Inspections, Compliance, Enforcement, and Criminal Investigations

Michele Sewell, M.D. 4/30/14

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: 14-HFD-45-04-03

Michele A. Sewell, M.D.
Stonecrest Pediatric and Adult Medicine
8225 Mall Parkway, Suite 250
Lithonia, GA 30058

Dear Dr. Sewell:

This Warning Letter informs you of objectionable conditions observed during the U.S. Food and Drug Administration (FDA) inspection conducted at your clinical site between June 17 and August 19, 2013. Ms. Nicole Bell and Ms. Vanessa Coulter, representing FDA, reviewed your conduct of the following clinical investigations of the investigational drug albiglutide, performed for GlaxoSmithKline:

- Protocol GLP112754, "A Randomized, Open-Label, Parallel-Group, Multicenter Study to Determine the Efficacy and Long-Term Safety of Albiglutide Compared With Insulin in Subjects With Type 2 Diabetes Mellitus"; and
- Protocol GLP112757, "A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel-Group, Multicenter Study to Determine the Efficacy and Safety of Albiglutide Administered in Combination With Metformin and Glimepiride Compared With Metformin Plus Glimepiride and Placebo and With Metformin Plus Glimepiride and Pioglitazone in Subjects With Type 2 Diabetes Mellitus."

This inspection is a part of FDA's Bioresearch Monitoring Program, which includes inspections designed to evaluate the conduct of FDA-regulated research to ensure that the data are scientifically valid and accurate, and to help ensure that the rights, safety, and welfare of the human subjects of those studies have been protected.

At the conclusion of the inspection, Ms. Bell and Ms. Coulter presented and discussed with you Form FDA 483, Inspectional Observations. On September 5, 2013, FDA sent you Form FDA 483, Amendment 1, dated September 5, 2013. We acknowledge receipt of your September 12, 2013,

written response to both the Form FDA 483 and the Form 483, Amendment 1.

From our review of the FDA Establishment Inspection Report, the documents submitted with that report, and your written response dated September 12, 2013, we conclude that you did not adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations. We wish to emphasize the following:

1. You failed to ensure that the investigation was conducted according to the investigational plan [21 CFR 312.60].

As a clinical investigator, you are required to ensure that your clinical studies are conducted in accordance with the investigational plan. The investigational plan for Protocol GLP112757 includes certain requirements related to eligibility confirmation, sulfonylurea dosing prior to screening, and pharmacokinetic (PK) blood draws, as well as criteria for increasing study-drug dose. The investigational plan for Protocol GLP112754 includes certain requirements related to Serious Adverse Event (SAE) reporting and the performance of specific assessments and procedures at certain study visits. Both protocols require that study visits occur within specified time frames. You failed to adhere to these requirements. Specifically:

a. Subject 1398757001, Protocol GLP112757:

i. Protocol GLP112757 requires that subjects receive a sulfonylurea dose that is equivalent to at least 4 mg glimepiride for at least three months prior to screening. The protocol indicates that 4 mg glimepiride is equivalent to 5 mg glyburide dosed twice daily.

Subject 1398757001 was ineligible for Protocol GLP112757 at screening on August 19, 2009, while on glyburide 5 mg daily (half of the protocol-required dose). The medication log for this subject indicates that the dose of 5 mg once daily was changed to 5 mg twice daily sometime in September 2009 (after screening), and the subject was randomized on January 6, 2010. The dose correction should have occurred at least three months before, and not after, screening.

In your September 12, 2013, written response to the Form FDA 483, you indicated that after additional review, you found that you did not have proper documentation of the required dosage of glimepiride. You also indicated that, as corrective action, your study staff would receive or had received additional training to ensure protocol compliance.

Your response is inadequate because it is not sufficiently detailed with respect to your corrective action plan. You have not provided any details or documentation regarding the training of your study staff, and you have not indicated what corrective action you personally have taken, as clinical investigator, to ensure your own compliance with study protocols. Without those details, we are unable to determine whether your corrective action is adequate to prevent similar violations in the future.

ii. Protocol GLP112757 requires that subjects who have a hemoglobinopathy that may affect determination of hemoglobin A1c (HbA1c) not be enrolled in the study.

