# Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices

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**U.S. Department of Health and Human Services**

**Food and Drug Administration**

**Center for Devices and Radiological Health**

**Office of In Vitro Diagnostic Device Evaluation and Safety** Contains Nonbinding Recommendations

# Preface

## Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to Docket No. 2008D-0031. Comments may not be acted upon by the Agency until the document is next revised or updated.

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# TABLE OF CONTENTS

# Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices

***This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for, or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.***

## I. INTRODUCTION

The Secretary of Health and Human Services has delegated to FDA the authority to determine whether particular tests are "simple" and have "an insignificant risk of an erroneous result" under CLIA and thus eligible for waiver categorization (69 FR 22849, April 29, 2004). The Centers for Medicare & and Medicaid Services (CMS) is responsible for oversight of clinical laboratories, which includes issuing waiver certificates. CLIA requires that clinical laboratories obtain a certificate before accepting materials derived from the human body for laboratory tests. 42 U.S.C. § 263a(b). Laboratories that perform only tests that are "simple" and that have an "insignificant risk of an erroneous result" may obtain a certificate of waiver. 42 U.S.C. § 263a(d)(2).

CLIA, 42 U.S.C. § 263a(d)(3) Examinations and Procedures, as modified by the Food and Drug Administration Modernization Act (FDAMA), reads as follows regarding tests that may be performed by laboratories with a Certificate of Waiver:

The examinations and procedures [that may be performed by a laboratory with a Certificate of Waiver]… are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that -- (A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or (B) the

Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

This guidance describes recommendations for device manufacturers seeking to submit information through a CLIA waiver application to FDA to support a determination whether the device meets CLIA statutory criteria for waiver.

In this document, FDA (we) recommends an approach for you to use to demonstrate that your device is simple and has an insignificant risk of an erroneous result. As part of demonstrating the latter, we recommend studies you can conduct to demonstrate the test is "accurate." While we recommend you adopt the approach we have outlined in this guidance for waiver applications, you may use another approach that you believe would be appropriate for your device's waiver application if it meets the CLIA statutory requirements. (See **Least Burdensome Approach**, below.)

We based the recommendations in this document on our interpretation of the law, experience with CLIA complexity determinations, and interactions with stakeholders. Interactions included an open public workshop on August 14-15, 2000, a proposal presented by AdvaMed (Advanced Medical Technology Association) at the September 2003 Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting, and recommendations proposed by CLIAC during the February 2004 meeting. In addition, we considered the comments received in response to a 2001 draft guidance and the 2005 draft guidance document, and incorporated revisions based on these comments as appropriate. [1]

Some of the changes reflected in this document (as well as in the 2005 draft guidance document) from the earlier 2001 draft guidance document entitled "Guidance for CLIA 1988 Criteria for Waiver," include the following:

- Greater emphasis on scientifically-based flex studies[2] and validation and/or verification studies, linked to the risk assessment for each device.

- Recognition that reference methods may not be available for every device type. (However, devices should be traceable to true reference methods of known accuracy, when such methods are available.)

- Additional emphasis on use of quality control procedures.

- Greater emphasis on intended users (which may include medical assistants, nurses or doctors, and lay people, as appropriate) during studies testing the device.

- Updated study recommendations with emphasis on use of patient specimens, in an intended use environment, over time.

[1] The draft document of September 7, 2005, entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications" (70 FR 53231) replaced the draft "Guidance for Clinical Laboratory Improvement Amendments of 1998 (CLIA) Criteria for Waiver," March 1, 2001 (66 FR 12939)).

[2] For the definition of this term and other technical terms, as they are used in this document, see Appendix C.



[3] For a description of this policy, see Guidance for Industry and FDA Staff; Replacement Reagent and Instrument Family Policy, http://www.fda.gov/cdrh/oivd/guidance/950.html

This document does not address test systems cleared or approved by FDA for over-the-counter or prescription home use since these automatically qualify for CLIA waiver. 42 U.S.C. 263a(d)(3). This guidance document also does not address use of the Office of *In Vitro* Diagnostic Device Evaluation and Safety (OIVD)'s replacement reagent and instrument family policy[3] for waived devices; that policy does not currently apply to CLIA waiver applications.

