



Steve Troxler
Commissioner

North Carolina Department of Agriculture
and Consumer Services
Food and Drug Protection Division

Joseph W. Reardon
Director

April 16, 2009

Mr. Troy Hopey- Owner
Amazing Savings
P.O. Box 693
Black Mountain, NC 28711

Dear Mr. Hopey:

A reinspection of Amazing Savings located at 3018 US Highway 70 East, Black Mountain, NC was conducted on March 05, 2009 by Food Regulatory Specialist Greg Slocum of this Department. This inspection revealed the continued sale of over the counter medications beyond the stated label "Use By" Date, insanitary conditions, as well as the sale of products subject to a manufacturer's voluntary recall. We specifically direct to your attention the following inspection observations and FDC # 0019241:

1. The following products subject to a manufacturer's voluntary recall were observed offered for sale:
 - a) Eight (8) Express Snacks Tropical Snack Mix -2.25 oz. bags - Best by: 03/04/09 - Hershey Import Co.
 - b) Two (2) Express Snack Peanuts Roasted & Salted - 3 oz. bags - Hershey Import Co.
 - c) One thousand eight hundred forty eight (1848) Genisoy Soy Protein Bars Crispy Chocolate Mix - 2.2 oz. Best by 09/24/08 - Genisoy Foods Company, Inc.
 - d) Three hundred twenty nine (329) Genisoy Protein Bars Creamy Peanut Yogurt - 2.2 oz. - Best by 09/24/08 - Genisoy Foods Company, Inc.
2. The following over the counter medications were offered for sale beyond the stated label "Use By" Date :
 - a) Nine (9) Bayer Extra Strength Caplets - 4 caplets per pack.
 - b) Three (3) cartons Nicorette Stop Smoking Aid Fresh Mix - 100 piece (2 mg each) - Exp. 10/2008 & 01/2009.
 - c) Two (2) cartons Nicorette Stop Smoking Aid Mint Gum - 110 piece (2 mg each) - Exp. 12/2008.
 - d) Four (4) cartons Nicorette Stop Smoking Aid Fresh Mint - 100 piece (2 mg each) - Exp. 10/2008.
 - e) Two (2) cartons Nicorette Stop Smoking Aid Fruit Chill Gum - 100 piece (2 mg each) - Exp. 12/2008 & 01/2009.
 - f) Three (3) cartons Nicorette Stop Smoking Aid Mint Gum - 110 piece (4 mg each) - Exp. 09/2008.
 - g) Four (4) cartons Nicorette Stop Smoking Aid Fresh Mint - 100 piece (4 mg each) - Exp. 12/2008.
 - h) Four (4) cartons Nicorette Stop Smoking Aid Fruit Chill - 100 piece (4 mg each) - Exp. 12/2008 & 01/2009.

The above referenced products subject to voluntary recall and over the counter medications with an estimated value of One Thousand Four Hundred Thirty dollars (\$1430.00) were placed under State Embargo FDC 0019434 and were voluntarily removed from sale and disposed of by management during inspection.

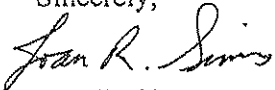
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- 3) One (1) suspect dead mouse was noted on glue board located behind floor display on south side of hallway leading to bathroom.
- 4) Suspect mouse filth was noted on north wall was of west warehouse floor.
- 5) A one inch (1") hole was noted on back north wall of warehouse near double doors.
- 6) No end caps were noted on reach-in cooler fluorescent tubes located in retail produce area (east wall).
- 7) Outside door leading to motor room was noted with a one inch (1") opening at floor level.
- 8) No thermometer noted in slice cheese cooler located near front door.

Our records indicate that similar conditions involving the sale of regarding outdated products and insanitary conditions were documented by Mr. Slocum and Food Regulatory Specialist Harold McDowell of this Department, during a previous inspection of your facility conducted on January 08, 2009. Please be advised that the sale of outdated over the counter medications constitutes a violation of sections §106-133(2) and/or Section § 09N .0101 of the North Carolina Food, Drug and Cosmetic Act.

