Investor News

Birgit Grund
Senior Vice President
Investor Relations

Fresenius SE & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
Germany
T +49 6172 608-2485
F +49 6172 608-2488
birgit.grund@fresenius.com
www.fresenius.com

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Fresenius Kabi receives FDA Warning Letter for Fenwal plant in Puerto Rico

Fresenius Kabi received a Warning Letter, dated August 16, from the U.S. Food and Drug Administration (FDA) related to an April 2013 inspection of its Fenwal blood bag manufacturing plant in Maricao, Puerto Rico. Fresenius Kabi acquired Fenwal in December 2012.

The Warning Letter observations are primarily related to complaint-handling procedures, labeling issues, and filing of field alerts not in accordance with FDA regulations. The Warning Letter was not issued as a result of adverse events related to patient safety.

Following the inspection, Fresenius Kabi submitted a detailed remediation action plan to the FDA. The company has made significant progress in remedying the issues cited in the Warning Letter including improvements to its procedures and documentation. Production at the plant is continuing.

The company takes this matter very seriously and intends to respond in a timely and comprehensive manner to the Warning Letter. No material sales and earnings impact on Fresenius Kabi's business is expected. Fresenius Kabi fully confirms its 2013 guidance.

# # #

A copy of the FDA Warning Letter is attached to this document.

About Fresenius
Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2012, Group sales were €19.3 billion. On June 30, 2013, the Fresenius Group had 173,325 employees worldwide.

For more information visit www.fresenius.com.

This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

Fresenius SE & Co. KGaA
Registered Office: Bad Homburg, Germany
Commercial Register: Amtsgericht Bad Homburg, HRB 11852
Chairman of the Supervisory Board: Dr. Gerd Krick

General Partner: Fresenius Management SE
Registered Office: Bad Homburg, Germany
Commercial Register: Amtsgericht Bad Homburg, HRB 11673
Management Board: Dr. Ulf M. Schneider (Chairman), Dr. Francesco De Meo, Dr. Jürgen Götz, Mats Henriksson, Rice Powell, Stephan Sturm, Dr. Ernst Wastler
Chairman of the Supervisory Board: Dr. Gerd Krick

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Juan District
Compliance Branch
466 Fernandez Juncos Ave.
San Juan, PR 00901

Telephone. 787-474-9500
Fax: 787-729-6658

AUG 16 2013

WARNING LETTER
13-SJN-WL-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Christian Hauer, President
Fenwal, a Fresenius-Kabi Company
Else-Kröner-Straβe 1
61352 Bad Homburg
Germany

Dear Mr. Hauer:

During our April 9, 2013 to April 25, 2013 inspection of your pharmaceutical and medical device manufacturing facility, located at Rd. 357, Km 0.8, Maricao, Puerto Rico, an investigator from the US. Food and Drug Administration (FDA) identified significant violations of the Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause your drug product(s) to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)] in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with CGMP.

In addition, the inspection disclosed that your firm failed to submit NDA Field Alert Reports (FARs) to the FDA as required by 21 C.F.R. § 314.81(b)(1)(i) and (ii), and section 505(k) of the Act [21 U.S.C. § 355(k)].

Specific violations found during the inspection include, but are not limited to, the following:

CGMP Violations

1. You failed to thoroughly investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications whether or not the batch has already been distributed. In addition, you failed to extend the investigation to other batches of the same product and other products that might have been associated with the discrepancy [21 C.F.R. § 211.192]. Our inspection in 2012, and the current inspection, found that you have received multiple consumer complaints related to mislabeled bags, inadequate bag size,

defective product components, and product mix-ups in your blood collection and component preparation units. You have confirmed most of these quality issues. Your investigations have failed to identify the deficiencies in need of correction to avoid the distribution of blood products which are not in full compliance with regulatory specifications. In addition, the scope of your investigations was not expanded to other lots and products potentially affected by these deviations.

This is a repeat deficiency also documented in our 2010 and 2012 inspections

2. You failed to establish and follow written procedures designed to assure that correct labels, labeling, and packaging materials are used for the products, including procedures to prevent mix-ups and cross-contamination by physical or spatial separation from operations on other drug products [21 C.F.R. § 211.130(a)]. Since 2010, you have received multiple complaints associated with missing or incorrect labels on your drug products. This deficiency was brought to your attention in our 2012 inspection. In your 2012 written response addressing this deficiency you acknowledged that in-process control improvement was needed and committed to revise multiple procedures to correct this deficiency. Nevertheless, our April 2013 inspection disclosed that you have continued receiving multiple complaints associated with this product defect, which shows that your corrective actins addressing this deficiency were ineffective.

