



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

34662d

60 8th Street, N.E.
Atlanta, Georgia 30309

April 4, 2003

VIA FEDERAL EXPRESS

WARNING LETTER
(03-ATL-17)

Robert F. Melcher
President
Resource Materials LLC
3210 Moon Station Road
Kennesaw, Georgia 30144

Dear Mr. Melcher:

Two recent inspections were conducted of your animal feed fat blending operation on 8/15-16/02 and 9/09-10/4/02 by the Food and Drug Administration. The inspections revealed several significant concerns over the use of ingredients which are not feed grade in feed fat blends supplied to feed mills. You have used two Fatty Acid Residues [REDACTED] in Feed Fat Blend F-549 and F-524 sold to your customers. These Fatty Acid Residues are clearly identified on the incoming Certificate of Analysis as "****FOR INDUSTRIAL USE ONLY; NOT FOR FEED USE****". These ingredients are purchased "AS IS" from your supplier, [REDACTED]. You conduct no routine analysis of these ingredients to determine their suitability for use in animal feeds. The use of these fatty acid residues in this manner is not acceptable for use in animal feed for at least two reasons.

First, these residues are considered adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) in that they are unfit for food. These fatty acid residues are not "feed grade" fats and oils. Only fat ingredients that are obtained from animal origin or from the processing of edible vegetables and plants are suitable for feed grade food. Our inspections revealed that you are using industrial grade fatty acid residues, obtained from petroleum distillate by-products, in your feed fat blends.

Second, the feed fat blends produced are adulterated under Section 402(a)(4) of the Act in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You do not have manufacturing records, batch records, or formulations for these feeds and you do not have established quality control procedures. Moreover, you do not test the incoming ingredients for contaminants before using them in the feed blends and you do not test the feed blends before shipping them to your animal feed mill customers.

Such testing is particularly important since the incoming ingredients used in feed fat blends contain at least one toxic contaminant, nickel. The Material Safety Data Sheet (MSDS) for [REDACTED] provided by [REDACTED] lists Nickel Catalyst (as soap) at concentrations of .2 - .4 (Wt.%). It includes an additional warning that "This product contains nickel. Nickel and nickel salts have been classified as cancer hazards based on tests with laboratory animals." The MSDS provided by [REDACTED] for [REDACTED] states that the product contains nickel catalyst at concentrations of .2 - .3 (Wt.%). It also includes the same warnings about the product containing nickel. In addition, it was noted that you are using another fatty acid residue, [REDACTED], in the production of feed fat blends. While this product claims to be feed grade on incoming shipping documents, the MSDS on this product indicates that this ingredient can contain levels of nickel at .1 - 1.0%. Although you indicated to our investigators that you were aware of these high levels of nickel in these residues, your response was that your blending process will bring the amount down to a level acceptable for use in animal feeds. It is not clear how you could substantiate this opinion as the blending process is not consistently performed and no testing is performed on the incoming ingredients or outgoing feed fat blends for nickel content. Even if you did substantiate the nickel levels, this would not alter the fact that your failure to exercise other adequate controls over the feed fat blends causes those products to be adulterated.

You also referred our investigators to the 2002 Official Publication of the Association of American Feed Control Officials, which lists suggested guidelines for contaminants in feed ingredients. The only reference we found prohibits nickel levels over 2000 ppm in mineral feed ingredients and over 50 ppm in complete feed. The incoming fatty acid residue ingredients you use far exceed the 2000 ppm limit. In addition, FDA collected finished feed samples from farms that use your feed fat blends, and the nickel levels exceeded 50 ppm in five of the six samples. These farms were unaware of the nickel levels in the fat blends being sold by your firm.

As a supplier of fats and oils to the animal feed industry, it is incumbent upon you to be aware of your responsibilities under the law. Fats and oils that are not suitable for feed use should be identified and segregated accordingly. You must also take adequate measures to prevent feed grade ingredients from being adulterated through commingling or cross-contamination with industrial grade ingredients.

At the conclusion of each inspection, you or your representatives were issued our Inspectional Observations (FDA 483). Copies of the two FDA 483's issued are enclosed. The above is not intended to be an all-inclusive list of deviations from the regulations or requirements. As a manufacturer and distributor of materials intended for animal feed use, you are responsible for ensuring that your overall operation and the products you blend and distribute are in compliance with the law. We note that you were issued a Warning Letter in November 1994 for using grease of unknown origin and using it as a component in a fat blend. Your response indicated that you were going to implement appropriate controls to insure that you would not purchase non feed grade fats in the future.

You should take prompt action to correct these violations and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice. These actions include, but are not limited to seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be taken within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Please include copies of any available documentation which demonstrates that corrections have been made. We are in receipt of your response dated December 19, 2002, to the Inspectional Observations. This response did not adequately address the concerns addressed in this letter. We will issue a response to your December 19 letter separately.

Your reply should be directed to Philip S. Campbell, Compliance Officer, at the address indicated on the letterhead.

Sincerely,

A handwritten signature in cursive script that reads "Mary Woleske".

Mary H. Woleske, Director
Atlanta District

Enclosures