SUBJECT: ALFOODACT 020-2014 Caraco Pharmaceutical Laboratories Initiates a Voluntary Recall of Cetirizine Hydrochloride Chewable Tablets (5 mg and 10 mg)

Date Issued: **April 11, 2014**

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:

Class II Recall (Over-The-Counter Drug Recall)

Caraco Pharmaceutical Laboratories is voluntarily initiating this recall based upon stability results. The product may not meet the drug release specification throughout it expiry period.

Intended Use/Indication: Indicated for the relief of symptoms associated with seasonal allergic rhinitis, perennial allergic rhinitis, and also for the treatment of the uncomplicated skin manifestations of chronic idiopathic urticaria (commonly referred to as hives, is a kind of skin rash notable for pale red, raised, itchy bumps).

Action by Retailer:

1. Stop dispensing and distributing and quarantine these lots.

2. Directions for return:

A. Non partials:

If you find any of the referenced product/lot#, full wholesale units, please generate a request for Return Authorization from your AmerisourceBergen drug division. Upon receipt of return authorization, please return directly to your AmerisourceBergen drug division.

B. Open or partials are to be returned to: Contact Inmar at 800-967-5952 select option 1 then option 3 for return instructions.

C. P.O.C. for this recall: Robert Kurkiewicz, Sr. Vice President, Regulatory.

This recall is being carried out to the retail level. Immediately examine your inventory and quarantine lot subject to this recall. Please stop distributing these lots immediately. For return of affected product, please email recallnotice@inmar.com or call 800-967-5952.

3. PRODUCTION DATES/IDENTIFYING CODES:

(1) Cetirizine Hydrochloride Chewable Tablets, 5 mg, 30 count CRC pack; NDC47335-0343-83.

Lot No(s): JKM2067A, JKM2068A, JKM2069A, JKM6399A

(2) Cetirizine Hydrochloride Chewable Tablets, 10 mg, 30 count CRC pack; NDC47335-0344-83 and NDC68016-0353-30.

Lot No(s): JKM2070A, JKM2071A, JKM2072A, JKM2072B and JKM6400A.

4. MANUFACTURER/DISTRIBUTOR:
Recalling Firm: Caraco Pharmaceutical Laboratories, 1150 Elija McCoy Dr., Detroit, MI.
Manufacturer: Sun Pharmaceutical Industries, Ltd.
Distributor: AmerisourceBergen 1300 Morris Dr, Ste 100, Chesterbrook, PA.
For return of affected product, please email recallnotice@inmar.com or call 800-967-5952

5. DISTRIBUTION: All

6. REASON FOR ACTION: Due To Misbranding and Undeclared Allergens
Due to stability results, the product may not meet the drug release specification throughout it expiry period.

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 (For instructions on how to “Properly Prepare a Standard Form” (SF) 364 please use this link [http://www.landandmaritime.dla.mil/Offices/Packaging/PrepSF364.asp]) and forward to your supporting NAVSUP Fleet Logistics Center (NAVSUP FLC) and copy furnished to NAVSUP 51. Your supporting NAVSUP FLC 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 CW4 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.mil .

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

Regards,

Mr. Hemphill

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