Subject 1398757001 was ineligible for Protocol GLP 112757 at screening on August 19, 2009, with an "apparent hemoglobin variant observed during analysis of hemoglobin A1c" noted in the laboratory results. The same apparent hemoglobin variant was also observed and verified by repeat analysis in the laboratory results following the Week-4 visit on February 3, 2010. In the laboratory results following the April 22, 2011, visit, laboratory personnel noted that a hemoglobin pattern and concentration consistent with sickle-cell trait (heterozygous) was found, and suggested a clinical and hematologic correlation.

In your September 12, 2013, written response to the Form FDA 483, you indicate that no notation was made at screening because it was your professional opinion that the subject

should not be excluded because of sickle-cell trait. In addition, you stated, "I felt, at the time, that there was some evidence but no definitive evidence that HbA1c could not be used for accurate glucose monitoring based on the methodology employed for accurate measurement by **(b)(4)**."

Your response is inadequate because Protocol GLP112757 requires exclusion of subjects who have hemoglobinopathies that may affect HbA1c determinations. Sickle-cell trait is one such exclusionary hemoglobinopathy.

iii. Protocol GLP112757 requires that all study visits occur within ±3 days, with the exception of Visit 7 (Week -1) and Visit 8 (Baseline). The protocol notes that subjects would not be considered out of compliance if visit windows extend because of extraordinary events that make it impossible for subjects to complete a visit within the visit window (e.g., holidays, vacations, personal emergencies). However, the protocol specifies that determination of the maximum visit window deviation is at the discretion of the medical monitor.

For Subject 1398757001, Visit 22 (Week 65) took place 15 days past the protocol-allowed time frame. The protocol required that Visit 22 occur 13 weeks after Visit 21 (Week 52), ±3 days. This subject's Visit 21 occurred on January 7, 2011, and Visit 22 occurred approximately 15 weeks later, on April 26, 2011. There is no evidence of an extraordinary event or of a determination by the medical monitor.

In your September 12, 2013, written response to the Form FDA 483, you did not provide any explanation for the delay in this subject's visit. However, you did acknowledge that problems with scheduling occurred. You noted that you have taken corrective action and that, as part of that corrective action, you hold weekly meetings with study staff and include the study staff in your weekly meetings with clinic staff. You also stated that you have Standard Operating Procedures (SOPs) on assessments, and that you, as well as the study staff, were retrained on this SOP.

Your response is inadequate because you have not provided documentation of any extraordinary events, or of any discussion with the medical monitor to determine maximum visit-window deviation in this case. In addition, you have not provided sufficient details about your corrective action plan. You have not provided a copy of the SOP on assessments, which you indicated that you have in place and on which you and your staff have been retrained, nor have you provided any details about that training. Without those details, we are unable to determine whether your corrective action is adequate to prevent similar violations in the future.

b. Subject 1398757002, Protocol GLP112757:

i. Protocol GLP112757 requires that subjects receive at least 1500 mg metformin daily for at least three months prior to screening; however, the protocol allows enrollment of subjects with a documented maximum tolerated dose of less than 1500 mg metformin daily, if the dose has been stable for at least eight weeks before randomization.

Subject 1398757002 was enrolled in the study despite the subject's not having received at least 1500 mg metformin daily for at least three months prior to screening, and despite the subject's not having received a documented maximum tolerated dose of less than 1500 mg daily that was stable for at least eight weeks before randomization. The concomitant medication study records show that as of August 20, 2009 (four days prior to screening), Subject 1398757002 was taking 500 mg metformin twice daily (1000 mg daily), which is 500 mg less than the requisite dose. On August 21, 2009, the dose was increased to 1000 mg metformin twice daily (2000 mg daily). This increase in the dose of metformin did not make the subject eligible for the study because the subject was not receiving at least 1500 mg metformin for a minimum of three months prior to screening. Nevertheless, Subject

1398757002 was screened for the study three days later, on August 24, 2009. Furthermore, you provided no documentation to indicate that the subject had a stable, maximum tolerated dose of less than 1500 mg metformin daily for at least eight weeks prior to randomization.

