

Michael R. Pence Governor

Jerome M. Adams, MD, MPH State Health Commissioner

DATE:

April 23, 2015

**Product Name** 

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

Laurie Kidwell, RRT Supervisor

Food Protection Program

SUBJECT:

RB (formerly Reckitt Benckiser) - RECALL [Drug]

**AFFECTED** 

PRODUCT:

MUCINEX® FAST-MAX® Night Time Cold & Flu; MUCINEX® FAST-MAX® Cold & Sinus; MUCINEX® FAST-MAX®

LOT NUMBER

MNT0004

MNT0021

MNT0022

MNT0023

MNT0024

MNT0025

AA037 AA060

080AA

**Expiry** 

7/31/2016

Severe Congestion & Cough and MUCINEX® FAST-MAX® Cold, Flu & Sore

SUMMARY:

Unclassified Recall; The recall has been initiated because the over-the-counter medications, which correctly label the product on the front of the bottle and lists all active ingredients, <u>may not have the</u>

**List of Potentially Impacted Batches** 

correct corresponding drug facts label on the back.

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	MNT0003	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
	MNT0012	7/31/2016
	MNT0013	7/31/2016
	MNT0011	7/31/2016
	MNT0014	10/31/2016
	MNT0015	10/31/2016
Marian Francisco Call & Flatin	MNT0017	10/31/2016
Mucinex Fast-MAX Night Time Cold & Flu Liq	MNT0016	10/31/2016
	MNT0016	10/31/2016
	AA080	1/31/2017
	MNT0018	11/30/2016
	MNT0019	11/30/2016
	MNT0020	12/31/2016



12/31/2016

12/31/2016

12/31/2016

12/31/2016

12/31/2016 12/31/2017

12/30/1940

1/31/2017

Product Name	LOT NUMBER AA097	<b>Expiry</b> 1/31/2017
	MCS0020 MCS0021 MCS0019 MCS0022 MCS0023 MCS0024 MCS0025	7/31/2016 7/31/2016 7/31/2016 8/31/2016 8/31/2016 9/30/2016 9/30/2016
Mucinex Fast Max Cold & Sinus Liquid	MCS0026 MCS0027 MCS0028 MCS0029 MCS0030 MCS0031 MCS0032 MCS0033	9/30/2016 11/30/2016 10/31/2016 10/31/2016 12/31/2016 12/31/2016 12/31/2016 12/31/2016
Mcinex FastMax Severe Congestion&Cough Liq	MSC0049 MSC0050 MSC0051 MSC0052 MSC0053 MSC0054 MSC0055 MSC0055 MSC0056 MSC0057 MSC0058 MSC0064 MSC0066 MSC0065 MSC0061 MSC0062 MSC0061 MSC0067 MSC0067 MSC0068 MSC0069 MSC0070 MSC0071 MSC0071 MSC0072 MSC0073 MSC0074 MSC0075 MSC0075 MSC0076 MSC0077 MSC0077 MSC0077 MSC0077 MSC0078 MSC0079 MSC0080 MSC0082	8/31/2016 8/31/2016 8/31/2016 8/31/2016 8/31/2016 8/31/2016 8/31/2016 9/30/2016 9/30/2016 10/31/2016 10/31/2016 10/31/2016 10/31/2016 10/31/2016 10/31/2016 10/31/2016 11/30/2016
Mucinex Fast-Max Cold,Flu & Sore Throat Liq	MCF0051 MCF0048 MCF0052 MCF0053 MCF0054 MCF0055	7/31/2016 7/31/2016 8/31/2016 8/31/2016 8/31/2016 8/1/2016

