February 21, 2017

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

RE: Docket No. FDA-2012-N-1021; Medical Device User Fee and Modernization Act; Notice to Public of Web Site Location of Fiscal Year 2017 Proposed Guidance Development

Dear Sir or Madam:

AdvaMed represents manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatment. Our members range from the smallest to the largest medical technology innovators.

AdvaMed appreciates the opportunity to comment on the Center for Devices and Radiological Health’s (CDRH’s) “Fiscal Year 2017 (FY 2017) Proposed Guidance Development.” Provided below are our thoughts on the prioritization of the proposed FDA CDRH FY 2017 guidance documents to be developed, along with our recommendations for guidance documents that we believe should be, but were not, included in CDRH’s FY 2017 plans, and our recommendations for guidance documents that should be updated or withdrawn.

We prioritized the documents contained in the Food and Drug Administration’s (FDA’s or “Agency’s”) “A” and “B” lists according to whether they were a “high,” “medium,” or “low” priority to our member companies. “High priority” documents are those that have the potential to broadly affect industry, have high impact on routine administrative and/or review procedures at FDA, address an area where guidance may be currently lacking, or it is required under the 21st Century Cures Act. “Medium priority” documents also may broadly impact industry, but may not be absolutely critical to FDA’s routine administrative and/or review procedures. “Low priority” documents have a lesser impact on FDA procedures, or address a subject that is highly specialized or narrowly focused. As FDA can appreciate, AdvaMed’s membership comprises a breadth of manufacturers of medical devices, and we hope that our comments and additional guidance recommendations will be meaningfully considered in finalization of FDA’s guidance development priorities.¹

¹ We will not comment on those guidance documents that already have been issued since the list was published.
Part 1: FY 2017 Lists of Prioritized Medical Device Guidance Documents

Final Guidance Documents

As a general note, we recommend that FDA finalize all of the draft guidances that it has issued within the last year. AdvaMed has submitted comments to many of those dockets, and requests that FDA refer to those comments.

Of those final guidance documents on the “A” list, the ones that are of highest priority to our members are:

- Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices: This is an important developing area that guidance with the appropriate scope would help foster. That being said, the narrow scope of the draft guidance greatly reduced its usefulness. We urge FDA to revise the draft guidance in a manner that reflects our comments.
- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices.
- New or revised procedural guidances for MDUFA IV implementation. We support efficient implementation of MDUFA IV.
- Suggested Format for Developing and Responding to Deficiencies of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS) - Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases
- Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases
- Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS) – Based In Vitro Diagnostics
- Infectious Disease Next Generation Sequencing Based Diagnostic Devices: Microbial Identification and Detection of Antimicrobial Resistance and Virulence Markers

The remainder of the proposed “A” list final guidance documents already have been issued or are of medium priority.

Of the “B” list final guidance documents, the ones that are of highest priority to our members are:

- FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare & Medicaid Services (CMS) with Coverage Decisions. This document can help align coverage decisions to advance innovation.
- Unique Device Identification (UDI): Direct Marking of Devices. We recommend FDA move this guidance to the “A” list because direct marking compliance dates for certain products began in 2016. Changes in interpretation will be costly and would create uncertainty regarding products in commercial distribution. Issuance of this guidance well in advance of the 2018 compliance date will provide manufacturers with the ability to plan and implement.
Draft Guidance Documents

Of those draft guidance documents on the “A” list, the ones that are of highest priority to our members are:

- Update to Section V Demonstrating Insignificant Risk of an Erroneous Result in the Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices guidance. We urge FDA to work with industry on updating this guidance consistent with the requirements of the 21st Century Cures Act, and the legislative intent of that Act.

- Dual 510(k) and CLIA Waiver. We also support issuance of this guidance to support the overall dual submission process and foster efficient and effective review and waiver of these critical devices, which play an important role in providing timely and effective care for patients.

- New or revised procedural guidances for MDUFA IV implementation. We support implementation of MDUFA IV.

The remainder of the “A” list draft guidance documents are of low or medium priority.

All of the “B” list draft guidance documents are of medium or low priority, with the exceptions of:

- Related Replacement Reagent and Instrument Policy: This is a key policy for the IVD industry that has worked well for many years and supports advances in instrument and reagent technologies and the overall public health. Recently, implementation questions have arisen, and a draft guidance that addresses some of those questions would be greatly welcomed by industry. We urge FDA to continue productive dialogue with industry and move the issuance of this draft guidance to the “A” list.

- Unique Device Identification System: Defining the Labeler. To implement UDI requirements aligned with the compliance dates, beginning in 2014 manufacturers have interpreted labeler and created systems centered around this interpretation. A change in policy/interpretation would be significant to manufacturers in terms of cost and rework.

