



June 13, 2017

Our STN: BL 125589/0

BLA COMPLETE RESPONSE

Oxford Immunotec, Inc.
Attention: Wolfgang Pieken, PhD
315 Norwood Park South
Norwood, MA 02062

Dear Dr. Pieken:

This letter is in regard to your Biologics License Application (BLA) for *Babesia microti* Arrayed Fluorescence Immunoassay (AFIA) manufactured at your Norwood, Massachusetts location and submitted under section 351 of the Public Health Service Act (42 U.S.C. 262).

We have completed our review of all the submissions you have made relating to this BLA with the exception of the information in the amendment dated May 18, 2017, and June 5, 2017, as noted below. After our complete review, we have concluded that we cannot grant final approval because of the deficiencies outlined below.

INSPECTIONAL ISSUES:

1. CBER conducted a Pre-License Inspection (PLI) of the Imugen, Inc. facility from March 6 through 10, 2017, and noted significant deviations at the end of the inspection. We received the response to the FDA Form 483 on April 17, 2017, and find that it does not sufficiently address the concerns noted during the inspection. Your corrective actions do not appear to be fully implemented or comprehensive to address the underlying issues. Examples include, but are not limited to:
 - a. Deviation investigations do not include an evaluation to determine if false positives or false negatives, which would adversely impact patient safety, could have resulted from the deviation.
 - b. Your manufacturing procedures are not sufficiently detailed to provide consistent lot-to-lot reproducibility of your finished device lots for the AFIA assay.
 - c. Changes to the device design are not verified or validated in accordance with your design change procedures.
 - d. Segregation between operations for blood donor screening and clinical testing is inadequate to prevent mix-up of equipment and test samples.

- e. The cleaning procedures and processes are insufficient to maintain a sanitary environment.
- f. Insufficient personnel are available to perform and oversee all aspects related to manufacturing of finished device lots and testing of donated blood samples.
- g. Investigations of exceptions are inadequate and do not determine root cause of events and initiate further corrective actions to prevent re-occurrence of issues.
- h. Operator training and instructions are not sufficient to manage the entry of the results of the blood donor samples to prevent vulnerabilities related to data integrity and traceability.
- i. The equipment maintenance and calibration program does not include the management of all pieces of equipment used for manufacturing and testing of blood donor samples.
- j. The amount of critical pieces of equipment is insufficient to continuously perform blood donor screening activities at the suggested throughput level.

The deficiencies described in the FDA Form 483 issued at the close of the inspection referenced above are an indication that your Quality system is not effective.

Approval of a Biologics License Application or issuance of a biologics license constitutes a determination that the establishment and the product meets applicable requirements to ensure the continued safety, purity, and potency of such products; whereas, for your situation, this applies to the continued accuracy of the test results. Applicable requirements for the maintenance of establishments for the manufacture of a product, or test result provider, include, but are not limited to, the good manufacturing practice requirements.

- a. Your corrective actions need to be more comprehensive with respect to addressing the underlying quality oversight issues, and,
- b. A second PLI will be necessary to verify the corrective actions once they have been fully implemented, validated, and established.

Your response will need to demonstrate that the corrective actions to the inspectional observations as listed on FDA Form 483 have been fully implemented and you will need to provide the supporting evidence of implementation including any related studies or verification/validation reports, as applicable. The unsolicited amendments received on May 18, 2017 and June 5, 2017 did not include implementation of all corrective actions to each inspectional observation.

REVIEW ISSUES:

Pre-Clinical

2. The change proposed by Imugen to their real time stability study is acceptable. Please provide an updated finished device stability protocol (DOC-STB-24) and updated report to date (DOC-STB-RPT-24) to reflect these changes.
3. In the ANA interference study, (DOC-PRO-49 and DOC-RPT-71), please indicate if the 3 ANA positive samples that were AFIA positive at a 1:64 cut off remained positive at a 1:128 cut off. Based on the number of ANA positive samples that are positive at the AFIA cut off of 1:128, please recalculate the percent interference over a denominator of 40 (i.e., the total number of ANA positive samples tested using the AFIA). Alternatively, provide a justification why the 20 ANA samples in the initial study should not be reported as part of the performance evaluation of the AFIA.