In your September 12, 2013, written response to the Form FDA 483, you stated that the subject's maximum tolerated dose was 1000 mg metformin (daily). In your written response, you also described corrective action that you have taken to ensure that protocol-required assessments are done in a timely manner. Your response is inadequate because you provided no documentation to support your statement that the subject's maximum tolerated dose was 1000 mg metformin daily. Of note, study records show that the subject's metformin dose was increased to 1000 mg twice daily on August 21, 2009, for a total daily dose of 2000 mg, and we have no documentation that the subject could not tolerate that dose.

Your response is also inadequate because it is not sufficiently detailed with respect to your corrective actions. Specifically, you have not provided a copy of the SOP on assessments, which you indicated that you have in place and on which your staff has been trained, nor have you provided any details about that training. Without those details, we are unable to determine whether your corrective action is adequate to prevent similar violations in the future.

ii. Protocol GLP112757 permits you to increase the dose of study drug only when the subject meets the protocol criteria for a dose increase. The protocol requires that a subject receive a dose increase at Week 4 only if the subject has a single fasting plasma glucose of at least 250 mg/dL, as confirmed by a second sample drawn within 7 days and analyzed by the central laboratory, and if the subject's HbA1c level is unchanged or increased from baseline. You failed to adhere to this requirement. Specifically:

Subject 1398757002 received an increased dose of study drug on December 3, 2009, even though the subject did not meet the protocol criteria for a dose increase. This subject had a fasting plasma glucose of 144 mg/dL at Week 4 on November 17, 2009. In addition to having a fasting plasma glucose below the required level, you provided no evidence that this level was confirmed by a second sample drawn within 7 days and analyzed by the central laboratory. Therefore, Subject 1398757002 should not have received a dose increase on December 3, 2009.

In your September 12, 2013, written response to the Form FDA 483, you acknowledged that several required protocol procedures, physical examinations, lab assessments, and electrocardiograms (ECGs) were not done within the appropriate time frames. You indicated that you have taken corrective action to ensure that study assessments are not missed in the future. You noted that as part of that corrective action, you include your research staff in your weekly meetings with clinic staff, and you hold weekly meetings with research staff to get subject status reports. In addition, you note that you and your study staff were retrained on the SOPs for study assessments.

Your response is inadequate because you have not provided sufficient details about your corrective action plan. Specifically, you have not provided a copy of the SOP on assessments, which you indicated that you have in place and on which you and your staff have been retrained, nor have you provided any details about that training. Without those details, we are unable to determine whether your corrective action is adequate to prevent similar violations in the future.

iii. Protocol GLP112757 requires that for Week 28, subjects have their PK blood samples taken at least 2 days after they receive a dose of study drug. You failed to adhere to these requirements. Specifically:

Study drug container #2201065 was administered to Subject 1398757002 on May 4, 2010 (Visit 18/Week 28), and the subject's PK blood sample was taken at the same visit.

In your September 12, 2013, written response to the Form FDA 483, you acknowledged that the assessments were not performed as required by the protocol, and you indicated that you have taken corrective action to ensure that study assessments are not missed in the future. You also noted that as part of that corrective action, you hold weekly meetings with study staff, and study staff were retrained on SOPs for study assessments.

Your response is inadequate because you have not provided sufficient details about the corrective action plan. Specifically, you have not provided a copy of the SOP on assessments, which you indicated that you have in place and on which your staff has been trained, nor have you provided any details about that training. Without those details, we are unable to determine whether your corrective action is adequate to prevent similar violations in the future.

c. Subject 1398754002, Protocol GLP112754:

i. Protocol GLP112754 requires that you report all SAEs to the sponsor within 24 hours. The Protocol defines SAEs as any untoward medical occurrence that results in death; is life threatening; requires hospitalization or prolongation of existing hospitalization; results in disability/incapacity; is a congenital anomaly/birth defect; or other medical event that, in the medical judgment of the clinical investigator, should be considered serious (such as an event that may require medical or surgical intervention to prevent one of the previously listed outcomes). You failed to adhere to this requirement. Specifically:

Subject 1398754002 experienced the SAE of unstable angina that resulted in hospitalization on **(b)(6)**. However, this SAE was not reported to the sponsor until June 9, 2011, approximately 15 months later.

