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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

October 1, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 01

Kenneth F. Fellerson
President
Ken's Meat and Deli
5725 Monona Drive
Monona, Wisconsin 53716

Dear Mr. Fellerson:

We inspected your firm, K & S Wholesale Meat, Inc., located at 1140 Wilburn Road, Sun Prairie, WI, on June 4-5, and 7, 2001, and found that serious deviations from the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations, Part 101 (21 CFR 101), Food Labeling. These deviations, some of which were previously brought to your attention, cause your sandwiches to be in violation of Sections 403(a)(1), 201(n), 403(i)(2) and 403(k) of the Act. You can find this Act and the applicable regulations through links on FDA's home page at www.fda.gov.

The deviations are as follows:

Your sandwich products are misbranded under Section 403(a)(1), 201(n) and 403(i)(2) of the Act and 21 CFR 101.4(b)(2) by failing to appropriately list the ingredients of the sandwich constituents, some of which are known allergens. The labeling deficiencies exist with all sandwiches produced with, or in part with, croissants, salad dressing, tuna salad and chicken salad. For example:

According to the croissant label the croissants are made, in part, with "...ENRICHED FLOUR...NONFAT MILK...EGGS..." Ready-to-eat sandwiches made with croissants include  brand Ham and Cheddar croissant sandwich, Turkey and Cheddar croissant sandwich, Roast Beef and Cheddar croissant sandwich, Tuna Salad croissant sandwich, Chicken Salad croissant sandwich, and Corned Beef and Swiss croissant sandwich.

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During the inspection the labels for these sandwiches were changed to include "egg" as an ingredient. The egg ingredient was placed at the end of the ingredient statement. The other ingredients in the croissant must also be declared on these labels. This may be accomplished by listing these ingredients along with the egg ingredient parenthetically following the declaration croissant.

According to [redacted] brand Whipped Salad Dressing label this ingredient is made, in part, with egg yolks. This salad dressing is used as an ingredient in [redacted] brand Deluxe Roast Beef Sub, Deluxe Ham Sub and Fresh Turkey Sub. The labels for the Roast Beef and Ham subs do not list salad dressing nor any ingredient of the dressing. The Turkey sub label identifies salad dressing but does not list the ingredients of the salad dressing. During the inspection the labels for these sandwiches were revised to declare "salad dressing" parenthetically followed by "egg yolks." Other ingredients in the salad dressing must also be declared.

According to the label for [redacted] brand Chunky Style Tuna Salad, this ingredient contains, in part, egg yolks and textured soy protein. This Tuna Salad is used to make the [redacted] brand Tuna Salad Sandwiches and Tuna Salad Croissant Sandwiches. The labels for these sandwiches do not list all the ingredients and, in particular, the egg yolk and textured soy protein ingredients. During the inspection the labels for these sandwiches were changed to include the "egg" ingredient at the end of the ingredient statement. Other ingredients and sub-ingredients in the bread and tuna salad, especially the textured soy protein ingredient must also be declared. This may be accomplished by listing the ingredients parenthetically following the tuna, the salad dressing, and the bread.

According to the label for [redacted] brand Deluxe Chicken Salad, faxed from the manufacturer, [redacted] this ingredient contains, in part, salad dressing that contains eggs. The labels for the [redacted] brand Chicken Salad Sandwich and Chicken Salad Croissant Sandwich include the salad dressing ingredient but do not list the egg ingredient. During the inspection, the label for [redacted] brand Chicken Salad Sandwich made from [redacted] brand Deluxe Chicken Salad was corrected to identify the egg ingredient. The egg ingredient was placed at the end of the ingredient statement. Other ingredients and sub-ingredients in the chicken salad must also be declared. The labels for the other sandwiches containing the chicken salad ingredient must also be revised to list all the ingredients.

Further, your sandwiches made with [redacted] brand Chunky Style Tuna Salad are misbranded under Section 403(k) of the Act and 21 CFR 101.22(k) in

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that the ingredient listing for the Tuna Salad includes Yellow #5 as a component of the pickle relish and your labels do not reflect this ingredient.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR 123) and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as an approved HACCP plan, sanitation records and corrected labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address listed in the letterhead.

Sincerely,



James A. Rahto
Director
Minneapolis District

TSW/ccl

TSW

xc: Thomas J. Mazzara
Plant Manager
K & S Wholesale Meat, Inc.
1140 Wilburn Road
Sun Prairie, WI 53590