Process/Product

AFIA Process Validation

4. In review of your process validation report, DOC-RPT-45 *Validation Report to Manufacture a Babesia microti AFIA Finished Device Lot*, you note two exceptions were encountered during the manufacture of the negative control lots, specifically exception E-16-063 due to product contamination on lot (b) (6) and E-16-061 due to lack of documentation regarding the negative blood donor on lot (b) (6)
 - a. Please provide the investigation for both exceptions and an evaluation of the impact of the exceptions on the outcome of the negative control lots, specifically lots (b) (6)
 - b. We note that these deviations were not included in the exception log provided to the FDA during the pre-license inspection. Please comment.

Chemistry Manufacturing and Controls

5. Your response to IR question#11 is not acceptable. The revised LAB-SER-BIFA-1 procedure does not clearly specify how many additional retests of a clinical specimen are allowed to reach a final result: Section 9.2.1. says that an initial reactive sample is retested twice at 1:128 and titrated out to endpoint (1:1024) and Section 9.2.2.6. says that additional re-tests may be required at the discretion of the supervisor to further evaluate any inconclusive findings. The FDA expects that a clear finite number of tests are performed to make an interpretation of non-reactive or repeatedly reactive in a serological test. Therefore the wording in Section 9.2.1 is acceptable. Remove the additional retests in Section 9.2.2.6.

Please revise LAB-SER-BIFA-1 to indicate how many retests are allowed and how the final interpretation of the results is reached.

6. BLA approval requires evaluation and lot release testing of at least three conformance lots that were manufactured using validated manufacturing processes described in the license application, in a lot size that is similar to that proposed for subsequent production. The time required for lot release testing and FDA review of the lot release test results must be considered in the production process. Please provide the batch size information of currently manufactured lots that can sustain uninterrupted supply of test reagents cleared through FDA Lot Release for ongoing testing requirements.
7. The formal agreement with (b) (4) for housing (b) (4), production and delivery of *Babesia* infected (b) (4) blood should be signed by the (b) (4) and Oxford Immunotec, Inc. before the pre-license inspection.

Software and Instrumentation

The following questions were sent on April 14, 2017, in response to information received on March 23, 2017, (to information request sent on February 17, 2017, to “BLA Complete Response BL125588/0 Imugen Response” dated Dec 14, 2016). The corresponding question numbers in the April 14 letter are indicated in each question below as “FDA Question _”. A status update on these questions was provided on May 23, 2017, which generally indicated that work was in progress and that the requested information would be provided. (In the following questions, the wording at times refers to responses to the NAT BLA. The (b) (4) software is used by both assays in similar ways and consequently the issues for acceptability of the software apply equally to the AFIA BLA)

8. *Performance requirements for (b) (4) hardware and software (sent as FDA Question 1):*

In the NAT amendment received March 23, 2017, in response to FDA Question 16, you stated that performance requirements “relevant to IT infrastructure for general lab operation ... is beyond the scope of the (b) (4) software” and were removed. This is not reasonable because the (b) (4) software requires proper operation of the underlying infrastructure to meet its intended use. Your documentation has inconsistently described the components of the system, and it is not clear what hardware supports the (b) (4) software and database functionality. You should include requirements related to the infrastructure that is necessary to support the intended use of the device for both the NAT and AFIA assays. This appears to include the components in the Hardware Network Diagram in section 2.3.2 in your Architectural Design document provided in Attachment 29.4 of your response received December 14, 2016, and any other relevant components not identified in this diagram.

