Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

**DATE:** April 23, 2015

**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® 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, may not have the correct corresponding drug facts label on the back.**

**List of Potentially Impacted Batches**

| Product Name | LOT NUMBER | Expiry |
|---|---|---|
| Mucinex Fast-MAX Night Time Cold & Flu Liq | MNT0004 | 7/31/2016 |
| | 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 |
| | MNT0017 | 10/31/2016 |
| | MNT0016 | 10/31/2016 |
| | MNT0016 | 10/31/2016 |
| | AA080 | 1/31/2017 |
| | 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 |
| | AA037 | 12/31/2017 |
| | AA060 | 12/30/1940 |
| | AA080 | 1/31/2017 |

| Product Name | LOT NUMBER | Expiry |
|---|---|---|
| | AA097 | 1/31/2017 |
| | | |
| | MCS0020 | 7/31/2016 |
| | MCS0021 | 7/31/2016 |
| | MCS0019 | 7/31/2016 |
| | MCS0022 | 8/31/2016 |
| | MCS0023 | 8/31/2016 |
| | MCS0024 | 9/30/2016 |
| | MCS0025 | 9/30/2016 |
| Mucinex Fast Max Cold & Sinus Liquid | 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 |
| | | |
| | 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 |
| | MSC0064 | 10/31/2016 |
| | MSC0066 | 10/30/2016 |
| | MSC0065 | 10/31/2016 |
| | MSC0063 | 10/31/2016 |
| | MSC0061 | 10/31/2016 |
| | MSC0062 | 10/31/2016 |
| Mcinex FastMax Severe Congestion&Cough Liq | MSC0060 | 10/31/2016 |
| | MSC0071 | 11/30/2016 |
| | MSC0079 | 12/31/2016 |
| | MSC0067 | 11/30/2016 |
| | MSC0068 | 11/30/2016 |
| | MSC0069 | 11/30/2016 |
| | MSC0070 | 11/30/2016 |
| | MSC0071 | 11/30/2016 |
| | MSC0072 | TBD |
| | 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 |
| | | |
| | MCF0051 | 7/31/2016 |
| | MCF0048 | 7/31/2016 |
| | MCF0052 | 8/31/2016 |
| Mucinex Fast-Max Cold,Flu & Sore Throat Liq | MCF0053 | 8/31/2016 |
| | MCF0054 | 8/31/2016 |
| | MCF0055 | 8/1/2016 |

| Product Name | LOT NUMBER | Expiry |
|---|---|---|
| MUCINEX FAST-MAX Liquid combination - Day Night Severe Cold and Night-Time Cold & Flu. | 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 |
| | MCF0070 | 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 |
| | 3O00726865 | 8/20/2015 |
| | WO00726864 | 6/30/2016 |
| | WO00737979 | 1/31/2017 |
| | WO00740405 | 1/31/2017 |
| | 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 |
| MUCINEX FAST-MAX Liquid combination packs - Daytime Severe Congestion & Cough Nighttime Cold& Flu | 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 |
| | WO00707825 | 5/31/2016 |
| | WO00713226 | 7/31/2016 |
| | WO00715310 | 6/30/2016 |
| | WO00715505 | 7/31/2016 |

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

**SUGGESTED ACTION:**

**For consumer inquiry only. 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.**

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## 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 & 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*

**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 |
|---|---|---|
| Mucinex Fast-MAX Night Time Cold & Flu Liq | MNT0004 | 7/31/2016 |
| | MNT0003 | 7/31/2016 |
| | MNT0005 | 7/31/2016 |
| | MNT0006 | 7/31/2016 |
| | MNT0007 | 7/31/2016 |
| | MNT0008 | 7/31/2016 |

| Product Name | LOT NUMBER | Expiry |
|---|---|---|
| | 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 |
| | MNT0017 | 10/31/2016 |
| | MNT0016 | 10/31/2016 |
| | MNT0016 | 10/31/2016 |
| | AA080 | 1/31/2017 |
| | 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 |
| | AA037 | 12/31/2017 |
| | AA060 | 12/30/1940 |
| | AA080 | 1/31/2017 |
| | AA097 | 1/31/2017 |
| | MCS0020 | 7/31/2016 |
| | MCS0021 | 7/31/2016 |
| | MCS0019 | 7/31/2016 |
| | MCS0022 | 8/31/2016 |
| | MCS0023 | 8/31/2016 |
| | MCS0024 | 9/30/2016 |
| | MCS0025 | 9/30/2016 |
| Mucinex Fast Max Cold & Sinus Liquid | 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 |
| | 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 |
| Mcinex FastMax Severe Congestion&Cough Liq | MSC0059 | 10/31/2016 |
| | MSC0064 | 10/31/2016 |
| | MSC0066 | 10/30/2016 |
| | MSC0065 | 10/31/2016 |
| | MSC0063 | 10/31/2016 |
| | MSC0061 | 10/31/2016 |
| | MSC0062 | 10/31/2016 |
| | MSC0060 | 10/31/2016 |
| | MSC0071 | 11/30/2016 |
| | MSC0079 | 12/31/2016 |

| 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 |
| | 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 |
| | | |
| | 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 |
| | MCF0065 | 9/30/2016 |
| | MCF0066 | 9/30/2016 |
| | MCF0067 | 9/30/2016 |
| | MCF0068 | 9/30/2016 |
| | MCF0070 | 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 |
| | | |
| | 3O00726865 | 8/20/2015 |
| | WO00726864 | 6/30/2016 |
| | WO00737979 | 1/31/2017 |
| | WO00740405 | 1/31/2017 |
| | WO00706571 | 7/31/2016 |
| | WO00707442 | 7/31/2016 |
| MUCINEX FAST-MAX Liquid combination - Day Night Severe Cold and Night-Time Cold & Flu. | 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 |

| Product Name | LOT NUMBER | Expiry |
|---|---|---|
| MUCINEX FAST-MAX Liquid combination packs - Daytime Severe Congestion & Cough Nighttime Cold& Flu | WO00721171 | 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 |
| | 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**