The draft of this document was issued September 7, 2005. We have also issued a draft guidance entitled "Guidance for Administrative Procedures for CLIA Categorization," www.fda.gov/cdrh/ode/guidance/1143.html. In it, we propose recommendations to device manufacturers on FDA's administrative procedures for CLIA categorization.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

# II. COMPONENTS OF A CLIA WAIVER APPLICATION

This guidance discusses the following components that we recommend you include in a CLIA waiver application:

- A description of your device that demonstrates it is simple to use. (Section III.)
- The results of risk analysis including the identification of potential sources of error for your device. (Section IV.)
- The results of flex studies demonstrating insensitivity of the test system to environmental and usage variations under conditions of stress. (Section IV.)
- The results of risk evaluation and control including a description of (1) measures you have implemented to mitigate the risk of errors, and (2) validation and/or verification studies demonstrating the ability of failure alert, fail-safe mechanisms, and other control

[4] In this guidance, intended operator refers to a test operator with limited or no training or hands-on experience in conducting laboratory testing. Laboratory professional refers to a person who measures that you have incorporated into your device to mitigate the risk of errors, even under conditions of stress. (Section IV.)

- A description of the design and results of clinical studies you conducted to demonstrate that the device has an insignificant risk of erroneous result in the hands of the intended user (hereinafter operator). (Section V.)

- Proposed labeling with instructions for use consistent with a device that is “simple.” (Section VI.)

# III. DEMONSTRATING "SIMPLE"

CLIA requires that tests performed by laboratories with a Certificate of Waiver be "simple." 42 U.S.C. 263a(d)(2), (3). We recommend that, as a first step in the process of deciding whether your device could be a candidate for waiver, you determine whether your device is simple.
Under the approach recommended in this guidance, FDA believes that a simple test should have characteristics such as the following:

- Is a fully automated instrument or a unitized or self-contained test.

- Uses direct unprocessed specimens, such as capillary blood (fingerstick), venous whole blood, nasal swabs, throat swabs, or urine.

- Needs only basic, non-technique-dependent specimen manipulation, including any for decontamination.

- Needs only basic, non-technique-dependent reagent manipulation, such as “mix reagent A and reagent B.”

- Needs no operator intervention during the analysis steps.

- Needs no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes.

- Needs no electronic or mechanical maintenance beyond simple tasks, e.g., changing a battery or power cord.

- Produces results that require no operator calibration, interpretation, or calculation.

- Produces results that are easy to determine, such as ‘positive’ or ‘negative,’ a direct readout of numerical values, the clear presence or absence of a line, or obvious color gradations.

- Provides instructions in the package insert for obtaining and shipping specimens for confirmation testing in cases where such testing is clinically advisable.

- Has test performance comparable to a traceable reference method as demonstrated by studies in which intended operators[4] perform the test. If a reference method is not


meets the qualifications to perform moderate or high complexity testing, such as a medical technologist (MT) or medical laboratory technician (MLT).

available for a test you are proposing for waiver, please contact OIVD to discuss your proposed plan prior to submitting your application.

- Contains a quick reference instruction sheet that is written at no higher than a 7th grade reading level.

We believe a test that is simple should **not** have the following characteristics:

- Sample manipulation is required to perform the assay. (For example, tests that use plasma or serum are not considered simple.) Sample manipulation includes processes such as centrifugation, complex mixing steps, or evaluation of the sample by the operator for conditions such as hemolysis or lipemia.

- Measurement of an analyte could be affected by conditions such as sample turbidity or cell lysis.

After you consider whether your device is “simple” based on the items listed above, it may be helpful for you to contact OIVD for feedback on this issue prior to conducting clinical studies to support waiver. In your waiver application, you should describe features of your device that address the issues listed above. Whenever possible (for example, if your test system consists of a unitized device), you should include sample(s) of the device with your waiver application to aid FDA in its determination of whether your device is “simple.” You may also schedule a meeting to bring your device to FDA to aid FDA in making this determination.

# IV. DEMONSTRATING "INSIGNIFICANT RISK OF AN ERRONEOUS RESULT" – Failure Alerts and Fail-Safe Mechanisms

Generally, the risk of an erroneous result should be far less for waived tests than non-waived tests. You should demonstrate in your CLIA waiver application that (1) the test system design is robust, e.g., insensitive to environmental and usage variation, and (2) that all known sources of error are effectively controlled. In general, flex studies should be used to demonstrate robust design while risk management should be used to demonstrate

identification and effective control of error sources, although the two are not mutually exclusive.

Most risk control measures should be fail-safe measures or failure alert mechanisms. Appropriate fail-safe mechanisms and failure alert mechanisms help assure that a test has “an insignificant risk of an erroneous result.” Examples of fail-safe mechanisms are lock-out functions to ensure that a test system does not provide a result when test conditions are inappropriate, such when there is a component malfunction or operator error. Other examples are measures within the system to prevent operator error, such as guides or channels that prevent improper strip placement. We recommend that test system design incorporate fail-safe mechanisms whenever it is technically practicable.

