



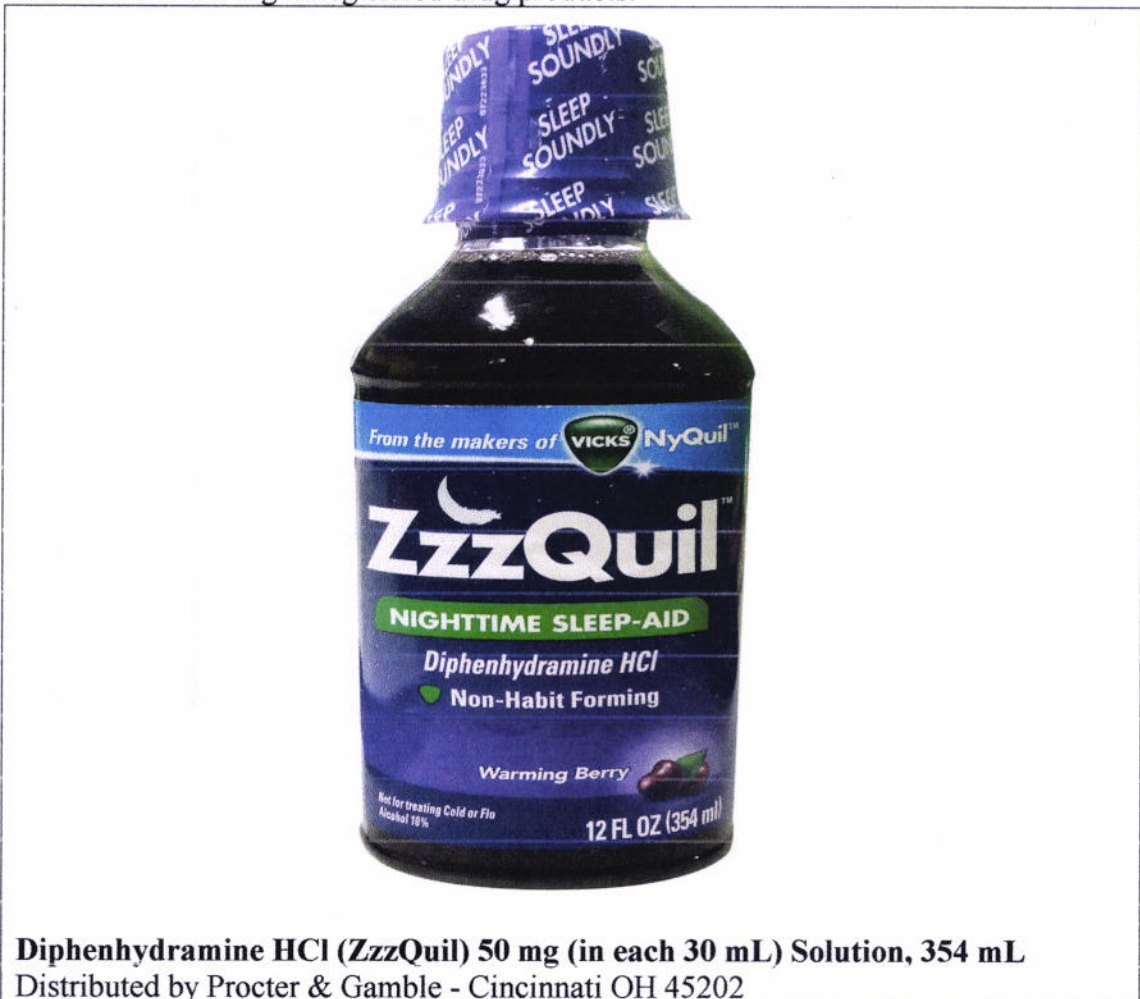
FDA ADVISORY
No. **2017-150**

TO: ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

1. Diphenhydramine HCl (ZzzQuil) 50 mg (in each 30 mL) Solution, 354 mL
2. Bacitracin Zinc-Neomycin Sulfate-Polymyxin B Sulfate (Neosporin) 400 units / 3.5 mg / 5000 units (in each gram) Ointment
3. Acetaminophen / Doxylamine succinate / Dextromethorphan HBr (NyQuil) 650 mg / 12.5 mg / 30 mg (in each 30 mL) Solution, 354 mL

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



Diphenhydramine HCl (ZzzQuil) 50 mg (in each 30 mL) Solution, 354 mL
Distributed by Procter & Gamble - Cincinnati OH 45202

Figure 1. Unregistered Drug Product





Bacitracin Zinc-Neomycin Sulfate-Polymyxin B Sulfate (Neosporin) 400 units / 3.5 mg / 5000 units (in each gram) Ointment
 Distributed by Johnson & Johnson Consumer Inc. – Skillman, NJ 08558 USA

Figure 2. Unregistered Drug Product



Acetaminophen / Doxylamine succinate / Dextromethorphan HBr (NyQuil) 650 mg / 12.5 mg / 30 mg (in each 30 mL) Solution, 354 mL
Distributed by Procter & Gamble, Cincinnati OH 45202

Figure 3. Unregistered Drug Product

Food and Drug Administration (FDA) post-marketing surveillance (PMS) activities have verified that the abovementioned drug products have not gone through the registration process of the agency and have not been issued with proper authorization in the form of Certificate of Product Registration.

Pursuant to Republic Act No. 9711, otherwise known as the “Food and Drug Administration Act of 2009”, the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, promotion, advertising or sponsorship of health products without proper authorization from FDA is prohibited.

Accordingly, since these unregistered drug products have not gone through evaluation and testing process of the FDA, the agency cannot guarantee its quality and safety. The use of such violative products may pose potential health hazards.

In light of the above, the public is advised not to purchase the aforementioned violative products and to be vigilant against drug products that might not be duly registered with the FDA. Always check if a drug product has been registered with the FDA before purchasing it by making use of the embedded *Search* feature of the FDA website accessible at www.fda.gov.ph. You may also look for the FDA Registration number on the product label.

All concerned establishments and/or entities are warned not to distribute the above-identified violative drug products until these have already been covered by the appropriate authorization, otherwise, regulatory actions and sanctions shall be strictly pursued.

All Local Government Units (LGUs) and Law Enforcement Agencies (LEAs) are requested to ensure that these products are not sold or made available in their localities or areas of jurisdiction.

For more information and inquiries, please e-mail us at info@fda.gov.ph. To report continuous sale or distribution of unregistered health products, kindly e-mail us via report@fda.gov.ph, or through the online reporting facility, **eReport**, at www.fda.gov.ph/ereport. You may also call the Center for Drug Regulation and Research at telephone number **(02) 809-5596**. For any suspected adverse drug reaction (ADR), report immediately to FDA through this link: www.fda.gov.ph/adr-report-new and fill out all the required fields.

Dissemination of the information to all concerned is requested.



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