

Governor  
John R. KasichLieutenant Governor  
Mary TaylorODA Director  
David T. DanielsODH Director  
Theodore E. Wymyslo, M.D.

DATE: June 20, 2013

TO: Health Commissioners, Directors of Environment Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2013-071

**Advance Pharmaceutical Inc. Issues Voluntary Recall of One Lot of Enteric Coated Aspirin Tablets, 81 mg, Due to Health Risk**

**Holtsville, NY**, Advance Pharmaceutical Inc. today announced that this firm is conducting a voluntary nationwide recall to the user level of the over-the-counter drug product, **Rugby label Enteric Coated Aspirin Tablets, 81 mg, Lot 13A026**. Advance Pharmaceutical Inc. first initiated the recall on June 17, 2013, after receiving a complaint about a bottle labeled as Enteric Coated Aspirin Tablets, 81 mg, actually containing Acetaminophen 500 mg tablets.

The product is indicated for the temporary relief of minor aches and pains and is packaged in bottles of 120 tablet with **NDC 0536-3086-41 and UPC 3 0536-3086-41 9**. The affected lot of Enteric Coated Aspirin Tablets is **Lot 13A026 with Expiration Date 01-2015**. The lot was manufactured and packaged by Advance Pharmaceutical Inc. under the label of Rugby Laboratories. Rugby Laboratories (Major Pharmaceuticals) distributed the product nationwide to wholesalers and retailers.

Consumers may be inadvertently taking Acetaminophen 500 mg instead of Enteric Coated Aspirin 81 mg which may cause severe liver damage to those who take other drugs containing acetaminophen, consumers who take 3 or more alcoholic drinks every day, or those who have liver disease. The labeled directions instructs patients to take 4-8 tablets every 4 hours, but not more than 48 tablets in 24 hours. Consumers who take 48 tablets daily of the defective product may be ingesting up to 24,000 mg of Acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Advance Pharmaceutical Inc. notified Rugby Laboratories of the recall by e-mail and overnight mail, and is arranging for return of all recalled bottles. Consumers who have the affected lot should immediately discontinue its use and return it to the pharmacy or store where it was purchased. Consumers with questions about the recall may contact Advance Pharmaceutical Inc., Monday-Friday, 9 am- 5 pm EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Any adverse reactions experienced with the use of this product should be reported to the FDA's MedWatch Program either by fax, regular mail, or online: by Fax at 1-800-FDA-0178; by Regular Mail: use postage-paid, pre-addressed Form FDA3500 available at <http://www.fda.gov/MedWatch/getforms.htm><sup>1</sup>; Online: <http://www.fda.gov/MedWatch/report.htm><sup>2</sup>.

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