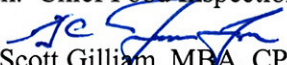




**DATE:** January 9, 2012

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:**   
A. Scott Gilliam, MBA, CP-FS  
Director, Food Protection Program

**SUBJECT:** Novartis Consumer Health, Inc. Recall

**SUGGESTED**

**ACTION:** **Unclassified Recall; all lots of select bottle packaging configurations of Excedrin® and NoDoz® products with expiry dates of December 20, 2014 or earlier as well as Bufferin® and Gas-X Prevention® products with expiry dates of December 20, 2013 or earlier, in the United States. NCH is taking this action as a precautionary measure because the products may contain stray tablets, capsules, or caplets from other Novartis products, or contain broken or chipped tablets; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. These over-the-counter products were distributed nationwide to wholesalers and retailers. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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.

**Novartis Consumer Health Inc. Issues Voluntary Nationwide Recall Of Certain Over-The-Counter Products Due to Potential Presence of Foreign Tablets or Chipped or Broken Tablets or Gelcaps**

**Contact:**  
Consumer:  
1-888-477-2403 Monday-Friday 9 a.m. to 8 p.m. Eastern Time

Media:

**Julie Masow**

Novartis Corporation

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julie.masow@novartis.com

List of products affected in this recall (PDF 206 kb)

**FOR IMMEDIATE RELEASE - Parsippany, January 8, 2012** – Novartis Consumer Health, Inc. (NCH) announced today that it is voluntarily recalling all lots of select bottle packaging configurations of Excedrin® and NoDoz® products with expiry dates of December 20, 2014 or earlier as well as Bufferin® and Gas-X Prevention® products with expiry dates of December 20, 2013 or earlier, in the United States. NCH is taking this action as a precautionary measure because the products may contain stray tablets, capsules, or caplets from other Novartis products, or contain broken or chipped tablets.

The affected bottle sizes are attached to this release. The Novartis Consumer Health Inc. Lincoln, NE facility has voluntarily suspended operations and shipments to accelerate maintenance and other improvement activities at the site.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration (FDA).

Mixing of different products in the same bottle could result in consumers taking the incorrect product and receiving a higher or lower strength than intended or receiving an unintended ingredient. This could potentially result in overdose, interaction with other medications a consumer may be taking, or an allergic reaction if the consumer is allergic to the unintended ingredient. NCH is not aware of adverse events reported with the issues leading to the recall.

These over-the-counter products were distributed nationwide to wholesalers and retailers.

Novartis Consumer Health Inc. is notifying its distributors and customers and is arranging for return of all recalled products. Wholesalers and retailers should stop distribution and return the affected product using Novartis Product Return information that is being provided to them.

Consumers that have the product(s) being recalled should stop using the product(s) and contact the Novartis Consumer Relationship Center at 1-888-477-2403 (available Monday-Friday 9 a.m. to 8 p.m. Eastern Time) for information on how to return the affected products and receive a full refund. For more detailed information, consumers should visit our website at [www.novartisOTC.com](http://www.novartisOTC.com)<sup>1</sup> as of January 9, 2012. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Adverse events that may be related to the use of these products may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

- Online: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)<sup>2</sup>

- Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)<sup>3</sup>.  
Mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

These actions announced today, highlight the strong Novartis commitment to a single quality standard for the Novartis Group. The Novartis Group is making the necessary investments and committing the right resources to ensure these are implemented across the entire Novartis Group network. The high quality of Novartis products and operations has been critical to building the Novartis Group reputation over the past 15 years. Novartis Group is committed to ensuring the highest standard for patients who rely on our products and medicines.

Novartis Consumer Health Inc. plans to gradually resume operations at its Lincoln, NE site following implementation of planned improvements and in agreement with the FDA. The Novartis Consumer Health Inc. Lincoln, NE facility produces a variety of products mainly for the US market with annual sales value of less than 2% of Novartis Group sales. At this stage, it is not possible to determine when the plant will resume full operations and the full financial impact of these events. NCH will take a one-time charge currently estimated at USD 120 million in the fourth quarter of 2011, relating to the recalls and improvement work at the Lincoln, NE facility.

#### **Novartis commitment to quality**

The Novartis Group is fully committed to ensuring the quality, safety and integrity of its products. All Novartis Group companies have a clear commitment to patients and Health Authorities to ensure high quality standards for all our products and services. Novartis Group companies stand behind the safety and efficacy of their products, and are fully committed to maintaining high quality standards at all production sites in the US and around the world. All Novartis Group products are subjected to strict manufacturing, testing and monitoring standards. Where they fall outside the standards, Novartis Group companies take actions to correct the issue and may recall products as a precaution.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as “potential,” “will,” “committed,” “commitment,” “plans,” or similar expressions, or by express or implied discussions regarding the potential length of the shutdown of our Lincoln, NE production facility, regarding the potential for any further regulatory actions at the Lincoln, NE production facility, regarding the potential for any further quality issues arising at any additional Novartis manufacturing facilities, or regarding the potential financial impact of the Lincoln, NE facility shutdown. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that our Lincoln, NE production facility will reopen at any particular time. Nor can there be any guarantee that actions described in this release will be the only regulatory actions required at the Lincoln, NE facility. Neither can there be any guarantee that further quality issues will not arise at any additional Novartis Group manufacturing facilities. Nor can there be any guarantee as to the potential financial impact on Novartis resulting from the shutdown of the Lincoln, NE production facility. In particular, management’s expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected manufacturing issues, including unexpected inability to satisfy regulators’ requirements for the reopening of the Lincoln, NE production

facility; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

### **About Novartis**

Novartis Group provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 121,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com><sup>4</sup>.

Novartis is on Twitter. Sign up to follow @Novartis at <http://twitter.com/novartis><sup>5</sup>.

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