

QUAD SERVICE MMQC FT DETRICK MD//USAMMA/AFMLO/NMLC//

IMMEDIATEMESSAGE RELEASED: 04/19/2012

*****UNCLASSIFIED*****

SUBJ: MMQC-12-1239

IMMEDIATE MSG / GLENMARK GENERICS INC. / NORGESTIMATE AND ETHINYL ESTRADIOL TABLETS USP
/ FDA CLASS I RECALL / DLA 12-061A

REF: MMQC-12-1150

RECALL TO THE CONSUMER LEVEL.

ACTIVITIES MUST ACKNOWLEDGE RECEIPT OF THIS MSG: SEE PARA 02.

SUSPENSE: 4/24/2012

01. FDA CLASS I RECALL ON FOL MATL. REASON: IMPLEMENTED BECAUSE OF A PACKAGING ERROR, WHERE SELECT BLISTERS WERE ROTATED 180 DEGREES WITHIN THE CARD, REVERSING THE WEEKLY TABLET ORIENTATION AND MAKING THE LOT NUMBER AND EXPIRY DATE VISIBLE ONLY ON THE OUTER POUCH. DISP: COMPLY W/MFR/DIST INSTRS IF RECD. PATIENTS WHO HAVE THE AFFECTED PRODUCT (LOT NUMBERS ARE PROVIDED BELOW) SHOULD NOTIFY THEIR PHYSICIAN AND RETURN THE PRODUCT TO THE PHARMACY. QUESTIONS, CALL 888-721-7115 OR 201-684-8000.

NSN: 6505-NS1 UI: BT

NOM: NORGESTIMATE-ETHINYL ESTRADIOL 7DAYSX3 28 TABLET 28

NDC: 68462056529

MFR: GLENMARK GENERICS

LOT/SERIAL NUMBER(S):

04110101 04110106

04110107 04110114

04110124 04110129

04110134

NOTE: DISTRIBUTED BETWEEN 21 SEP 2011 AND 30 DEC 2011.

02. CONUS AND OCONUS ACTIVITIES WILL ACKNOWLEDGE RECEIPT OF THIS MESSAGE NLT 24 APRIL 2012, VIA USAMMA WEBPAGE AT: [HTTP://WWW.USAMMA.ARMY.MIL](http://www.usamma.army.mil) SELECT "PRODUCTS," SELECT "DOD MEDICAL MATERIEL QUALITY CONTROL MESSAGES (MMQC) & IMAGES," THEN SELECT "DOD IMMEDIATE MMQC MESSAGE RECEIPT ACKNOWLEDGEMENT." THE DIRECT LINK IS [HTTP://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/MMQC_ACK_SERVICE.CFM](http://www.usamma.army.mil/assets/apps/nala_qaweb/mmqc_ack_service.cfm) THE RESPONDER NEEDS TO SELECT THE APPROPRIATE SERVICE AND FILL IN THE APPROPRIATE INFORMATION. UPON SUBMITTING THIS INFORMATION IT IS THEN ELECTRONICALLY FORWARDED TO THE APPROPRIATE SERVICE REPRESENTATIVE.

03. PASS MSG TO MEDICAL LOG OFCRS, CMD CHANNELS, PHARMACY, MED STAFF, SUPPLY OFCRS, AND SUPPORTED ACTYS/CTRS.

04. AUTHORITY: DODD 5105.22 AND DODD 6025.13. ADDITIONALLY:

A. ARMY: SEE ARMY REGULATION (AR) 40-61, 28 JANUARY 2005, CHAPTER 4, AND THE DEPARTMENT OF THE ARMY SUPPLY BULLETIN (SB 8-75-11) FOR APPLICABLE POLICIES AND PROCEDURES.

B. AIR FORCE: AF ACTIVITIES WILL TAKE ACTION AS PRESCRIBED IN AFI 41-209, MEDICAL LOGISTICS SUPPORT, CHAPTERS 3 AND 9. FOR MAJCOMS & NGB--THIS MSG HAS BEEN TRANSMITTED TO ALL DESIGNATED SUBORDINATE MEDICAL ACTIVITIES.

05. SERVICE SPECIFIC POCS ARE AS FOLS (FAX NOS. ARE AVAILABLE 24 HRS);

ARMY: TELEPHONE COM: 301-619-4300, DSN: 343, FAX: 4468,
E-MAIL: QUADSERVICEMMQC@AMEDD.ARMY.MIL

ARMY MEMBERS MAY SUBSCRIBE TO DOD MMQC MESSAGES AND MANY OTHER TOPICS AT THE FOLLOWING WEBSITE:

[HTTP://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/NALA_INDEX.CFM](http://WWW.USAMMA.ARMY.MIL/ASSETS/APPS/NALA_QAWEB/NALA_INDEX.CFM)
CLICK ON "SUBSCRIBE TO MMQC MESSAGES HERE."

USAMMC-E: TELEPHONE COM: 011-49-6331-86-7118/7181, DSN: 495-7118, FAX: 6218,
E-MAIL: USAMMCE_QA@AMEDD.ARMY.MIL

AIR FORCE: TELEPHONE COM: 301-619-4170, DSN: 343, FAX: 2557
EMAIL: AFMOA.SGALC@DETRICK.AF.MIL

AIR FORCE MEMBERS MAY SUBSCRIBE TO THE DOD MMQC MESSAGES AND RECEIVE EMAIL NOTIFICATIONS DIRECTLY FROM USAMMA WHEN THEY ARE PUBLISHED AT THE FOL WEBSITE: [HTTPS://MEDLOG.DETRICK.AF.MIL/](https://MEDLOG.DETRICK.AF.MIL/), GO TO "SITE SETTINGS" AND CHECK "SUBSCRIBE TO MMQC MESSAGES."

NAVY: TELEPHONE COM: 301-619-3085, DSN: 343, FAX: 3087,
EMAIL: MMQC2@MED.NAVY.MIL

NAVY MEMBERS MAY SUBSCRIBE TO RECEIVE DODMMQC MESSAGES AT [HTTP://WWW.USAMMA.ARMY.MIL](http://WWW.USAMMA.ARMY.MIL) CLICK ON "SUBSCRIBE TO MMQC MESSAGES."