- a. Please clarify all of the required components for your system, including PCs, printers, network connections, etc. Explicitly identify the boundaries of the system with respect to your corporate network.
 - b. Please include all requirements related to required capacity for throughput, database capacity and accessibility, connectivity, uptime, etc., in order for the underlying infrastructure system to meet the required needs of the system. These requirements should include testable metrics to ensure that they can be met.
 - c. Include all test plans, test results and verification and validation testing for these performance requirements.
 - d. Update your traceability matrix to include this information.
 - e. Update your risk documentation to include risks associated with the performance needs of the system, and include the mitigations you implemented to reduce those risks to acceptable levels.
9. *Verification and validation testing (sent as FDA Question 2):*
In the NAT amendment received December 14, 2016, in response to FDA Question 33, you provided an updated traceability matrix in Attachment 29.3 and referred to IQ and OPQ testing. The testing is incomplete. Note that process validation testing (Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)) testing are not the same as verification and validation testing outlined in part (a) of Question 33. Please refer to FDA's guidance document, "General Principles of Software Validation," with a particular focus on section 5.2.5, located at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf>. As outlined in the premarket software guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," please ensure that you provide unit, integration and system level test protocols, including pass/fail criteria, test report summary, and tests results. It is difficult to assess the adequacy of a test script by viewing only raw test steps without a description of the test plan and protocol and a summary of results.
10. *User interface error checking (sent as FDA Question 3):*
In the NAT Amendment received March 23, 2017, in response to FDA IR Question 15, you stated that two additional risks were added, but it is not clear if this represents all unexpected conditions. Two conditions were included: R26b "Software must protect against import of corrupt or incomplete source file" and R26c "Software must not allow input of invalid result values." Testing for R26b does not describe what was tested and why; it just illustrates that an uncharacterized file was rejected on import. Testing for R26c is limited to error checking on the IFA Slide screen. R29 describes software error detection functionality but the testing that is included in the traceability matrix

(Attachment_15.2-IT-CSV-IMD14-16-TM&DocDetails.pdf refers to IT-CSV-IMD14-07-OPQb, 6.8.11, #11) does not appear to test or detect error conditions.

- a. Please provide a summary description of all user interface requirements and the types of error checking that is performed to identify problems with data interactions with the user via keyboard, barcode scanning, etc., and list the corresponding testing used to ensure proper functionality of the system. Please do not refer to entire design documents, but develop a direct response to this question. This is necessary to assess how the system responds to unexpected conditions and assess the scope of the error checking of the system.
- b. Please provide the corresponding design control documentation for the user interface requirements and error checking in (a).

11. *Documentation package for Build 1.0.5.5 (sent as FDA Question 5):*

In the NAT Amendment received March 23, 2017, in response to FDA Question 14, you stated that the (b) (4) software will no longer be compiled for commercial release, but that the final version will be Build 1.0.5.5. Please review the documentation provided and ensure that all design documentation including appropriate verification and validation testing corresponding to version Build 1.0.5.5 has been provided.

12. *Risk management process (sent as FDA Question 6):*

In the AFIA Amendment received March 20, 2017, in response to FDA Question 13, you stated that you updated your risk analysis to better align with ISO 14971. Your process appears to have changed as a result of your last amendment with the elimination of “likelihood” from your risk analysis and other changes as described in your document “Re-Analysis of Risk Assessment LAB-DSN-5” (Attachment_13.3-DOC-RPT-91.pdf). We are trying to locate the relevant processes/procedure(s) because they don’t appear to be aligned with ISO 14971.

In section 2 of the re-analysis document, you stated that the risk analysis was performed according to “LAB-QA-62 Risk Management Procedure.” However, in response to FDA Question 33 in your response document (001_AFIA Response to AI p 1 to 260.pdf) received December 13, 2016, you stated on page 35 that LAB-QA-62 was obsoleted and that the information was included in the revised LAB-QA-67 (Attachment 33.3). We reviewed the Design and Development Procedure (LAB-QA-67) (003_AFIA Response to AI p 497 to 737.pdf); however, LAB-QA-62 is not listed as obsoleted, but is referenced for use in developing the Risk Analysis.

Please provide the document LAB-QA-62 and any other risk related procedures that apply to the NAT and AFIA assays and to the (b) (4) software and associated hardware. Because it appears that you have updated your processes, please provide the latest documentation describing how you perform your risk related procedures.

13. Risk Management and ISO 14971 alignment (sent as FDA Question 7):

In the AFIA Amendment received March 20, 2017, in response to FDA Question 13, you provided updated risk information. We requested that you describe how your processes align with ISO 14971 but you did not provide an explanation. Language in your “Re-Analysis of Risk Assessment LAB-DSN-5” (Attachment_13.3-DOC-RPT-91.pdf) suggests misunderstandings in the application of ISO 14971 “Medical device – application of risk management to medical devices.” We are attempting to understand what you changed by comparing your previous risk documentation to the latest documentation, in order to identify what should be addressed.