9 Contains Nonbinding Recommendations

If fail-safe mechanisms are not technically practicable for some risks, failure alert mechanisms should be used. Failure alert mechanisms notify the operator of any test system malfunction or problem. They may include measures such as external controls, internal procedural controls, or electronic controls. Devices with such mechanisms allow the operator to correct the error, or put the operator on notice that the results will be unreliable due to the error. For example, in cases where the result exceeds the reportable range (e.g., extremely high or low glucose result) and the result is a critical value, the device should give a message such as "out of range high" or "out of range low."

We recommend a two-tiered approach, outlined below, to demonstrate that your device is robust and has appropriate and effective risk control measures to ensure insignificant risk of an erroneous result.

**Tier 1: Risk Analysis and Flex Studies.** You should conduct a systematic and comprehensive risk analysis that identifies all potential sources of error, including test system failures and operator errors, and identifies which of these errors can lead to a risk of a hazardous situation. We recommend that the "Operator error/Human factors" examples on pages 12-13 be used as an analytical aid to complement the risk analysis method(s) you use. You should conduct flex studies, i.e., studies that stress the operational limits of your test system. Flex studies should be used to validate the insensitivity of the test system to variation under stress conditions. Where appropriate, flex studies should also be used to verify and/or validate the effectiveness of control measures at operational limits. [See also *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (http://www.fda.gov/cdrh/ode/guidance/337.html) for further discussion.]

In your waiver application you should include:

- The risk analysis results which serve as a basis for the tabular reporting of risk management results. (See Tier 2.)
- A summary of the design and results of your flex studies.
- Conclusions you draw from the flex studies.

**Tier 2: Fail-Safe and Failure Alert Mechanisms**. Once you have identified the potential sources of error, you should identify the control measures, including fail-safe and failure alert mechanisms that will reduce risks for these sources of error. When the control measures have been implemented, you should (1) verify that each control measure has been properly implemented, and (2) verify and/or validate the effectiveness of each control measure.

We recommend that this risk management information be presented in tabular form in your waiver application. It should include the following information for each risk for each potential source of error:

- Identification of each risk and the potential source of error that causes it.
- Identification and physical description of the risk control measure or combination of



[5] However, it may not always be appropriate to justify that risks are acceptable based solely on the "As Low As Reasonably Practicable" principle described in Annex D of *ISO 14971*: 2007.

measures used to reduce risk to an acceptable level. This includes fail-safe mechanisms, failure alert mechanisms, external controls as well as any other controls used or that you recommend the operator use for your device. It also includes a description of the manner in which the control measure(s) either reduces the probability of occurrence of the error, mitigates the effect of the error, or both.

- Objective evidence verifying that each control measure or combination of measures has been implemented, including a description of the method of verification.

- Objective evidence from testing, confirming the effectiveness of fail-safe and/or failure-alert mechanisms in preventing and/or mitigating the effects of false results. The evidence and results should also support your recommended control procedures and frequencies. Any limitations of fail-safe and failure alert mechanisms, including all internal and external controls, should be described.

## A. Tier 1: Risk Analysis and Flex Studies

As noted above, you should identify all potential sources of error by conducting a systematic and comprehensive risk analysis. This analysis should be part of your risk management process consisting of risk analysis, evaluation, and control. FDA recognizes the process of the International Standard *ISO 14971, Medical Devices - Application of Risk Management to Medical Devices*.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Detail.CFM?STANDARD__IDENTIFICATION_NO=5188. This guidance is consistent with that process and uses the same risk management terminology. In general, the standard and its annexes can be used to obtain more detailed information about risk management concepts and practices[5].
Based on the results of the risk analysis and identification of potential problems with sensitivity to environmental or usage variation, you should conduct flex studies. Flex studies are designed to challenge the system under conditions of stress to identify potential device deficiencies, including failures, and determine the robustness of the test system. Examples are shown in Table 1.
In your analysis, you should consider multiple skill levels of users, as well as potential instrument and reagent problems. The following websites contain additional information to consider concerning human factors that may affect test performance:
http://www.fda.gov/cdrh/humanfactors/index.html,
http://www.fda.gov/cdrh/humanfactors/resource-manufac.html#2.
Examples of potential sources of error to consider for the risk analysis and flex studies are listed below. See also CLSI EP-18A for examples (See [1]). You should consider each of these potential sources of error, as applicable to your device, and also consider any other potential system failures that may be specific to your device.

