UNCLAS

SUBJECT: ALFOODACT 2015-016 RB Issues Voluntary Recall of Liquid Bottles of MUCINEX ® FAST-MAX® Night Time Cold & Flu; MUCINEX® FAST-MAX® Cold & Sinus; MUCINEX® FAST-MAX® Severe Congestion & Cough and MUCINEX® FAST-MAX® Cold, Flu & Sore Throat Due to Undeclared Levels of Acetaminophen, Dextromethorphan, Guaifenesin, Phenylephrine and/or Diphenhydramine

Date Issued: April 27, 2015

1. REFERENCES:

a. DLAR 4155.26/AR 40-660/NAVSUPINST 10110.8c/AFI 48-116/MCO 10110.38c, DOD Hazardous Food & Nonprescription Drug Recall System.

b. Allied Communications Publication 121, US SUPP-1 (f).

2. BACKGROUND/UPDATE:

RB Issues Voluntary Recall of Liquid Bottles of MUCINEX ® FAST-MAX® Night Time Cold & Flu; MUCINEX® FAST-MAX® Cold & Sinus; MUCINEX® FAST-MAX® Severe Congestion & Cough and MUCINEX® FAST-MAX® Cold, Flu & Sore Throat Due to Undeclared Levels of Acetaminophen, Dextromethorphan, Guaifenesin, Phenylephrine and/or Diphenhydramine

April 21, 2015 — Parsippany, NJ, RB (formerly Reckitt Benckiser) has recalled certain lots of liquid bottles of MUCINEX® FAST-MAX® Night Time Cold & Flu; MUCINEX® FAST-MAX® Cold & Sinus; MUCINEX® FAST-MAX® Severe Congestion & Cough and MUCINEX® FAST-MAX® Cold, Flu & Sore Throat because the over-the-counter medications, which correctly label the product on the front of the bottle and lists all active ingredients, may not have the correct corresponding drug facts label on the back. This recall was due to a confirmed report from a retailer.

This mislabeling could cause the consumer to be unaware of side effects and/or risks associated with the ingestion of certain product ingredients which include Acetaminophen, Dextromethorphan, Guaifenesin, Phenylephrine and/or Diphenhydramine. The voluntary recall is being issued nationwide as a precautionary measure to ensure our consumers have all relevant facts and warnings for the active ingredients contained in the bottle.

Consumers could take a product with undeclared levels of Acetaminophen, Dextromethorphan, Guaifenesin, Phenylephrine and/or Diphenhydramine. Consumers would not be adequately warned of side effects which could potentially lead to health complications requiring urgent medical intervention, particularly in the case of acetaminophen use in people with liver impairment, taking three or more alcoholic drinks or when taking other medicines containing this active ingredient without consulting a doctor.

RB is notifying its distributors and customers by direct correspondence. As a precautionary measure, RB is asking consumers to responsibly dispose of any unused product in accordance with the following recommended guidance for drug disposal in your household trash:

•Mix liquid medicines with an unpalatable substance such as kitty litter or used coffee grounds;
•Place the mixture in a container such as a sealed plastic bag; and
•Throw the container in your household trash. Consumers who have purchased this product can also contact the RB MUCINEX FAST-MAX recall toll free number at 1-888-943-4215 between the hours of 8:00 a.m.- 8:00 p.m eastern standard time with any questions or to speak with a representative,

and should refer to our website, www.mucinex.com/recall for the accurate related drug facts information. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

3. PRODUCTION DATES/IDENTIFYING CODES:

The following products are subject to recall:

CONSUMER MUCINEX RECALL LIST: Products, Lots and Expiry Dates
Product Name Batch/ Lot Expiry
MUCINEX FAST-MAX Night-Time Cold & Flu Liq AA037 12/31/2016
AA060 1/31/2017
AA080 1/31/2017
AA097 1/31/2017
MNT0003 7/31/2016
MNT0004 7/31/2016
MNT0005 7/31/2016
MNT0006 7/31/2016
MNT0007 7/31/2016
MNT0008 7/31/2016
MNT0009 7/31/2016
MNT0010 7/31/2016
MNT0011 7/31/2016
MNT0012 7/31/2016
MNT0013 7/31/2016
MNT0014 10/31/2016
MNT0015 10/31/2016
MNT0016 10/31/2016
MNT0016 10/31/2016
MNT0017 10/31/2016
MNT0018 11/30/2016
MNT0019 11/30/2016
MNT0020 12/31/2016
MNT0021 12/31/2016
MNT0022 12/31/2016
MNT0023 12/31/2016
MNT0024 12/31/2016
MNT0025 12/31/2016