High Priority Guidance Documents Not Included in the “A” or “B” Lists

There are a number of guidance documents/guidance document topics that are of high priority to industry that were not included in the FY 17 priority lists. In particular, these two critical guidance documents are missing from the Final Guidances “A” list, and we recommend that they be added as an “A” list priority: 510(k) modifications and software modifications. We urge FDA to take industry comments into consideration, and finalize a reasonable and helpful guidance by the end of the year. In addition, we appreciate the significant ongoing efforts of FDA to work closely with industry on a software modifications guidance. We urge that this be an “A” list priority for completion this year.

We appreciate FDA’s issuance of the final regulation on the use of symbols and the active engagement with stakeholders. Furthermore, we support FDA guidance clarifying implementation of the final regulation. Prioritization of this guidance on the “A” list is recommended.
The FY2016 list included the draft “Critical to Quality Information for Hydrophilic Coated and Hydrophobic Coated Vascular and Neurological Devices” guidance document. We continue to view issuance of this document as a high priority and recommend FDA reinstate this guidance on its “A” list.

Part 2: Retrospective Review Guidances

❖ 1977

AdvaMed recommends that the following guidance documents be updated/revised:

- Emission Delay - Remote Interlock Connector (Laser Notice 21)
- Optional Interlocks - Labeling (Laser Notice 17)

❖ 1987

AdvaMed recommends that the following guidance documents be updated/revised:

- Master Files Part III; Guidance on Scientific and Technical Information. We recommend clarification/definition around submission content, and an overall update to align with current guidances and standards.
- Color Additive Petitions: It would be helpful to update this guidance.
- Industry Representatives on Scientific Panel. We seek more information and clarification on this proposed item and what updates may be useful.
- Guide for Preparing Annual Reports on Radiation Safety Testing of Electronic Products (General)

❖ 1997

AdvaMed recommends that the following guidance documents be updated/revised:

- Industry-Supported Scientific and Educational Activities: We support updates consistent with appropriate scientific exchange and First Amendment jurisprudence.
- Convenience Kits Interim Regulatory Guidance: An update would be useful to consolidate information on the topic that currently is located in multiple sources. More detail on what constitutes a convenience kit, and references to requirements for a premarket submission/UDI would be useful in the guidance.
- Premarket Notification 510(k) Guidance for Contact Lens Care Products.
- Reviewers Guidance Checklist for Intramedullary Rods.
- Review Criteria for Assessment of Rheumatoid Factor (RF) In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (EIA), Enzyme-Linked Immunosorbent Assay (ELISA), Particle Agglutination Tests, and Laser and Rate Nephelometry
- 510(k) Information Needed for Hydroxyapatite-Coated Orthopedic Implants.
AdvaMed also recommends the withdrawal of:


2007

AdvaMed recommends that the following guidance documents be updated/revised:

- CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition. We believe that the provision in 21st Century Cures regarding recognition of standards would require revision of this guidance. We recommend updated standards guidance to reflect the process for requesting recognition of standards, response process, and principles to consider outlined in Sec. 3053. Recognition of Standards of the recently enacted 21st Century Cures Act to facilitate implementation and training.

- Guidance for Industry and FDA Staff - Non-clinical Information for Femoral Stem Prostheses. We would recommend updating the references to recent guidances, standards, and product codes list.

- Guidance for Industry and FDA Staff - Biological Indicator (BI) Premarket Notification [510(k)] Submissions.

- Warning Labels for Dye And Multiple Wavelength Lasers (Laser Notice 16)

- Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Remote Medication Management System

- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device. Since the special controls guidance was released in 2007, numerous new technologies and design features have been developed and incorporated into spinal intervertebral body fusion cages. These new technologies include non-metallic cage materials, integrated fixation, standalone use indications (without additional supplemental fixation), expandable designs, and others. Due to these developments, testing expectations are often unclear until feedback is received from FDA. In some cases, new test methods or configurations are expected by FDA which differ from testing conducted on predicate devices with similar design features and indications. Therefore, this special controls guidance should be revised to include the Agency’s current thinking on spinal intervertebral body fusion device test methods, and include specific situations where additional performance or clinical testing would be expected (e.g., for multi-level indications or standalone use indications). Providing this additional clarity will help manufacturers plan for appropriate device testing as well as establish a consistent method across manufacturers.

- Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material

- In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path - Guidance for Industry and FDA Staff

- Approval of Alternate Means of Labeling for Laser Products (Laser Notice 53)

- Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests
Other

- We recommend FDA revise its guidance “Coronary and Cerebrovascular Guidewires” dated January 1995 because it is now out of date and does not align well with current industry standards.

Thank you for the opportunity to submit these comments.

Sincerely,

/s/

Jamie Wolszon
Associate Vice President
Technology and Regulatory Affairs