In your September 12, 2013, written response to the Form FDA 483, you indicated that the subject did not disclose the hospitalization to the study coordinator during five separate visits in 2010. You stated that the hospitalization was discovered on June 9, 2011, after your site received and reviewed the subject's medical records for a separate incident.

Your response is inadequate because a printed note at the bottom of the hospital record related to the subject's **(b)(6)**, admission for unstable angina indicates that a copy of this record was sent to you. You have not adequately explained your failure to report the SAE experienced by Subject 1398754002, nor have you explained how you will correct this failure in the future.

ii. Protocol GLP112754 (original version dated December 8, 2008) requires that all study visits have a treatment window of ±3 days. Amendment 1 (dated August 6, 2009) of this protocol requires the same time frame for all study visits, with the exception of Visit 6 (Baseline), which will have a treatment window of ±6 days. The protocol notes that subjects will not be considered out of compliance if visit windows extend because of extraordinary events that make it impossible for subjects to complete a visit within the visit window (e.g., holidays, vacations, personal emergencies). However, determination of the maximum visit window deviation is at the discretion of the medical monitor.

Subject 1398754002 had multiple study visits that took place significantly outside of the protocol-specified time frames.

Visit/Wk	**Date of Actual Visit**	**Days Past/Early Relative to the Expected Time Frame (Allowed Range)**
Visit 6/Wk 0	9/25/2009	15 days past due (±6 days)

Visit 16/Wk 28	5/17/2010	28 days past due (±3 days)
Visit 17/Wk 36	6/19/2010	20 days early (±3 days)
Visit 18/Wk 48	8/24/2010	15 days early (±3 days)

In your September 12, 2013, written response to the Form FDA 483, you referred to Protocol GLP112754's specifications for out-of-window visits (original version dated December 8, 2008): "All study visits will have a treatment window of ±3 days. Subjects will not be out of compliance if visit windows extend because of extraordinary events that make it impossible for subjects to complete a visit window within the ±3 day window (e.g., holidays, vacations, personal emergencies). However, determination of the maximum visit window deviation is at the discretion of the medical monitor."

Your response is inadequate because you have not explained why there were significant delays in the subjects' visits noted above, and you have not provided documentation of any extraordinary events, or of any discussion with the medical monitor to determine maximum visit-window deviations in each of these cases. Your response is also inadequate because you have not provided a corrective action plan to prevent the recurrence of similar violations in the future.

d. Subject 1398754001, Protocol 112754:

i. Protocol 112754 requires that you perform a complete physical examination at Visit 1 (Screening). You failed to adhere to this requirement. Specifically:

You failed to perform a complete physical examination on Subject 1398754001 (written incorrectly on Form FDA 483 as Subject 1398764001) at Visit 1 (Screening).

In your September 12, 2013, written response to the Form FDA 483, you acknowledged that your study staff failed to perform the required physical examination at screening. You indicated that the Visit-1 physical examination was completed at Visit 2, before other study procedures were done to determine the subject's eligibility, and that the missed physical examination was listed on a "DVE report." In addition, you indicated that in 2011 your study staff were provided with and instructed on a flow chart of visit events to ensure that assessments for this study are not missed in the future.

Your response is inadequate because you have not provided any documentation of the subject's physical examination at Visit 2, or the flow chart of visit events that you provided to study staff, and you have not provided any details about how the staff were instructed on the use of the flow chart. Without those details, we are unable to determine whether your corrective action is adequate to prevent similar violations in the future.

ii. Protocol 112754 requires that you obtain triplicate ECGs and a blood sample for hematology and chemistry assessments at Visit 23 (Week 104).

Subject 1398754001 (written incorrectly on Form FDA 483 as Subject 1398764001) did not have triplicate ECG recordings or laboratory assessments at Visit 23 (Week 104). Although the subject's study records document why the ECGs and blood draw could not be performed at this visit, there is no evidence that they were performed at a later date.

