DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	07/25/2012 - 08/08/2012* FEI NUMBER 1000159898

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Scott A. Weinstein, President/CEO

FIRM NAME	STREET ADDRESS
Safetec Of America Inc	887 Kensington Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Buffalo, NY 14215-2720	Drug Establishment

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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

LABORATORY

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically, the firm failed to investigate a stability failure at the 6 month time-point for Safetec First Aid & Burn Cream, Lot Number T950 (Stability Protocol (b) (4)). The 6 month stability results on 2/29/12 were confirmed OOS by the firm and recorded as "failed" and "invalid" for % Benzalkonium Chloride (BZK). The stability study was *terminated* by the firm at this point. No investigation was commenced by the firm including batch record review, review of any other batches of the same drug product or placing any other subsequent batches on stability. Lot number T950, consisting of approximately (b) (4) pouches, was distributed between August 2011 and present. The expiration date for Lot T950 is 7/30/2014.

In addition, the 3 month time-point stability test for Lot T950 was also documented as OOS for % BZK. For this confirmed OOS, the firm initiated Investigation # (b) (4) on 11/30/11 with Quality Review findings of " Study to continue with next testing at 6 months. No action with product or lot unless failure at 6 month." The firm's recommendation to perform this impact analysis at the 6 month-time was not performed.

You have also failed to follow your procedure SOP-LAB-039, Procedure for Handling OOS Results and the OOS Detected Decision Tree for the classification and testing of OOS results for the following:

a. Medicated Lip Ointment, Investigation # (b) (4), initiated on 2/9/12, was classified as Inconclusive for an initial OOS for % Camphor and retesting was done in duplicate at the step that should be a single retest per the (b) (4) in order to invalidate the initial OOS.
b. First Aid Cream, Investigation # (b) (4), initiated on 2/17/12, was classified as Reversible for an initial OOS for % Lidocaine and retesting was done in triplicate instead of a single retest as per the (b) (4) to invalidate the initial OOS.
c. IPA 70% , Investigation # (b) (4), initiated on 3/7/12, was classified as Reversible for an initial OOS for % IPA and retesting was done in duplicate instead of a single retest as per the (b) (4) to invalidate the initial OOS.
d. Anti-Itch Cream, Investigation #(b) (4), initiated on 4/8/12, was classified as Reversible for an initial OOS for %

AMENDMENT 1

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	Karen L. Kosar, Investigator Marlene L. Davis, Investigator	08/21/2012

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Hydrocortisone and retesting was done in duplicate instead of a single retest per the (b) (4) to invalidate the initial OOS.

*Note: This observation was cited during the previous FDA inspection.

OBSERVATION 2

The written stability testing program is not followed.

Specifically, you have failed to follow your written procedure, SOP-LAB-025, Product Stability Testing Procedure which requires a minimum of (b) (4) production lots/batches be tested. For the following drug products you have not placed the required lots/batches on stability even though you have manufactured muliple batches:

a. Burn Spray, Product #9900038
b. Cut and Scrape, Product #9900042
c. Single Antibiotic Ointment w/Bacitracin, Product #9900050
d. Triple Antibiotic Ointment w/Lidocaine, Product #9900056
e. Triple Antibiotic Ointment, Product #9900057

In addition, your drug products do not bear an expiration date determined by appropriate stability data. SOP-LAB-025 requires that (b) (4) complete stability studies on (b) (4) separate lots of each product be completed in order to set a definitive expiration date. You have not followed this in that you have determined the expiration date for First Aid Cream is 3 years even though only one lot of the product has completed stability testing. Also, you have determined that the expiration date for Triple Antibiotic Ointment w/Lidocaine is 3 years with no lots yet placed on stability.

*Note: This observation was cited during the previous FDA inspection.

OBSERVATION 3

The establishment of sampling plans including any changes thereto, are not drafted by the appropriate organizational unit.

Specifically, you lack written procedures for the monthly microbiological sampling at the water hose sample ports for Purified Water in the Batch Mix Room.

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OBSERVATION 4

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually (b) (4) for evidence of deterioration.

Specifically, the firm does not follow procedure SOP-QUA-008, Quality Control Procedure for Sampling and Storage of QC Retainers, requiring (b) (4) review of drug retains. No (b) (4) retain sample review has been performed for any of your products.

*Note: This observation was cited during the previous FDA inspection.