**Operator error/ Human factors**

- Use of incorrect specimen type.
- Incorrect application of the specimen to the device (e.g., incorrect placement, incorrect volume).
- Incorrect handling of reagents including those in self-contained unitized test devices.
- Incorrect placement of device (e.g., non-level surface).
- Incorrect placement of reagents, including strips, or other components that contain reagents.
- Use of incorrect reagents (for example, reagents that are not specific for the particular device or lot or generic reagents).
- Incorrect order of reagent application.
- Use of incorrect amount of reagent.
- Incorrect timing of procedures (e.g., specimen application, running the test, or reading results).
- Incorrect reading of test results.
- Incorrect reading due to color blindness.

**Specimen integrity and handling**

- Error in specimen collection.
- Use of inappropriate anticoagulant.
- Clotted specimen.
- Error in specimen handling.
- Incorrect specimen transport and/or storage.
- Presence of interfering substances.
- Presence of bubbles in the specimen.

**Reagent integrity (Reagent viability)**

- Use of improperly stored reagents.

- Use of outdated reagents.
- Use of improperly mixed reagents.
- Use of contaminated reagents.

**Hardware, software, and electronics integrity**

- Power failure.
- Power fluctuation.
- Incorrect voltage.
- Repeated plugging and unplugging of the device.
- Hardware failure.

• Software failure (see *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* http://www.fda.gov/cdrh/ode/guidance/337.pdf)

- Electronic failure.
- Physical trauma to unit.

**Stability of calibration and internal controls**

- Factors that affect calibrator and calibration stability, including determination of calibration stability over time and after power failures.
- Factors that may interfere with calibration.

**Environmental factors**

- Impact of key environmental factors (heat, humidity, barometric pressure changes, altitude (if applicable), sunlight, surface angle, device movement, etc.) on reagents, specimens, and test results.
- Impact of key environmental factors (including electrical or electromagnetic interference) on instruments, if appropriate.

# B. Tier 2: Fail-Safe and Failure Alert Mechanisms

## 1. Points to consider for designing fail-safe and failure alert mechanisms

We recommend that you consider including the items on the following list, as appropriate. You should consider incorporating fail-safe mechanisms when possible.

- Lock-out functions that do not allow output of results if controls or system checks are not successfully completed.
- Lock-out functions that do not allow output if expired reagents are used.
- Lock-out functions that do not allow output of results if the device was mishandled (e.g., dropped) and the device detects damage during internal electronic system checks.
- Physical features to ensure correct placement of components, such as strips or cartridges.
- Monitors of environmental conditions (e.g., indicator desiccants) incorporated into the test system or the kit container to alert the user to environmental conditions that are outside of the recommended storage conditions.

- Battery checks.

- Internal procedural controls to flag procedural problems such as improper sample flow, incorrect use of components, or improper addition of specimen. (However, procedural controls generally provide limited problem detection and, by themselves, are generally not sufficient to serve as a failure alert mechanism.)

13 Contains Nonbinding Recommendations

- Internal non-procedural controls (e.g., for checking the integrity of the reagents).
- Controls to check that electronic features of the device are within specifications.
- External control material.

When designing controls, you should consider the unique features of the test system and link control procedures to the robustness of the assay, as determined by your flex studies. The controls you devise to mitigate the risks you identify may be based on procedures typical for laboratory-based methodologies (e.g., testing external materials at two levels at a time interval of once per shift or on each day of testing) or may be a combination of features, such as those listed above, that ensure complete system quality monitoring. When designing packaging for your device, you should also consider that the number of tests per kit should depend on the stability of the reagents or the robustness of your test as demonstrated through testing.

When appropriate, you should incorporate capabilities into the test system software that allow for data retention, identification of outliers, and trend detection in order to alert the user to the occurrence of random or systematic errors.

Procedural controls, which are typically internal, are desirable for waived devices. However, these types of controls generally do not replace external controls especially because they often only control for adequate volume. Your flex studies and validation and/or verification studies should evaluate the sensitivity of internal control reagents to all applicable test system errors. The total quality control (QC) system (including all control procedures and internal checks) should control for all aspects of test performance, including electronic aspects and integrity of reagents.

We do not recommend training as a sole means of mitigating potential sources of harm. Aspects of the device design that are controlled and maintained by the manufacturer can potentially be considered as mitigations.

## 2. External control materials

Whenever feasible, you should include external control materials in the test kit.