MUCINEX FAST-MAX Cold & Sinus Liquid MCS0019 7/31/2016
MCS0020 7/31/2016
MCS0021 7/31/2016
MCS0022 8/31/2016
MCS0023 8/31/2016
MCS0024 9/30/2016
MCS0025 9/30/2016
MCS0026 9/30/2016
MCS0027 11/30/2016
MCS0028 10/31/2016
MCS0029 10/31/2016
MCS0030 12/31/2016
MCS0031 12/31/2016

MCS0032 12/31/2016
MCS0033 12/31/2016

MUCINEX FAST-MAX Severe Congestion & Cough Liquid MSC0049 8/31/2016
MSC0050 8/31/2016
MSC0051 8/31/2016
MSC0052 8/31/2016
MSC0053 8/31/2016
MSC0054 8/31/2016
MSC0055 8/31/2016
MSC0056 9/30/2016
MSC0057 9/30/2016
MSC0058 9/30/2016
MSC0059 10/31/2016
MSC0060 10/31/2016
MSC0061 10/31/2016
MSC0062 10/31/2016
MSC0063 10/31/2016
MSC0064 10/31/2016
MSC0065 10/31/2016
MSC0066 10/30/2016
MSC0067 11/30/2016
MSC0068 11/30/2016
MSC0069 11/30/2016
MSC0070 11/30/2016
MSC0071 11/30/2016
MSC0072 11/30/2016
MSC0073 11/30/2016
MSC0074 11/30/2016
MSC0075 11/30/2016
MSC0076 11/30/2016
MSC0077 12/31/2016
MSC0078 12/31/2016
MSC0079 12/31/2016
MSC0080 12/31/2016
MSC0082 12/31/2016

MUCINEX FAST-MAX Cold,Flu & Sore Throat Liq MCF0048 7/31/2016
MCF0051 7/31/2016
MCF0052 8/31/2016
MCF0053 8/31/2016
MCF0054 8/31/2016
MCF0055 8/1/2016
MCF0056 8/31/2016
MCF0057 8/31/2016
MCF0058 8/31/2016
MCF0059 10/1/2016
MCF0060 8/31/2016
MCF0061 8/31/2016
MCF0062 8/31/2016
MCF0063 9/30/2016
MCF0064 9/30/2016
MCF0065 9/30/2016

MCF0066 9/30/2016
MCF0067 9/30/2016
MCF0068 9/30/2016
MCF0069 10/1/2016
MCF0070 10/31/2016
MCF0071 10/31/2016
MCF0072 10/31/2016
MCF0073 10/31/2016
MCF0074 10/31/2016
MCF0075 10/31/2016
MCF0076 10/31/2016
MCF0077 10/31/2016

MUCINEX FAST-MAX Liquid combination - Day Night Severe Cold and Night-Time Cold & Flu.
WO00706571 7/31/2016
WO00707442 7/31/2016
WO00707443 7/31/2016
WO00707444 7/31/2016
WO00707822 7/31/2016
WO00709953 7/31/2016
WO00709955 6/30/2016
WO00720780 7/31/2016
WO00721052 7/31/2016
WO00721170 7/31/2016
WO00721171 7/31/2016
WO00726864 6/30/2016
WO00726865 7/31/2016
WO00728864 12/31/2016
WO00728865 12/31/2016
WO00728866 12/31/2016
WO00730003 12/31/2016
WO00730004 12/31/2016
WO00735142 12/31/2016
WO00736753 12/31/2016
WO00737477 1/31/2017
WO00737979 1/31/2017
WO00738556 12/31/2016
WO00739050 12/31/2016
WO00740405 1/31/2017
WO00740406 1/31/2017

