Division of Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-D-5625; Draft Guidance on Recommendations for Dual 510(k) and CLIA Waiver by Application Studies

Dear Sir or Madam:

On behalf of AdvaMedDx, a Division of the Advanced Medical Technology Association (AdvaMed), we provide these comments on the Food and Drug Administration (FDA) “Draft Guidance on Recommendations for Dual 510(k) and Clinical Laboratory Improvements Amendments (or “CLIA”) Waiver by Application Studies” (hereinafter “guidance”). Notice of this draft guidance and request for comments were published in the Federal Register, Vol. 83, No. 230 (issued Thursday, November 29, 2018).

AdvaMedDx member companies produce advanced, in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and, in many cases, reduce overall health care costs. Functioning as an association within AdvaMed, AdvaMedDx is the only multi-faceted, policy organization that deals exclusively with issues facing in vitro diagnostic companies both domestically in the United States and abroad. Our membership includes manufacturers engaged in the development of innovative technologies that support the public health in the U.S. and promote timely access at the point of care, including doctors’ offices and clinics from traditional tests to advanced molecular technologies (otherwise referred to as “CLIA waived tests”).

GENERAL COMMENTS

AdvaMedDx appreciates FDA’s (or “Agency”) efforts in issuance of this updated guidance to describe study designs to support use of the dual 510(k) clearance and CLIA waiver by application (otherwise referred to as “dual submissions”). We agree with the goal that the pathway be in many cases the least burdensome and fastest approach for manufacturers to seek a CLIA waiver in addition to 510(k) clearance for these timely, simple to use tests. We believe such a pathway option can help support an efficient and effective process for developers rather than a historically required stepwise process for innovators.

We are pleased to see recent increases in the number of dual submissions, which we hope will yield increased timely access to new innovative CLIA-waived devices for healthcare professionals and the patients they serve. A least burdensome process for new tests under the pathway coupled with timely reviews meeting performance goals will be critical to success of the
program. We appreciate FDA’s undertaking to clarify its policy regarding dual submission study designs. These efforts are critical to ensure timely access to CLIA-waived diagnostic tests at the point of care as part of today’s modern healthcare system.

We note that we also provided comments to a related docket, “Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of IVD Devices.” While we view this guidance with similar importance, our comments in this case are specific to study designs that would apply in the case where a submitter seeks a dual submission rather than a sequential 510(k) followed by CLIA waiver approval.

AdvaMedDx appreciates FDA’s efforts to address stakeholder comments and provide improved clarity regarding the appropriate types of comparison studies for purposes of CLIA waiver. In particular, we support the guidance’s focus on specific study design aspects for dual submissions and use of internationally recognized consensus standards (e.g., CLSI EP09, CLSI EP12, CLSI EP21, and CLSI EP27). Through improved understanding of study design expectations, in this case of dual submissions, we can support new timely tools for healthcare providers, help meet unmet needs, harness critical window of care, and support patient care through timely, simple to use tests that help address medical needs for the patient at the point of care.

The future of innovation is rapidly changing in today’s modern healthcare system. The diagnostics industry is committed to providing the best tools to diagnose and treat patients. CLIA-waived tests are an example of such critical innovation and a cornerstone of modern healthcare.

Thank you for the opportunity to provide comments. AdvaMedDx has a few suggested edits, which are included in the table below. Thank you again for your efforts to provide improved clarity in the CLIA waiver process while ensuring confidence in today’s modern healthcare system to provide these timely and vital tools for healthcare professionals and their patients at the point of care.

Sincerely,

/s/

Khatereh Calleja
Senior Vice President, Technology and Regulatory Affairs
### ADVAMEDDX SPECIFIC COMMENTS ON

**FDA Draft Guidance**

*Recommendations for Dual 510(k) and CLIA Waiver by Application Studies*

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<th>Section</th>
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<th>Proposed Change</th>
<th>Comment/Rationale</th>
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<td>277</td>
<td>Revise as follows so it reads: “For qualitative tests: CLSI EP12^{15}”</td>
<td>Grammatical error. Correction of footnote placement and no comma needed.</td>
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