In your September 12, 2013, written response to the Form FDA 483, you acknowledged that several laboratory assessments and ECGs were not performed according to the time frames required by the protocol. You also noted that you have taken corrective action to ensure that study assessments are not missed in the future. You noted that as part of that corrective action, you include your research staff in your weekly meetings with clinic staff, and you hold

weekly meetings with research staff. You and your study staff were also retrained on an SOP for study assessments, and in 2011 your study staff were provided with and instructed on a flow chart of visit events to ensure that assessments for this study are not missed in the future.

Your response is inadequate because you have not provided sufficient details about your corrective action plan. You have not provided a copy of the SOP on assessments, which you indicated that you have in place and on which you and your staff have been retrained, and you have not provided any details about that training. You also have not provided the flow chart o visit events that you provided to study staff, and you have not provided any details about how the staff were instructed on the use of the flow chart. Without those details, we are unable to determine whether your corrective action is adequate to prevent similar violations in the future.

As detailed above, you failed to conduct the investigation in accordance with the investigational plan. Specifically, enrollment of subjects who do not meet eligibility criteria, failure to report SAEs t the sponsor promptly, failure to adhere to protocol restrictions related to dose increases, failure to perform protocol-required assessments and procedures, and failure to conduct study visits within the protocol-specified time frames jeopardize subject safety and data integrity. In addition, failure to obtain blood samples for PK testing raises concern about the validity and integrity of the data collected at your site.

2. You failed to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. [21 CFR 312.62(b)]

As a clinical investigator, you are required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as a control in the investigation. Case histories include records of adverse events that occur. You have failed to maintain adequate and accurate case histories with respect to these records. Examples of this failure include, but are not limited to, the following:

a. For Protocol GLP112754, laboratory results for Subject 1398754002 at Visit 14/Week 20 (February 12, 2010) showed decreased hemoglobin, hematocrit, and red blood cell count levels. The lab results were initially marked as "not clinically significant," with a signature dated February 19, 2010. However, on December 12, 2012, this determination was changed to "clinically relevant" with an additional notation that the subject had clinically significant anemia, without an explanation for the change made almost three years later.

In your September 12, 2013, written response to the Form FDA 483, you indicated that upon more detailed review of the protocol's definition of an adverse event, you changed your professional judgment regarding Subject 1398754002's hematology report, and you documented the subject's anemia as clinically significant.

Your response is inadequate because you have failed to document your rationale for the changes you made in the clinical significance of anemia nearly three years after the anemia was noted. Without the inclusion of your rationale, these documents are inadequate to capture the adequate and accurate case history of this subject. In addition, you have not provided a corrective action plan to prevent the recurrence of similar violations in the future.

b. In addition to the adverse event noted above, Subject 1398754002 experienced other adverse events that were recorded in the Adverse Event Log, such as memory loss, cough, anemia, and pain in the right lower extremity. These adverse events were originally marked as "Yes" for "Possible IP relationship" in the Adverse Event Log. However, the same adverse events were changed to "No" fo "Possible IP relationship" three years later, on February 13, 2013, without an explanation for the

change.

In your September 12, 2013, written response to the Form FDA 483, you note that the change made in the Adverse Event Log for anemia was due to entry error only. Your response with regard to this change is inadequate because you failed to explain the relationship between the entry error and the changed notation. In addition, your response was inadequate because you failed to document your rationale for the changes you made in the relationship of other adverse events (specific examples provided above) to the study drug, nearly three years after the adverse events were noted. Without the inclusion of your rationale, these documents are inadequate to capture the adequate and accurate case history of this subject. In addition, your response is inadequate because you have not provided a corrective action plan to prevent the recurrence of similar violations in the future.

Your failure to maintain adequate and accurate case histories, including the failure to document a rationale for changes in adverse event classification and in the assessment of adverse events' relationship to the study drug, jeopardizes subject safety and welfare and compromises the validity and integrity of data captured at your site.