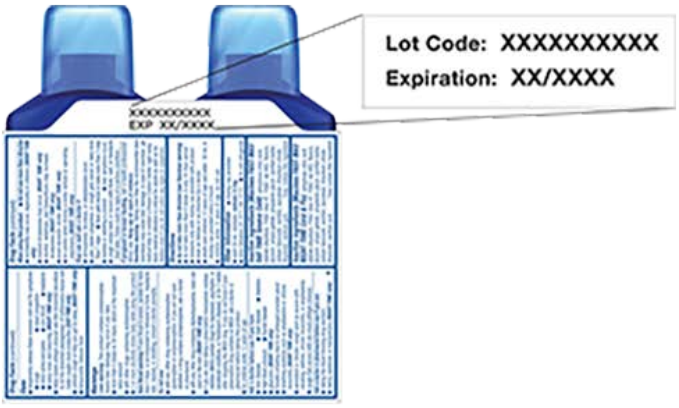
MUCINEX FAST-MAX Liquid combination packs - Daytime Severe Congestion & Cough Night-Time Cold & Flu WO00707825 5/31/2016
WO00713226 7/31/2016
WO00715310 6/30/2016
WO00715505 7/31/2016
WO00721174 9/30/2016
WO00721177 10/31/2016
WO00726860 10/31/2016
WO00726862 6/30/2016
WO00726952 8/31/2016
WO00728861 6/30/2016
WO00728878 7/31/2016

WO00728879 9/30/2016

*Lot List Current as of 4/23/15

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

•Complete and submit the report Online: www.fda.gov/medwatch/report.htm
•Regular Mail or Fax: Download formwww.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.



4. MANUFACTURER/DISTRIBUTOR:

RB (formerly Reckitt Benckiser
Parsippany, NJ

1-888-943-4215

5. DISTRIBUTION: All

6. REASON FOR ACTION: Due to Undeclared Levels of Acetaminophen, Dextromethorphan, Guaifenesin, Phenylephrine and/or Diphenhydramine

7. INSTRUCTIONS AND ADDITIONAL INFORMATION FOR MESSAGE RECIPIENTS:

a. Immediately inventory stocks to identify the above items and secure in a "Medical Hold" status to provide assurance of no further issue/sale/use.

POSITIVE FINDINGS should be reported to Accountable Officers/Vendor Representatives of that facility. Accountable Officer/Agency representatives/Buyers/Contracting Officers should seek/refund/credit/replacement through the normal distribution channel with which the product was received (i.e. Distribution Centers, Prime Vendors, or Manufacturers).

b. Ships at sea are authorized to destroy or dispose of recalled products at their discretion. Documentation for the number of pounds and cases, and any additional pertinent information must be signed by the Accountable Officer and is required for the purpose of recouping to the government the cost of the product involved. In order to get credit please use a SF 364 (For instructions on how to “Properly Prepare a Standard Form” (SF) 364 please use this link [http://www.landandmaritime.dla.mil/Offices/Packaging/PrepSF364.asp]) and forward to your supporting NAVSUP Fleet Logistics Center (NAVSUP FLC) and copy furnished to NAVSUP 51. Your supporting NAVSUP FLC should forward to the account manager at DLA Troop Support. The form should include the number of the recall authorizing the survey action. Home-ported ships/galleys will utilize DD form 1149 to transfer w/ reimbursement to the PV. The PV will submit credit invoice to the account manager at DLA Troop Support.

c. DLA Troop Support Subsistence Prime Vendors must report POSITIVE and NEGATIVE RESPONSES directly to the their DLA Troop Support Contracting Officer with a courtesy copy to the Consumer Safety Officer (dscpconssafofc@dla.mil)..

d. DeCA, AAFES, MWR, VA, MCCS, or other non-DLA Troop Support agencies SHOULD NOT respond to the DLA Troop Support Consumer Safety Officer. These agencies should report POSITIVE and NEGATIVE responses in accordance with their agency recall policies.
e. When corresponding with DLA Troop Support concerning this message please include this message's subject in your subject line.
8. The Point of Contact for this ALFOODACT message is MAJ Joseph Eggers, Veterinary Liaison Officer at DLA-FTW. VOICE, DSN: 444-2934, Commercial (215) 737-2934, or by FAX, DSN: 444-7526, or Commercial, (215) 737-7526, email dscpconssafofc@dla.mil .
9. Individuals or groups that would like to receive recall messages electronically can forward their email address to dscpconssafofc@dla.mil , with "add to list" in the subject line. To be removed from the list place "remove from list" in the subject line.

10. Previous recalls and frequently asked questions are available at the following web site: http://www.troopsupport.dla.mil/subs/fso/alfood/alfood.asp. The navigation tool to the left allows you to also view DLA Troop Support Alerts and Archived Vendor Recalls.

Regards,
Joseph H. Eggers
Major , U.S. Army Veterinary Corps
Veterinary Liaison Officer
DLA Troop Support
700 Robbins Avenue
Philadelphia, PA 19111
Office: 215-737-2934
FAX: 215-737-7361