   You acknowledged that corrective actions taken in 2012 were not sufficiently robust to fully detect all missing labels. You indicated that the system will be updated to have automated detection in manufacturing lines to prevent product with missing labels from being released. You also indicated that you were in the process of conducting a 30-month retrospective review of complaints related to labeling issues.

   This is a repeat deficiency also documented in our 2012 inspection.

3. You failed to establish and follow written procedures describing the handling of all written and oral complaints regarding a drug product [21 C.F.R. § 211.198(a)]. Specifically, our review of your complaint files found that since the close of our 2012 inspection you received multiple complaints associated with mislabeled or mixed-up bags for your blood collection component preparation units. Although your internal investigation confirmed these complaints, no FAR was submitted to the Agency as required under the regulations. It is very concerning that it was not until this situation was brought to your attention during the inspection that you started to submit multiple FARs involving about 21 lots of your blood collection and component preparation units. As a result of this action, you are currently conducting two recalls due to missing labels on satellite bags of your [redacted]product, and the incorrect labeling of your [redacted]Solution, USP (CPD) Blood Pack Unit drug product.

   <u>Marketing Reports Violation</u>

4. You failed to submit NDA FARs within three (3) working days of receipt of information concerning certain incidence. This includes any incident that causes the drug product or its

labeling to be mistaken for, or applied to, another article [21 C.F.R. § 314.81(b)(1)(i)]. Specifically, NDA FARs were not submitted to FDA regarding confirmed complaint reports involving your drug product [redacted] Solution that was mislabeled or in the wrong bag.

This is a repeat deficiency also documented in our 2012 inspection.

After the close of the current inspection, your firm submitted additional FARs related to complaints reporting incorrect assembly, flat tubing, or incorrect volume of anti-coagulant in your blood collection and component preparation units. Your firm determined additional actions are not required because your investigations concluded that these were isolated events, and there were no further complaints received for these lots. Your Health Hazard Assessment determined that there is no safety issue because the defect makes the product not useable and/or the user is supposed to check the unit prior to use. These events are additional examples of the lack of adequate process controls to prevent the release of non-conforming product. We also find it deficient that you are relying on the user to identify defects that should have been corrected and prevented by your quality control unit.

The deficiencies described in the Form FDA 483 issued at the close the inspection referenced above and this letter are an indication of your quality control unit not fulfilling its responsibility to assure the identity, strength, quality, and purity of your licensed biological drug product(s).

We acknowledge receipt of your written responses, dated May 15, 2013, and June 14, 2013, which address the inspectional observations on the Form FDA 483 issued at the close of the inspection. We have reviewed your responses and the accompanying documents. The corrective actions addressed in your responses may be referenced in your reply to this letter, as appropriate; however, your responses did not provide sufficient detail to fully assess the adequacy of your corrective actions. For example while there are numerous inspectional observations pertaining to a lack of thorough investigations into complaints, your responses failed to discuss implementation of adequate quality assurance oversight to ensure prompt identification, correction, and follow-up for all problems associated with the blood collection and component preparation units.

In your response to this letter, please include all of your revised applicable procedures for our review. You should indicate the sections that you updated to address this deficiency, and how you plan to determine the effectiveness of your proposed corrective actions addressing this deficiency.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. It is your responsibility to assure compliance with all requirements of federal law and FDA regulations within your corporation. While these deviations were documented during the most recent inspection of your facility, we note that similar significant deviations were also documented during the inspection of January 24 to February 24, 2012. A Form FDA 483 was

issued at the close of the February 2012 inspection, but the recent inspection has shown that adequate and effective corrective actions have not been implemented.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts. Additionally, FDA may withhold approval of requests for export certificates, or approval of pending drug applications listing your facility, until the above violations are corrected. FDA may re-inspect to verify corrective actions have been completed.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction.

Your reply should be sent to the following address: Food and Drug Administration, Attention: Margarita Santiago, Compliance Officer, 466 Fernández Juncos Avenue, San Juan, Puerto Rico 00901-3223.

Sincerely,

Maridalia Torres
Director
San Juan District

Cc:

Mr. Ron Labrum
President and CEO
Fenwal International, Inc.
Three Corporate Drive 2nd Floor
Lake Zurich, IL 60047

Mr. Manuel S. Palma
General Plant Manager
Fenwal, a Fresenius-Kabi Company
Carr 357, Km 0.8
Maricao, PR 00606