We have directed this matter to your attention as owner of Amazing Savings in order that you take immediate steps to address the above noted objectionable conditions and make the necessary corrections. Your written response outlining the actions you are taking to correct the above referenced conditions including your company's policy regarding outdated medications will be anticipated by this office within fifteen (15) days of receiving this letter.

Sincerely,

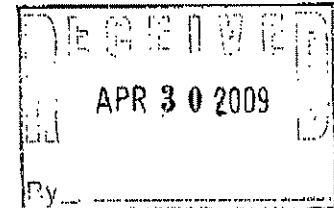


Joan R. Sims
Food Compliance Officer

cc: Greg Slocum, Food Regulatory Specialist
Matt Dantone, Store Manager
Harold McDowell, Food Regulatory Specialist

SHOPPER'S NIRVANA, LLC DBA AMAZING SAVINGS

**P. O. BOX 693
BLACK MOUNTAIN, NC 28711
(828) 669-8988
(828) 669-8990 FAX**



North Carolina Department of Agriculture and Consumer Services
Food and Drug Protection Division
4000 Reedy Creek Rd.
Raleigh, NC 27699

Regarding the re-inspection of Amazing Savings in Black Mountain on March 5, 2009 there were eight action items listed.

Numbers 3 and 4 were a by-product of 5 (one inch hole on back of north wall.) A new door has been ordered to replace the existing swinging doors in the facility and this should alleviate the potential problem of rodents getting into the store via holes and/or cracks. Numbers 6, 7, and 8 have been addressed by my store manager and remedied. This leaves us with only two items left: number 1 and 2.

First, allow me to inquire about number one on your list. I was under the impression that "voluntary" recalls were not mandated by State and/or Federal agencies (they were primarily precautionary recalls that limited the liability of the manufacturer.) In the case of the Genisoy bars, the bars in question did not even contain peanuts; they were simply manufactured in the same plant as other bars that may have contained peanuts. The first two items listed in section 1 should have been removed (due to their containing peanuts,) but how can there be "mandatory" and "voluntary" recalls if not to allow discretion on the part of the retailer? Please advise as to official policy and I will make sure to comply with it, I was just laboring under the assumption that no violations were being made and that products that did NOT contain peanuts were safe to sell.

SHOPPER'S NIRVANA, LLC DBA AMAZING SAVINGS

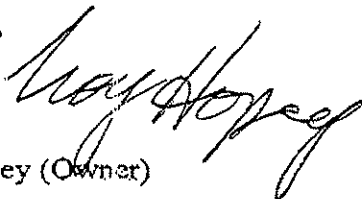
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As far as number 2, I am really confused. I have owned Amazing Savings for over five years and have managed a retail store for over twelve years, and I have heard a dozen different versions of what can and cannot be sold in the line of medicines, vitamins, homeopathics, topicals, etc...I have read the North Carolina Food, Drug and Cosmetic Act section 106-133(2) and have used the United States Pharmacopoeia as a reference, but I must be missing something. There is NO reference to sell by/best if used by in this section and the US Pharmacopoeia does not clearly define "quality" as being associated with outdated or expired product (as far as I have been able to discover in my readings.) Please forward me some clearly defined guidelines and/or regulations so that I can avoid any future confusion.

I believe that I have demonstrated my desire and willingness to comply with you department in the past (I have ALWAYS removed and destroyed any and all product you have asked me to remove) and have never questioned your rationale behind your decisions. But since I seem to be always getting cited for something (this time it was Nicorette, which I did not know was even considered by your department as a regulated drug) it is clear that I need further assistance in policing what can and cannot be sold to the public. I have no intention of selling ANYTHING that should not be legally offered for sale, but I need to have clear-cut guidelines so my graders, stockers, pricers, and managers can help enforce the rules more effectively.

Thank you for your cooperation and understanding.

Sincerely,



Troy Hopey (Owner)