PRODUCTION AND PROCESS CONTROLS

OBSERVATION 5

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically, you have not followed your written procedure SOP-QUA-011, Process Validation and Re-Validation in that you have manufactured multiple lots of the following drug products but you have not initiated process validation as required for the following:

a. Triple Antibiotic Ointment w/Lidocaine
b. Triple Antibiotic Ointment

OBSERVATION 6

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, your cleaning validation study for Antifungal Cream and Anti-Itch Cream failed to demonstrate that your sanitization procedures and frequency are sufficient. However, your firm continues to manufacture these drug products and other drug products on failed cleaning validation production lines. For example, the Antifungal Cream cleaning validation study (Protocol (b) (4) Batch #00402) dated 4/12 failed and a subsequent batch (Batch #20118) was manufactured on 5/9/12. Anti-itch Cream cleaning validation study (Protocol (b) (4), Batch #00402) dated 6/10 failed and subsequent

batches of Anti-Itch Cream were manufactured since then including: Batches 00713, 00916, 01011, 01020, 01213, 10407, 10436, 10636, 10813, 11127, 20212, and 20513.

OBSERVATION 7

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically, the firm has not conducted GMP compliant bulk hold studies, at each relevant phase of manufacture (i.e. blend, bulk), in accordance with a study protocol with pre-approved acceptance criteria, for any of the drug products it manufactures and packages. For example, the following batches have been held in the bulk blend phase (b) (4) days even though the firm has not conducted a formal bulk hold study to support that such a bulk blend hold time will not adversely impact the quality of the drug product, through expiry.

a. Antifungal Cream, batch #20118, was blended on 5/9/12, and final fill and packaging was performed on 7/3/12.
b. Oral Pain Relief, batch #20427, was blended on 5/31/12, and has been stored as a bulk blend since that time.
c. Single Antibiotic Ointment, batch #20533, was blended on 6/19/12, and has been stored as a bulk blend since that time.
d. P.A.W.S. New Fresh Scent, batch #20711, was blended on 7/5/12, and has been stored as a bulk blend since that time.
e. Burn Spray, batch #20704, was blended on 7/11/12, and has been stored as a bulk blend since that time.
f. Pain Spray, batch #20614, was blended on 7/16/12, and has been stored as a bulk blend since that time.

OBSERVATION 8

Procedures prescribing a system for reprocessing batches to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics are not.

Specifically, you performed rework twice for First Aid Cream w/Aloe, Batch 91259, without written provision for this in accordance with SOP-OPR-14, Rework Procedure. In addition, rework instructions and analytical calculations were documented on loose-leaf paper and not documented with any secondary check and approval.

QUALITY SYSTEM

OBSERVATION 9

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically, you have failed to follow your procedure SOP-QUA-013, Annual Product Reviews, requiring product reviews

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be conducted in February - April of each year. This requirement was not followed for Product Reviews for 2010 (not inclusive) as follows:

You have not conducted *any* reviews for the following products:

1. Burn Free Aerogel
2. p.a.w.s. New Citrus Scent
3. IV Prep Wipe
4. BZK Antiseptic Wipe
5. Benzocaine Sting Relief

You have conducted *late* reviews for the following products:

1. Product Number 9900038, Product Name: Burn Spray (due 4/11, completed 8/24/11)
2. Product Number 9900056, Product Name: Triple Antibiotic Ointment w/ Lidocaine (due 4/11, completed 8/25/11)
3. Product Number 9900077, Product Name: Oral Pain Relief (due 4/11, completed 8/31/11)
4. Product Number 9900081, Product Name: Premiere Enterprises Pain Spray (due 4/11, completed 8/31/11)
5. Product Number 9900063, Product Name: First Aid Cream w/Aloe (due 4/11, completed 8/25/11)

In addition, Stability Test information was not included in the Annual Product Reviews as required by your procedure SOP-QUA-013.

OBSERVATION 10

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically, training for the analysts' consists of only SOP reviews and does not include any other job-specific GMP training or proficiencies/competencies documentation. The Quality Manager's training records also do not reflect the responsibilities of his role.

OBSERVATION 11

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, your firm's written procedure, SOP-PUR-044, Vendor/Supplier Qualification/Disqualification Procedure, is

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deficient in that it does not provide for the requirement that raw materials be subjected to periodic full testing at specified intervals to verify that they meet the specifications and quality represented within the supplier's Certificate of Analysis.

*Note: This observation was cited during a previous FDA inspection.

OBSERVATION 12

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

~~Specifically, you have not followed your written procedure SOP-QUA-011, Process Validation and Re-Validation in that although you have manufactured multiple lots of drug products, you have not performed process validation as required as follows:~~

~~a. Triple Antibiotic Ointment w/Lidocaine~~
~~b. Triple Antibiotic Ointment~~

"This observation was removed as the observation was already cited as Observation #5 on the FDA-483"

*** DATES OF INSPECTION:**
07/25/2012(Wed), 07/26/2012(Thu), 07/27/2012(Fri), 07/30/2012(Mon), 08/01/2012(Wed), 08/03/2012(Fri), 08/08/2012(Wed)

AMENDMENT 1

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