External control materials for waived tests should be ready to use or employ only very simple preparation steps, e.g., breaking a vial in order to mix liquid and dry components of the control material. Reconstitution steps should not require pipetting by the user. For both quantitative and qualitative tests, the levels of the control materials should correspond to the medical decision level(s) relevant to the indications for use for your test. More than one level may be needed in order to ensure accuracy for quantitative tests. For qualitative tests, you should ensure that control materials include those with concentrations sufficiently close to the cutoff to provide adequate assessment of test performance for patient samples near the clinical cutoff.

You should alert operators about control procedures and the availability of control materials and integrate instructions for external control testing within the test procedure instructions (package insert and Quick Reference Instructions), in order to increase the

likelihood that operators will perform QC correctly. In the test instructions, you should specify minimum frequency for running controls and include recommended levels of control materials that correspond to medical decision levels. The labeling should indicate in bold why external controls are important and the consequences of not performing all QC procedures.

In addition, when control materials are not included in the test kit, you should also recommend, in the package insert and Quick Reference Instructions, the use of specific control material(s) that will ensure optimal verification of the test system performance. Providing or recommending external control materials may not be critical in those limited cases where sufficient fail-safe mechanisms are in place for the entire system. Although we are currently unaware of any such systems, should you develop one, we recommend that you explain, in your waiver application, your rationale for omitting these control materials.

You should describe, in your application, how you established the QC limits and how you demonstrated that the chosen limits provide adequate assessment of test performance with patient samples. For quantitative tests, you should consider the precision of the test system, as well as the total allowable error for the particular analyte. Ranges that are too broad may be incapable of reliably detecting unacceptable levels of imprecision or bias.

Control materials should mimic performance of patient samples as closely as possible. When the matrix of the material differs from that of the specimen, you should determine and describe in your application how these differences may affect or limit the information provided by the control result. You can accomplish this by testing control materials in parallel with actual patient samples of similar known values and comparing the results of the control material and patient samples with respect to precision or bias observed. You should account for matrix effects when setting the limits for control material to be used with your test.

### 3. Additional points concerning control materials

If you did not previously submit information addressing the items below in your premarket submission, you should provide them in your waiver application:

- Opened and unopened control material stability data. You should include acceptance criteria and results. The term "unopened" refers to shelf-life stability whereas "opened" refers to reconstituted conditions, or other conditions after the vial is initially opened by the user.

- Lot-to-lot reproducibility, conducted on at least three consecutive lots of control material.

## C. Validating Fail-Safe and Failure Alert Mechanisms, including External Control Procedures

You should conduct studies that validate all fail-safe and failure alert mechanisms (including any procedures you recommend that use external control materials) that address all the



[6] Spiked samples may also be appropriate for a portion of the study; See Section V.B.3.a, below.

causes of test errors that you identified in your risk analysis. These studies should be conducted under conditions that stress the device in order to demonstrate how fail-safe and failure alert mechanisms respond to such conditions. You should describe your validation and/or verification studies and the results of these studies in your waiver application and indicate how the results support the ability of fail-safe and failure alert mechanisms to detect and mitigate test errors. You should include a description of how your recommendations for external control materials and procedures (including frequency) are supported by your validation and/or verification studies and confirmed by the clinical studies described in Section V, below.

**Table 1 - Examples of approaches to flex studies and control validation studies under conditions of stress**

| POTENTIAL SOURCE OF ERROR | EXAMPLES OF FLEX STUDIES | EXAMPLES OF VALIDATION STUDIES |
|---|---|---|
| Operational storage is 2-4° C.<br>What happens when the kit is stored improperly? | Environmental studies included storing the kit at 0°, 2°, 10°, 25°, and 37° C.<br>Studies showed that when frozen, or stored at 25° C for over 3 days, the device failed. | Studies to validate that fail-safe mechanisms, or failure alerts, including external control procedures, alert the operator to frozen conditions or storage at 25° C for more than 3 days. |
| Procedure is to add 3 drops.<br>What happens when an improper number of drops are added to the test procedure? | Flex studies consist of adding 1, 2, 3, 4, 5, and 6 drops and observing when incorrect results are obtained.<br>Studies show that <2 drops or >5 drops give erroneous results. | Studies to validate that fail-safe mechanisms, or failure alerts, including control procedures, alert the operator of an error when <2 drops or > 5 drops are added. |

## PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The time required to complete this information collection is estimated to average [x] (minutes)/(hours) per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

[Insert FDA Program Office Address (NOT the Division of Dockets Management)]

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 801 and 809.10 have been approved under OMB control umber 0910-0485 and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

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| An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is OMB control number 0910-0598, which expires xx/xx/xxxx. |