. (REVISED LABEL)

1. The product is misbranded within the meaning of Section 403(a)(1) of the Act in that the label statement "Smoked...by City Smoked Fish Co." is false and misleading since the inspection revealed that the product is not smoked or heat processed, but that liquid smoke flavor is added. Products flavored with liquid smoke are not considered as smoked. Consequently, the product should be labeled "Smoke flavored" as required by 21 CFR 101.22(i), and the term "Smoked" unqualified should be removed from the label.

2. The product is misbranded within the meaning of Section 403(k) of the Act in that sodium nitrite is added to the product however, the ingredients listing does not identify this ingredient as a preservative as required by 21 CFR 101.22(j).

3. The product is misbranded within the meaning of Section 403(i)(2) of the Act in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient. FDA's inspection at the firm revealed that water and sorbic acid are added to the product; however, the label fails to declare these ingredients as required by 21 CFR 101.4.

4. The product is misbranded within the meaning of Section 403(q)(1) of the Act because it fails to bear nutritional labeling in the formats required by 21 CFR 101.9.

In addition to the above violations, we note that the label statement of the place of business fails to include the ZIP code as required by 21 CFR 101.5(d). The ingredient designated as

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"vegetable oil" fails to be declared by its specific common or usual name as required by 21 CFR 101.4(b)(14). If the ingredient declared as "paprika oil" is used as a color, it should be designated in the ingredient statement in accordance with 21 CFR 101.22(k)(2) (e.g., "color added" or "colored with paprika oil").

CITY BRAND NOVA SALMON-LOX, 3 LB., SHIPPING BOX

1. The product is misbranded within the meaning of Section 403(a)(1) of the Act in that the identity statement "Smoked Salmon" is false and misleading since the inspection revealed that the product is not smoked or heat processed, but that liquid smoke flavor is added. Products flavored with liquid smoke are not considered as smoked. Consequently, the product should be labeled "smoke flavored" as required by 21 CFR 101.22(i), and the term "Smoked" unqualified should be removed from its label.

KING NOVA SALMON SLICED LOX, 3 OZ.

1. The product is misbranded within the meaning of Section 403(a)(1) of the Act in that label statements appearing on the back panel (i.e., "Smoked Nova Scotia Salmon or Lox" and "Smoked Nova Scotia Salmon and Lox") are false and misleading since they imply that the product is smoked. However, the inspection revealed that the product is not smoked or heat processed, but liquid smoke flavor is added. Products flavored with liquid smoke are not considered as smoked. Consequently, the product should be labeled "smoke flavored" as required by 21 CFR 101.22(i), and the term "Smoked" unqualified should be removed from its label.

2. The product is misbranded within the meaning of Section 403(i)(2) of the Act in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient as required by 21 CFR 101.4.

3. The product is misbranded within the meaning of Section 403(k) of the Act in that, based on inspectional evidence, the product contains sodium nitrite, but the label fails to declare its function in the product as required by 21 CFR 101.22(j) (e.g., "sodium nitrite (preservative)").

4. The product is misbranded within the meaning of Section 403(q)(1) of the Act in that the label fails to bear nutritional labeling in the formats required by 21 CFR 101.9.

KING NOVA SALMON SLICED LOX, 3 OZ., DISPLAY CARTON

1. The product is misbranded within the meaning of Section 403

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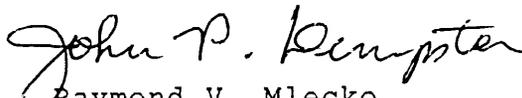
(a)(1) of the Act in that the label statement "Smoked...by City Smoked Fish Co." is false and misleading since the inspection revealed that the product is not smoked or heat processed, but liquid smoke flavor is added. Products flavored with liquid smoke are not considered as smoked. Consequently, the product should be labeled "smoke flavored" as required by 21 CFR 101.22(i), and the term "Smoked" unqualified should be removed from its label.

This is not intended to be a complete list of violations which may be present on your food labels. As a manufacturer of food products, it is your responsibility to assure that all of your products comply with applicable regulations. You should take prompt action to assure your labels are brought into compliance. Failure to take such action may result in regulatory action, such as seizure and/or injunction, without further notice.

For your information, the law requires net contents to be declared in metric units as well as inch-pound units. However, FDA has not published final regulations on how the declaration is to be made. The Agency recommends that firms wishing to avoid having to change labels again when the regulations on metric declaration become effective should add the metric contents statements now, using the guidance provided in the proposed regulations published in the Federal Register of December 21, 1993. We expect that any difference between that proposal and the final regulations will be minor and will not by themselves require a label change.

Please notify us in writing, within fifteen (15) working days of the receipt of this letter, of the specific actions you have taken to correct these violations and to prevent their recurrence. Your response should include copies of each of your proposed new labels and a proposed time frame for their implementation. Your response should be directed to this office to the attention of Mr. John E. Klemmer, Compliance Officer.

Sincerely yours,


Raymond V. Mlecko
for Acting District Director
Detroit District