3. You failed to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects [21 CFR 312.62(a)].

As a clinical investigator, you are required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. According to Protocol GLP112757, the disposition of the investigational drug should be recorded in product accountability documents stating the amounts of albiglutide/matching placebo, glimepiride, and pioglitazone/matching placebo dispensed and/or administered to study subjects; the amounts returned by study subjects; and the amounts received from and returned to the sponsor, when applicable. You did not adequately maintain records of these documents. Examples of this failure include, but are not limited to, the following:

a. For Subject 1398757001, the study-drug disposition label and the Investigational Supplies Inventory Log show that the subject received two injections on July 28, 2010: Container #2459470, administered at 10:00 a.m., and Container #2144353, administered one hour later, at 11:00 a.m.

In addition, study-drug disposition labels show that this subject received two injections (Containers #2359363 and #2565372) on August 3, 2011, at 10:00 a.m. The Investigational Supplies Inventory Log does not contain the dates and times of study-drug administration for either of these containers

b. For Subject 1398757002:

i. The Investigational Supplies Inventory Log notes that Container #2592361 was administered on November 21, 2010, but the case report form notes that this container was administered on January 21, 2011.

ii. The Investigational Supplies Inventory Log notes that Container #2305273 was administered on March 9, 2010, and was returned to the site at an earlier date, on March 6, 2010. The case report form has no recording for the date of study-drug administration and indicates that this container was not returned to the site.

iii. The study-drug disposition label and the Investigational Supplies Inventory Log contain discrepancies regarding the injection received on July 13, 2010, at 10:02 a.m. The label indicates that the subject was administered Container #2306486 on July 13, 2010, but the log indicates that the subject was administered Container #2276486 on that date. The log indicates that Container #2306486 was administered on August 24, 2010, instead.

In addition, the study-drug disposition label shows that this subject was administered Container #2133370 on May 10, 2011, at 10:26 a.m., and was administered Container

#2425379 six minutes later, at 10:32 a.m. The Investigational Supplies Inventory Log does not contain the dates and times of study-drug administration for either of these containers.

In your September 12, 2013, written response to the Form FDA 483, you acknowledged the presence of discrepancies between the recordings on the returned study-drug disposition labels and the logs. You attributed the discrepancies to the following:

- Study coordinator's error in recording the information;
- Study coordinator's putting information in the wrong section of a form;
- Mismatch between the sponsor forms and study-drug disposition labels with regard to the recording of the study-drug administration information;
- Long lapse in time between subjects' injection/dose and return of the injection pens to the site, resulting in the subjects' having difficulty in recalling the information;
- Subjects' filling out study-drug disposition labels improperly or not at all; and
- Study coordinator's failing to verify the accuracy of study-drug disposition labels before subject left the site, resulting in lack of accurate information.

You stated that you recognized a need to address deficiencies in accurate recording of investigationa drug disposition, and that you understood the importance of accurate and complete documentation of the use of study drug by each subject. You indicated that your site was retrained on study-drug handling and recording, and you provided us with a copy of the forms that documented this training. We believe that the training you and your staff received should be adequate to prevent a recurrence of similar violations.

Your failure to maintain adequate and accurate drug accountability records jeopardizes subject safet and welfare,andcompromises the validity and integrity of the data at your site.

This letter is not intended to be an all-inclusive list of deficiencies with your clinical study of an investigational drug. It is your responsibility to ensure adherence to each requirement of the law and relevant FDA regulations. You should address these deficiencies and establish procedures to ensure that any ongoing or future studies will be in compliance with FDA regulations.

Within fifteen (15) working days of your receipt of this letter, you should notify this office in writing of the actions you have taken to prevent similar violations in the future. Failure to address the violations noted above adequately and promptly may result in regulatory action without further notice. If you believe you have complied with FDA regulations, include your reasoning and any supporting information for our consideration.

If you have any questions, please contact Constance Cullity, M.D., M.P.H., at 301-796-3397; FAX 301-847-8748. Your written response and any pertinent documentation should be addressed to:

Constance Cullity, M.D., M.P.H.
Branch Chief
Good Clinical Practice Enforcement Branch
Division of Good Clinical Practice Compliance
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Building 51, Room 5354
10903 New Hampshire Avenue
Silver Spring, MD 20993

Sincerely yours,

{See appended electronic signature page}
Sean Y. Kassim, Ph.D.
Acting Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SEAN Y KASSIM
04/30/2014

Page Last Updated: 06/09/2014
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page: