



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**

No. ~~2016-037~~


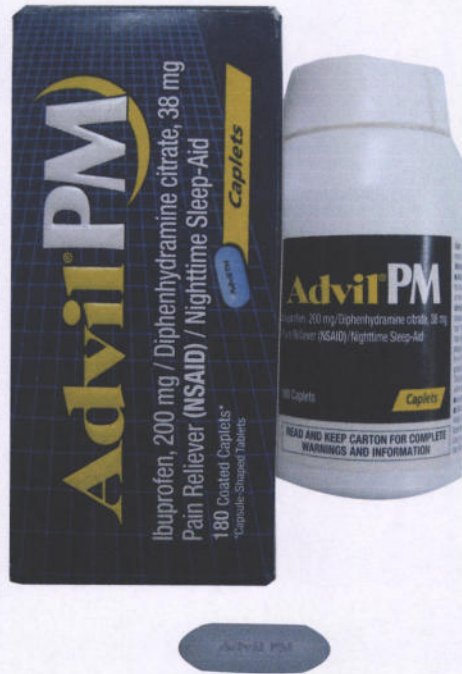
17 MAY 2016

**TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

**SUBJECT: Public Health Warning Against the Use of the Following Unregistered Drug Products:**

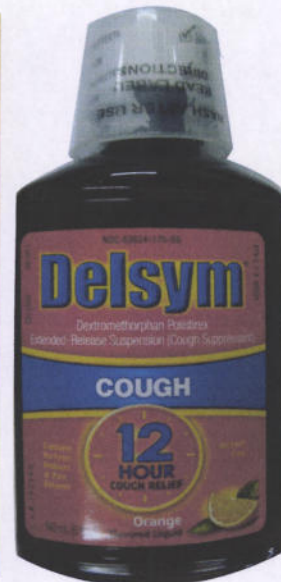
1. Acetaminophen (Tylenol Extra Strength) 500 mg Caplet (McNeil Consumer Healthcare – Fort Washington, PA USA)
2. Ibuprofen / Diphenhydramine Citrate (Advil PM) 200 mg / 38 mg Caplet (Pfizer – Madison, NJ USA)
3. Dextromethorphan Polistirex (Delsym) Extended-Release Suspension 30 mg / 5 mL
4. Ammeltz Cura-Heat Patch

The Food and Drug Administration (FDA) advises the public against the use of the following unregistered drug products:

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|--|---|
|  <p><b>Acetaminophen (Tylenol Extra Strength) 500 mg Caplet</b><br/>Distributed by: McNeil Consumer Healthcare<br/>Division of McNEIL-PPC, Inc. - Fort Washington, PA 19034 USA</p> |  <p><b>Ibuprofen / Diphenhydramine Citrate (Advil PM) 200 mg / 38 mg Caplet</b><br/>Pfizer, Madison, NJ 07940 USA</p> |
|--|---|







**Dextromethorphan Polistirex (Delsym) Extended-Release Suspension**  
**30 mg / 5 mL**

Distributed by: Reckitt Benckiser, Parsippany, NJ 07054-0224



**Ammeltz Cura-Heat Patch**  
**Kobayashi**

Table 1. Unregistered Drug Products

All healthcare professionals and the general public are hereby warned to be vigilant of the abovementioned drug products. These pose potential danger or injury to the consuming public and the importation, selling or offering for sale of such is in direct violation of Republic Act No. 9711 or the Food and Drug Administration Act of 2009.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act. No. 9711.

All establishments and outlets are hereby warned against selling and/or dispensing the above identified products. Anyone found selling the said products will be penalized.

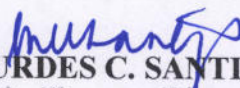


Likewise, all local government units and law enforcement agencies are requested to ensure that these products are not sold or offered for sale in their localities or area of jurisdiction.

All consumers are advised to purchase their medications only from FDA-licensed establishments. Please note that, in addition to inspection of establishments, product evaluation, registration, and testing are measures that the government undertakes to ensure the quality, safety, and efficacy of health products. Please look for the FDA Registration number on the product label. Moreover, please be reminded that drug products registered with FDA Philippines bear in their labels information in English and/or in Filipino for all consumers to understand.

For more information and inquiries, please e-mail us at [info@fda.gov.ph](mailto:info@fda.gov.ph). To report continuous sale or distribution of unregistered health products, kindly e-mail us via [report@fda.gov.ph](mailto:report@fda.gov.ph) or you may call the telephone number (02)807-8275. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: [www.fda.gov.ph/adr-report-new](http://www.fda.gov.ph/adr-report-new) and fill out all the required fields.

Dissemination of the information to all concerned is requested.

  
**MARIA LOURDES C. SANTIAGO, MSc, MM**  
Officer in Charge – Director General

DTN: 20160121161014