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Guidance for Industry

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

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**GUIDELINE ON
VALIDATION OF THE LIMULUS AMEBOCYTE LYSATE TEST,
AS AN END-PRODUCT ENDOTOXIN TEST FOR HUMAN
AND ANIMAL PARENTERAL DRUGS, BIOLOGICAL PRODUCTS, AND
MEDICAL DEVICES**

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PUBLIC HEALTH SERVICE
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AS AN END-PRODUCT ENDOTOXIN TEST FOR HUMAN
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MEDICAL DEVICES

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INTRODUCTION

This guideline sets forth acceptable conditions for use of the Limulus Amebocyte Lysate test. It also describes procedures for using this methodology as an end-product endotoxin test for human injectable drugs (including biological products), animal injectable drugs, and medical devices. The procedures may be used in lieu of the rabbit pyrogen test.

For the purpose of this guideline, the terms "lysate" or "lysate reagent" refer only to Limulus Amebocyte Lysate licensed by the Center for Biologic Evaluation and Research. The term "official test" means that a test is referenced in a United States Pharmacopeia drug monograph, a New Drug Application, New Animal Drug Application or a Biological License.

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