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Product Name	LOT NUMBER MCF0056	Expiry 8/31/2016
	MCF0056 MCF0057	8/31/2016
	MCF0057	8/31/2016
	MCF0059	10/1/2016
	MCF0059	8/31/2016
	MCF0060	8/31/2016
	MCF0062	8/31/2016
	MCF0063	9/30/2016
	MCF0064	9/30/2016 9/30/2016
	MCF0065	
	MCF0066	9/30/2016
	MCF0067	9/30/2016
	MCF0068 MCF0070	9/30/2016 10/31/2016
	MCF0069	10/1/2016
	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
	MDM0044	11/30/2016
	3000726865	8/20/2015
	WO00726864	6/30/2016
	WO00737979	1/31/2017
	WO00740405	1/31/2017
	WO00706571	7/31/2016
	WO00707442	7/31/2016
MILIONEY FACT MAY I found continue to the Devillent	WO00707443	7/31/2016
MUCINEX FAST-MAX Liquid combination - Day Night Severe Cold and Night-Time Cold & Flu.	WO00707444	7/31/2016
Severe Cold and Night-Time Cold & Fid.	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
	WO00721174	9/30/2016
	WO00721177	10/31/2016
	WO00726860	10/31/2016
MUCINEX FAST-MAX Liquid combination packs -	WO00726862	6/30/2016
	WO00726952	8/31/2016
	WO00728861	6/30/2016
Daytime Severe Congestion & Cough Nighttime Cold&	WO00728878	7/31/2016
Flu	WO00728879	9/30/2016
•	WO00707825	5/31/2016
	WO00713226	7/31/2016
	WO00715310	6/30/2016
	WO00715505	7/31/2016
	6	

The recalled products were distributed <u>nationwide</u>.

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.

## **Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

RB Issues Voluntary Recall of Liquid Bottles of MUCINEX® FAST-MAX® Night Time Cold & Flu; MUCINEX® FAST-MAX® Cold & Simus; 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

Contact: Consumer: 1-888-943-4215

FOR IMMEDIATE RELEASE — 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.

List of Potentially Impacted Batches **Product Name** LOT NUMBER Expiry MNT0004 7/31/2016 MNT0003 7/31/2016 MNT0005 7/31/2016 Mucinex Fast-MAX Night Time Cold & Flu Liq MNT0006 7/31/2016 MNT0007 7/31/2016 8000TMM 7/31/2016

Product Name			
MNT0000	Product Name	LOT NUMBER	Expiry
MNT0010	1704401144110		
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Product Name	LOT NUMBER	Expiry
	MSC0067	11/30/2016
	MSC0068	11/30/2016
	MSC0069	11/30/2016
	MSC0070	11/30/2016
	MSC0071	11/30/2016
	MSC0072	TBD
	MSC0072 MSC0073	11/30/2016
	MSC0074	11/30/2016
	MSC0075	11/30/2016
	MSC0076	11/30/2016
	MSC0077	12/31/2017
	MSC0078	12/31/2016
	MSC0079	12/31/2016
	MSC0080	12/31/2017
	MSC0082	12/31/2016
	MOTOREA	7/04/0040
	MCF0051	7/31/2016
	MCF0048	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
Mucinex Fast-Max Cold, Flu & Sore Throat Liq	MCF0064	9/30/2016
THE OWNER THE ACTION CONTROL ENGINEER	MCF0065	9/30/2016
	MCF0066	9/30/2016
	MCF0067	9/30/2016
	MCF0068	9/30/2016
	MCF0070	10/31/2016
	MCF0069	10/3//2016
	MCF0009 MCF0071	
	MCF0071 MCF0072	10/31/2016 10/31/2016
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	MCF0073	
	MCF0074	10/31/2016
	MCF0075	10/31/2016
	MCF0076	10/31/2016
	MCF0077	10/31/2016
	MDM0044	11/30/2016
	3000726865	8/20/2015
	WO00726864	6/30/2016
	WO00737979	1/31/2017
	WO00740405	1/31/2017
•	WO00746403 WO00706571	7/31/2016
	WO00707442	7/31/2016
MILIOINEV FACT MAY Limits combination. Developed Courses C. M.	WO00707442 WO00707443	7/31/2016
MUCINEX FAST-MAX Liquid combination - Day Night Severe Cold and Night Time Cold & Etu		
and Night-Time Cold & Flu.	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

Product Name	LOT NUMBER	Expiry
	WO00721171	7/31/2016
	WO00721174	9/30/2016
	WO00721177	10/31/2016
	WO00726860	10/31/2016
	WO00726862	6/30/2016
	WO00726952	8/31/2016
MUCINEX FAST-MAX Liquid combination packs - Daytime Severe	WO00728861	6/30/2016
Congestion & Cough Nighttime Cold& Flu	WO00728878	7/31/2016
	WO00728879	9/30/2016
	WO00707825	5/31/2016
	WO00713226	7/31/2016
	WO00715310	6/30/2016
	WO00715505	7/31/2016

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 form www.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.

Photo - 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