- a. In your document “Re-Analysis of Risk Assessment LAB-DSN-5” (Attachment_13.3-DOC-RPT-91.pdf) in Table 3 in response to FDA Question 13, you provided estimates of Probability of Harm. Table 1 includes Failure Effect Codes mapped to both severity and probability. Specifying Severity for a particular harm is appropriate. However, please note that estimates of probability of harm are made within the context of each identified hazard and hazardous situation, and assigning probability of harm to a failure effect as you have done (independently of the hazardous situations and causes) is not consistent with risk analysis as outlined in ISO 14971. The different potential causes and resulting hazardous situations will affect the value of probability for that particular situation. Table 1 should be changed to align with ISO 14971, and the direct mapping to “Probability of Harm” removed.
- b. In concert with part (a) above, the “Probability of Harm” in the document “Babesia microti AFIA device risk analysis” (Attachment_13.1-LAB-DSGN-5.xlsm) should be updated to reflect your assessment of “Probability of occurrence of harm” as a combination of probability of the hazardous situation occurring and the probability that the hazardous situation leads to harm. You do not need to identify P1 and P2 in this document, but your assessment of “Probability” should be specific to the “Potential Cause(s)” that you have identified.
- c. You have added the term “failure effect” to your risk documentation. This term is used in FMEAs but is not used in ISO 14971. Please clarify how this maps to your support of ISO 14971. Your document “Re-Analysis of Risk Assessment LAB-DSN-5” (Attachment_13.3-DOC-RPT-91.pdf) does not explain how failure effects are related to harms, because they are not the same thing. One failure effect may be associated with more than one kind of harm; for example, a false positive and a false negative are generally associated with different harms and have different severities and sometimes different probabilities of harm. However, you combined false negative and false positive in several cases. You should consider consistently adopting terms from ISO 14971 and be consistent with a particular methodology. Please update your risk documentation accordingly. We suggest removing “failure effect” and including columns consistent with ISO 14971.

- d. In the document “Babesia microti AFIA device risk analysis” (Attachment_13.1-LAB-DSGN-5.xlsm) it appears you eliminated the term “likelihood” and replaced it with “probability.” In the “Front page” tab, the Probability definitions specifically refer to failures. This suggests that your probability is still focused only on P1 and does not include probability of a hazardous situation leading to harm. Please revisit your risk management processes and provide a clear description of your processes and how they align with ISO 14971. State explicit the scope of “probability” in your documentation and ensure your risk documentation includes all aspects of probability. As a start, we suggest removing the notion of “failure” from your definitions. Note that this will require more than changing column names and definitions, but will require that you ensure each row in the table is specific to one cause/situation, and that the value of Probability is the probability that the cause/situation would lead to harm. Harm should be added to the table. This is necessary to produce an assessment that is aligned with ISO 14971.

14. *Risk Analysis and Traceability (sent as FDA Question 8):*

In the AFIA Amendment received March 20, 2017, in response to FDA Question 14, you provided document “Babesia microti AFIA device risk analysis” (Attachment_13.1-LAB-DSGN-5.xlsm). In the NAT Amendment received March 23, 2017, in response to FDA Question 17, you provided the (b) (4) Hazard Analysis (Attachment_15.1-IT-CSV-PDF-41.xlsx) and the NAT Risk Analysis (Attachment_22.1-LAB-DSGN-11.xlsm). In the “Review hazards & risk” tab for both assay analyses, your risk information is presented generally, without specifics. You have not established clear one-to-one traceability between specific potential causes and hazardous situations and the “Countermeasures to take.” Many of the countermeasure entries include several individual countermeasures, and it is not clear how these countermeasures would be adequate to mitigate the potential causes, because the potential causes are not specific. For example, H80 in the AFIA analysis lists several potential causes related to mistakes in manual activities, but you have not explicitly listed the types of mistakes that could be made, the possible harm (severity) of each mistake and the probability associated with each. This should be done, so you can identify the appropriate countermeasures for each.

