Subject: ALFOODACT 004-2012 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

Date Issued: January 9, 2012

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:

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 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.com2 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 Regular Mail: use postage-paid FDA form 3500 available at:

www.fda.gov/MedWatch/getforms.htm
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.

3. PRODUCTION DATES/IDENTIFYING CODES:

(Explanation of product descriptions and codes)

Material Description
UPC Code
UCC Code
NDC Code
Material

Bufferin® Extra Strength Tablets 39CT
300672065391
10300672065398
0067206539
100007776

Bufferin® Low Dose Tablets 130CT
300676424132
10300676424139
0067642413
100007345

Bufferin® Regular Strength Tablets 130CT
300672063137
10300672063134
0067206313
100008631

Excedrin® Back & Body Caplets 100CT Account Specific
300676238920
10300676238927
0067623891
100008076

Excedrin® Back & Body Caplets 100CT Account Specific No Carton
300676238944
10300676238941
0067623894
100008075

Excedrin® Back & Body Caplets 100CT New Label
300676238913
10300676238910
0067623891
100008073

Excedrin® Back & Body Caplets 24CT New Label
300676238241
10300676238248
0067623824
100008074

Excedrin® Back & Body Caplets 50CT New Label
300676238500
10300676238507
0067623850
100008627

Excedrin® Extra Strength Caplets 100CT Account Specific
300672000927
10300672000924
0067200091
100005995

Excedrin® Extra Strength Caplets 100CT Account Specific
300672000941
10300672000948
0067200094
100008027

Excedrin® Extra Strength Caplets 100CT Account Specific
300672000941
10300672000948
0067200094
100008026

Excedrin® Extra Strength Caplets 100CT Account Specific
300672000910
10300672000917
0067200091
100003160

Excedrin® Extra Strength Caplets 100CT
300672000910
10300672000917
0067200091
100007201

Excedrin® Extra Strength Caplets 125CT Bonus Pack
300672000835
10300672000832
0067200083
100008434

Excedrin® Extra Strength Caplets 125CT Bonus Pack Account Specific
300672000842
10300672000849
0067200084
100008455

Excedrin® Extra Strength Caplets 125CT New Carton
300672000866
10300672000863
0067200086
100009008

Excedrin® Extra Strength Caplets 24+6CT Bonus Pack
300672000309
10300672000306
0067200030
100003157

Excedrin® Extra Strength Caplets 24CT
300672000248
10300672000245
0067200024
100008024

Excedrin® Extra Strength Caplets 24CT New Label
300672000248
10300672000245
0067200024
100004485

Excedrin® Extra Strength Caplets 250CT No Carton
300672000071
10300672000078
0067200007
100008033

Excedrin® Extra Strength Caplets 250CT No Carton New Label
300672000071
10300672000078
0067200007
100004868

Excedrin® Extra Strength Caplets 250CT Special Inner
300672000774
10300672000771
0067200077
100008029

Excedrin® Extra Strength Caplets 250CT New Label
300672000774
10300672000771
0067200077
100008635

Excedrin® Extra Strength Caplets 300CT Bonus Pack
300672000552
10300672000559
0067200055
100008025

Excedrin® Extra Strength Caplets 50CT New Label
300672000507
10300672000504
0067200050
100003158

Excedrin® Extra Strength Caplets 50S
300672000507
10300672000504
0067200050
100007982

Excedrin® Extra Strength Express Gel Caps 20CT New Label
300676270203
10300676270200
0067627020
100007987

Excedrin® Extra Strength Express Gel Caps 40CT New Label
300676270401
10300676270408
0067627040
100008630

Excedrin® Extra Strength Express Gel Caps 80CT Account Specific
300676270814
10300676270811
0067627080
100007988

Excedrin® Extra Strength Express Gel Caps 80CT
300676270807
10300676270804
0067627080
100007989

Excedrin® Extra Strength Express Gel Caps 80CT Account Specific
300676270944
10300676270941
0067627094
100008037

Excedrin® Extra Strength Gel Tablets 24CT
300672021243
10300672021240
0067202124
100004674

Excedrin® Extra Strength Tablets 100CT Special Inner
300672030917
10300672030914
0067203091
100008626

Excedrin® Extra Strength Tablets 100CT Account Specific
300672030931
10300672030938
0067203091
100008016

Excedrin® Extra Strength Tablets 100CT Account Specific
300672030948
10300672030945
0067203094
100008010

Excedrin® Extra Strength Tablets 100CT New Label
300672030917
10300672030914
0067203091
100007200

Excedrin® Extra Strength Tablets 125CT Bonus Pack
300672030832
10300672030839
0067203083
100008460

Excedrin® Extra Strength Tablets 125CT Bonus Pack New Carton
300672030863
10300672030860
0067203086
100008022

Excedrin® Extra Strength Tablets 200CT New Label
300672030924
10300672030921
0067203092
100009062

Excedrin® Extra Strength Tablets 24+6CT Bonus Pack
300672030306
10300672030303
0067203030
100003181

Excedrin® Extra Strength Tablets 24CT
300672030245
10300672030242
0067203024
100008008

Excedrin® Extra Strength Tablets 24CT New Label
300672030245
10300672030242
0067203024
100008807

Excedrin® Extra Strength Tablets 250+50CT Bonus Pack
300672030573
10300672030570
0067203055
100004173

Excedrin® Extra Strength Tablets 250CT No Carton
300672030078
10300672030075
0067203007
100008031

Excedrin® Extra Strength Tablets 250CT No Carton New Label
300672030078
10300672030075
0067203007
100004869

Excedrin® Extra Strength Tablets 250CT Special Inners
300672030771
10300672030778
0067203077
100008019

Excedrin® Extra Strength Tablets 250CT New Label
300672030771
10300672030778
0067203077

4. MANUFACTURER/DISTRIBUTOR:

Julie Masow
Novartis Corporation
+1 212 830 2465 (direct)
+1 862 579 8456 (mobile)
julie.masow@novartis.com

Pamela McKinlay
Novartis Consumer Health, Inc.
+1 973 503 7337(direct)
+1 862 221 0151(mobile)
pamela.mckinlay@novartis.com
e-mail: us.mediarelations@novartis.com

Milicent Brooks
Novartis Consumer Health, Inc.
+1 973 503 7483(direct)
+1 973 479 2078 (mobile)
milicent.brooks@novartis.com

5. DISTRIBUTION: ALL

6. REASON FOR ACTION: Due to Potential Presence of Foreign Tablets or Chipped or Broken Tablets or Gelcaps

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 and forward to your supporting FISC and copy furnished to NAVSUP 51. Your supporting FISC 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 CW3 Tony Hemphill, Consumer Safety Officer at DLA-FTW. VOICE, DSN: 444-2922, Commercial (215) 737-2922, or by FAX, DSN: 444-7526, or Commercial, (215) 737-7526, email dscpconssafofc@dla.mi l.

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.

CW3(P) Tony D. Hemphill
Consumer Safety Officer
DLA Troop Support
700 Robinson Ave.
Philadelphia, PA. 19111
Ph. (215) 737-2922
DSN 444-2922
Cell (215) 298-2808
Fax 215-737-7526
Tony.Hemphill@dla.mil
Tony.Hemphill@us.army.mil
TonyHemphill@ln.amedd.army.mil