DEPARTMENT OF HEALTH AND HUMAN SER. . .ES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax:(303) 236-3100 Industry Information: www.fda.gov/oc/industry	10/21/2013 - 10/30/2013 FEI NUMBER 1419106

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jeffrey V. Baldwin, Vice President of Operations

FIRM NAME	STREET ADDRESS
Baxter Corporation Englewood	14445 Grasslands Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Englewood, CO 80112-7062	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, CAPA (b)(4) was initiated (on 05/24/13) to address (b)(4) customer complaints of mismatch between the patient and the TPN (Total Parenteral Nutrition) ingredient order, whereby the Abacus TPN Calculation Software assigned the incorrect formulae to the patients (b)(4)
(b)(4)

CAPA (b)(4) states the root cause could not be determined with certainty, but concluded (b)(4)
(b)(4)

(b)(4) was revised, and (b)(4) were incorporated.

Your firm determined the newly revised software code (Version 3.1) would be provided to new customers, but that upgrades to products currently installed in the field would not be conducted because the risk was considered to be acceptable, given that (b)(4)
(b)(4)

However, review of the Product Risk Management procedure (Document #QM-04.02, Revision J, dated 10/20/10, revealed your firm calculated the risk from this hazard incorrectly because the Product Risk Management procedure's Software Risk Analysis (SRA) section states: (b)(4)
(b)(4)

(b)(4) Your firm incorrectly calculated the risk of this hazard using the (b)(4) (documented in the Product Risk Management for the Abacus, Document #PRM Abacus PRMS 07, dated 07/27/12), instead of (b)(4) to calculate the risk of this hazard.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Janet Pulver, Investigator, ~~Investigator~~ 10/30/13	10/30/2013

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Notwithstanding, review of the Product Risk Management for the Abacus (Document #PRM Abacus PRMS 07) revealed this risk analysis fails to include this hazard of patient / order mix-up; therefore, no risk control measures have been documented (see Observation #2). Actually, risk control measures incorporated into the revised software version 3.1 (b)(4) (b)(4) did not exist in the previous software version.

Furthermore, CAPA (b)(4) states (b)(4) Your firm failed to consider this scenario could result in an over-delivery of ingredients (due to a patient receiving another patient's TPN solution), which according to the Product Risk Management for the Abacus would have a Severity of (b)(4)

OBSERVATION 2

Risk analysis is incomplete.

Specifically, CAPA (b)(4) was initiated (on 05/24/13) to address (b)(4) customer complaints of mismatch between the patient and the TPN (Total Parenteral Nutrition) order, whereby the Abacus TPN Calculation Software assigned the incorrect formulae to the patients (see Observation #1). CAPA (b)(4) states (b)(4) (b)(4) The risk analysis for the Abacus TPN Software (Product Risk Management for the Abacus, Document #PRM Abacus PRMS 07, dated 07/27/12) is incomplete because it does not address this hazard of patient / order mix-up.

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Observation Annotations

Observation 1: Promised to correct.

Observation 2: Promised to correct.

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