For all your analyses, please provide additional specifics for each cause/hazardous situation that could occur, and provide countermeasures and pre/post risk assessment for each one. This should capture specific situations, how these situations could come about, and how you address each. For example, if a warning is to be placed in the operator’s manual to address an identified risk, a reference for the explicit warning would appear in your risk documentation for that particular situation. If the information is contained in a manual or SOP, a specific reference within that documentation should be provided. This is necessary to understand that you have identified and considered specific situations that could lead to harm, and identified, implemented and tested

mitigations to reduce these risks to acceptable levels. We expect to be able to trace from the identified situations to the specific warnings or guidance you provide as a countermeasure.

15. *Risk processes (sent as FDA Question 9):*

In the NAT amendment received March 23, 2017, in response to FDA Question 17, you included updated risk documentation. There is some better alignment with ISO 14971 “Medical device – application of risk management to medical devices,” but the table in the (b) (4) Hazard Analysis (Attachment_15.1-IT-CSV-PDF-41.xlsx) is not an FMEA and does not align with terminology used in ISO 14971. Consider the following:

- a. What does your “Probability” correspond to in ISO 14971? It is not clear what your “Probability” refers to so it is difficult to assess the risk table. The “Scoring System” tab refers to Likelihood, not Probability. For example, Risk 2 “password hacked” has a Probability of 4 which is high, so it is unclear if this refers to P1 or P2 or the combination. In the “Front page” tab of the NAT Risk Analysis (Attachment_22.1-LAB-DSGN-11.xlsm), the Likelihood definitions specifically refer to failures. This suggests that your probability is still focused only on P1 and does not include probability of a hazardous situation leading to harm. Please revisit your risk management processes and provide a clear description of your processes and how they align with ISO 14971. State explicit the scope of “probability” in your documentation and ensure your risk documentation includes all aspects of probability. As a start, we suggest removing the notion of “failure” from your definitions.
- b. What is your process to determine the new level of Probability as the result of the identified mitigation(s)? Please provide your risk documentation that describes how this is determined.
- c. Please refer to comments made regarding the “Babesia microti AFIA device risk analysis” (Attachment_13.1-LAB-DSGN-5.xlsm) and its alignment with ISO 14971, and ensure that you make the same changes to both risk documents for consistency regarding clear traceability with hazards, hazardous situations, causes, traceability to mitigations in manuals and SOPs, etc. We recommend that you should harmonize the format you are using to capture risk information so that all use the same terminology and methods, or you should provide a clear description and process for each that allows independent review.

16. *Cybersecurity considerations (sent as FDA Question 10):*

In the NAT Amendment received March 23, 2017, in response to FDA Question 20, you provided several documents including an updated (b) (4) Risk Analysis” (Attachment_15.1-IT-CSV-PDF-41.xlsx). Please note that we assess the adequacy of your cybersecurity features based on the threats and vulnerabilities you identify in your risk assessment. Without your analysis and identification, it is difficult for us to determine if the mitigations you implement are adequate. We

do not have a clear picture of the client server and database components and connectivity to other systems. We see mention of some mitigations and some evidence of threats in several documents, but you have not provided a comprehensive view of the security risks to your system. The following suggest that the analysis activities we requested and described in the cybersecurity premarket guidance have not occurred.

- a. Your system is networked but you have no requirements or specifications related to connectivity or use of a firewall. You included a firewall in the Hardware Network Diagram in your Architectural Design document in Attachment 29.4 of your response received December 14, 2016, but it is not referenced in your risk documentation. You have not identified which risks might be addressed by use of a firewall, and the residual risks. You have not identified vulnerabilities related to this architecture.
- b. You reference antivirus updates in your “Information Technology Security Policy” (Attachment_20.2-IT-SEC-POL-01&DocDetails.pdf) but you have not identified the vulnerabilities for which this mitigation would be effective. It also mentions physical security, but it is not clear if or how this applies to access to the software or hardware.
- c. Some features that represent suggest security vulnerabilities were not included; for example you mention USBs in the “Information Technology Security Policy” but you have not discussed the risks of allowing an open USB port.
- d. You have not identified functionality on the computer that should be restricted to limit exposure (e.g., disabling access to various unnecessary programs, unauthorized access through unattended workstation availability, etc.). Can users access the internet on the computer used to access the (b) (4) software? Can a user boot from a USB and alter the system? Can a user replace the (b) (4) software with an altered copy? Many scenarios related to misuse have not been explored.

