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May 29, 2001

Dockets Management Branch (HFA-305)
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 01D-0004
Medical Devices Draft Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA), Criteria for Waiver

Dear Dr. Hackett:

Carter Wallace, Inc. for its Wampole Laboratories Division is herein submitting comments in response to the FDA's request for public comment regarding the Draft Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver, as published in the Federal Register of March 1, 2001. Wampole Laboratories, division of Carter-Wallace, Inc., is a manufacturer and supplier of professional use diagnostic test kits for infectious diseases, autoimmune conditions, and pregnancy. Wampole Laboratories offers a broad range of testing options, ranging from ELISA kits for clinical laboratories to point-of-care membrane tests for physicians office laboratories.

Wampole Laboratories has 9 years of experience working with CLIAC and both the CDC and the FDA on various waiver issues. In 1992, Wampole Laboratories petitioned the CLIA committee for waived status for the Stat-Crit Hematocrit test system, which was subsequently granted in March 1997. In May of 1998, Wampole successfully petitioned for waived status for the Mono-plus test, making it the first waived mononucleosis test. Wampole has also prepared waiver submissions for other *in-vitro* diagnostic products that were subsequently marketed by Wampole, including two rapid Strep A tests waived by the FDA in May 2000. We believe the experience that we have gained working on waiver issues over the past nine years gives us a unique perspective for developing relevant and constructive suggestions to the proposed FDA waiver guidance that will help to streamline the waiver application review process. The comments provided herein are limited to the waiver requirements as applied to 'qualitative tests' only.

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Section I. Introduction: The FDA should issue one proposed regulation that is based on both the HCFA/CDC criteria as published in the Proposed Rule of September 13, 1995, and the FDA's guidance document. While we agree inherent flexibility in the guidelines is important, we believe that the existence of "alternative criteria" will create confusion in interpretation by both manufacturers and FDA personnel. A consolidation of the criteria agreed upon by FDA and industry will help streamline the waiver application process.

Section III. Demonstrating Insignificant Risk of Erroneous Result: "Other QC Concerns:"

- Stability data, which is required to support the expiry date for a product, is not typically submitted in a premarket notification. Under QSR, the manufacturer would be required to keep this information on file. Expiry dating is often initially based on accelerated stability, and confirmed with real-time data. Based on real-time data, a manufacturer may choose to extend the expiry on a product with subsequent lot numbers, and should not be limited by the expiration dating submitted in a waiver application. The manufacturer should be allowed the flexibility to extend dating, which is supported by real-time data.

Section IV. Demonstrating "Accurate"

- "Demographic Data:" Under this section, the requirement is to enroll individuals in the accuracy studies who represent "anticipated users," thus implying individuals who would be employed in a physician office laboratory. Physicians offices typically have small staffs, thus it would be unlikely that there would be 20 individuals available to perform testing at one site. In addition, "day-to-day" studies measure the stability of a device, which has been established under design control. The studies suggested would not adequately assess the precision of the device due to the variability of different operators and use of new samples that would need to be prepared fresh daily and requalified. We recommend deleting the requirement for conducting separate precision and accuracy studies. The accuracy of the device can adequately be supported by the untrained user/laboratory professional agreement study using lay participants versus three laboratorians.

- "Untrained/Professional Agreement Study for Qualitative Tests:" Wampole has consented to enrolling up to 300 untrained users in order prove comparability to laboratorian accuracy. However, we believe a manufacturer should be allowed to provide a justification for a statistically significant and defensible number of untrained participants, based on the particular test analyte, and not be required to enroll a minimum of 300 users.

Section V. Waiver Labeling—Quick Reference Instructions

- We agree that inclusion of quick reference instructions would be beneficial to the user. However, the quick reference instructions should be simple and contain only

Section VI. Voluntary Safeguards for Waived Tests

- We do not agree with the recommendation that MedWatch information appear in the waived test package insert. Under the "1995 Proposed Rule" waived tests are test systems that "must be simple laboratory examinations and procedures that have an insignificant risk of an erroneous result" (emphasis added) [§ 493.7(b)]. The FDA does not currently require that a description of the MedWatch program appear in the labeling of moderate and high complexity tests, where the significance of an erroneous result is greater.

- Surveillance of product performance is accomplished through a manufacturer's complaint handling system. Trend analysis of this type of data is maintained by the manufacturer and is made readily available to the FDA during QSR inspections. It would be an onerous requirement for manufacturers to contact and monitor each individual physician's office laboratory to confirm user compliance or drift in product performance. In addition, a waived test, by virtue of its definition of being a test that has "an insignificant risk of an erroneous result" need not be monitored with more vigilance than either a moderate or high complexity test.

Carter-Wallace, Inc. appreciates the opportunity to comment on this guidance document. We strongly support measures that will make available to physicians' offices a wide variety of accurate, point-of-care tests that will help provide immediate health care benefits to the public.

Sincerely yours,

Maureen N. Garner

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Manager, Regulatory Affairs

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