As requested previously, please perform the analysis described in the guidance, “Content for Premarket Submissions for Management of Cybersecurity in Medical Devices” and updated your design documentation accordingly.

The following question was generated in response to information provided in the May 23, 2017, communication to FDA.

17. In the (b) (4) status update received May 23, 2017, in response to FDA Question 1(a), you provided (b) (4) infrastructure details (b) (4) Infrastructure Details.docx).
 - a. The (b) (4) database server appears to be running on an unsupported operating system, Windows (b) (4) . As of July 14, 2015, Microsoft no longer

provides automatic fixes, updates or security updates for this product to protect against harmful viruses, spyware and other malicious software. Your Information Technology Security Policy (Attachment_20.2-IT-SEC-POL-01&DocDetails.pdf) does not provide a process for supporting an operating system when patches are no longer available. Please provide your plan for migrating to a supported operating system. If you do not intend to upgrade, please discuss the additional security risks, how you will identify vulnerabilities and manage the risks of this increased exposure.

- b. Please identify the cybersecurity product(s), including version number(s), running on each of the servers and computers identified in the (b) (4) specific infrastructure. Your Information Technology Security Policy (Attachment_20.2-IT-SEC-POL-01&DocDetails.pdf) references two generic product lines but does not indicate how the individual systems are protected.

Facility

18. *Categorical Exclusion from Preparation of an Environmental Assessment.*

Your justification for a categorical exclusion from preparation of an environmental assessment for the AFIA assay is not satisfactory as provided in your December 13, 2016, Complete Response Letter to Item #48. Please revise your justification to indicate how your finished device lots for the AFIA assay meets the exclusion criteria.

Equipment

(b) (4)

19. Please review your manufacturing and blood donor specimen preparation procedures and ensure the equipment settings for (b) (4) are defined in the manufacturing and blood donor testing procedures and that the settings correlate to the set-point or ranges tested in the (b) (4) equipment qualification report (DOC-RPT-65). Please provide a copy of all applicable manufacturing and blood donor testing procedures which describe the defined equipment settings for (b) (4) units (b) (4)

20. Please provide a justification for the selection of the target set-points for (b) (4) (b) (4) and duration for (b) (4) units (b) (4) in consideration of the processes in which the respective (b) (4) is used. Your report, DOC-RPT-65 (b) (4) *Validation Report*, did not include this explanation; therefore, it is unclear why the set-points were selected and are applicable for your processes. Please comment.

Incubators

21. For any manufacturing or blood donor screening procedure that requires the use of the incubator, please ensure the procedures describe the set-point temperature

for the incubators in order to ensure the process is consistent between operators. Please provide a copy of the applicable procedures highlighting the set-point temperature of the incubators.

Labeling

22. Please submit the updated summary of application.

Within one year after the date of this letter, you are required to resubmit or withdraw the application (21 CFR 601.3(b)). If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 601.3(c). You may also request an extension of time in which to resubmit the application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

You may request a meeting or teleconference with us to discuss the steps necessary for approval.

For MDUFA products, please submit the Submission Issue Q-Sub with a valid eCopy. Your submission should reference this BLA, identify the specific deficiencies you wish to discuss, and indicate your preferred feedback mechanism (i.e., email, meeting, or teleconference). For additional information regarding Q-Subs, please refer to the *Final Guidance for Industry and FDA Staff on Medical Devices: Request for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with FDA Staff* at

<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>, or you may request this document from the Office of Communication, Outreach, and Development, at (240) 402-8020.

We acknowledge receipt of your amendments dated May 18, 2017, and June 5, 2017. Please be aware that we have stopped the review clock with the issuance of this letter. We will reset and start the review clock when we receive your complete response. You may cross reference applicable sections of the amendments dated May 18, 2017, and June 5, 2017, in your complete response to this letter and we will review those sections as a part of your complete response.

If you have any questions regarding the above, please contact the Regulatory Project Manager, Iliana Valencia at (240) 447-4377.

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
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