October 25, 2012

Office of Regulatory Affairs
Office of Management and Budget (OMB)

Attention: FDA Desk Officer

Via e-mail to: submission@omb.eop.gov

Re: Docket No. FDA-2011-N-0090, Proposed Rule, Unique Device Identification System

Comments on Information Collection Issues under the Paperwork Reduction Act of 1995

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 and companies. Nearly 70 percent of our members have less than $30 million in annual sales.
AdvaMed supports the FDA’s goal to substantially reduce existing obstacles to the adequate identification of medical devices used in the United States. AdvaMed has long recognized the value of unique device identification and has been a leader in this area for almost ten years.

The implementation of a unique device identification (UDI) system is a costly proposition, one that should be carefully considered such that it is implemented correctly the first time, and such that its ongoing use is practical, economical, and of value to patients, healthcare providers, industry and FDA. We are taking this opportunity to comment on the Paperwork Reduction Act aspects of the proposed rule, as comments on this aspect of the rule are due by October 25, 2012. We intend to submit comments on the entirety of the proposed rule by November 7, 2012.

The proposed rule identifies requirements as having burdens that must be accounted for under the Paperwork Reduction Act (PRA). AdvaMed would like to address certain burdens which are not identified, or may be underestimated. We list below additional burdens that need to be accounted for under the PRA.

1) Date Format § 801.18
AdvaMed does not challenge the necessity of establishing a standard date format for device expiration and manufactured dates. The format chosen by FDA, however, would unnecessarily increase the burden to labelers by requiring the addition of translations of the FDA designated English language date format. This unnecessary burden could be ameliorated through the adoption of the internationally accepted date format, ISO 8601. Further, the FDA suggests an unreasonable implementation period for the date format change. AdvaMed suggests that rather than a 12 month period, FDA allow a three year period for implementation of the ISO 8601 date format for all medical devices.

2) Label requirements for UDI § 801.20
AdvaMed does not question the basic necessity for a UDI regulation requiring the placement of an AIDC symbol representation of the UDI on product labeling. We believe however, that
FDA has severely underestimated the burden of meeting the requirements of § 801.20. Manufacturers must redesign label art, scrap existing labeling inventory, interrupt existing labeling contracts, and interrupt manufacturing production lines to implement the many details of § 801.20. While the implementation period for class II and class I devices is reasonable and should not be shortened, AdvaMed strongly recommends that FDA allow 2 years for class III devices to implement the elements of § 801.20. This time period aligns with the time period specified by Congress in the FDA Safety and Innovation Act (2012).

3) Request for Exception § 801.35
AdvaMed acknowledges that the UDI System needs a robust method for issuing exceptions to the §§ 801.20 and 801.50. The allowance for alternative placement of the UDI is a necessary and significant accommodation to the extremely heterogeneous product mix characteristic of the medical device industry. The method proposed by FDA however, is vague, imprecise, and overly burdensome. Without a definitive and transparent system for exceptions and alternative placement accommodations, manufacturers will have no way of knowing if FDA has accepted its designation of an exception or alternative placement except through FDA’s enforcement authority. This is an unwise, wasteful means of informing the manufacturer as to FDA’s interpretation of the validity of an exception or alternative placement. Companies will unnecessarily face enforcement actions, such as warning letters, and be forced to undo an exception or alternative placement that the company had instituted with the best of intentions. AdvaMed suggests that FDA reduce this unnecessary burden to industry by prospectively stating, in the final rule, a list of categorical exceptions to §§ 801.20 and 801.50. Categorical exceptions would be based on the physical nature of the device, the device interaction with the human body, or the existence of regulation that accomplishes the purpose of UDI. The AdvaMed comments to the UDI proposed rule will elaborate on this suggestion.

4) Direct Marking § 801.50
Further to the topic of exceptions, AdvaMed recommends categorical exceptions for devices that meet specific criteria to be stated in the final rule. There is no reason why FDA cannot
list the product codes of those devices that are excepted from direct marking rather than requiring companies to document and submit their reasoning why a device like bone cement or absorbable sutures cannot be directly marked with the UDI. Furthermore, FDA has published several papers in medical journals as to the benefits of UDI to the postmarket surveillance effort through the integration of UDI with electronic health records (EHR) and registries. To the best of our knowledge, FDA has never promoted the direct marketing of UDI on an implanted device as a benefit to postmarket surveillance. The retrieval of the UDI through surgery, rather than through an inquiry to a database, is unconscionable. The technical ability to directly mark a product with UDI simply does not exist in most companies. Companies will have to develop new expertise, invest in new equipment, and validate new techniques and procedures simply to determine whether a product can be directly marked. AdvaMed recommends that implants not be subject to § 801.50. This will reduce an enormous burden to industry without compromising the postmarket surveillance of these products. AdvaMed is currently developing a financial model for the cost to accomplish initial design and development of direct marking techniques as well as the ongoing costs to production of directly marked products. This model will be submitted along with our main comments on UDI.

5) Information required for UDI § 830.310

Submission of UDI information § 830.320

AdvaMed commends FDA for developing a comprehensive list of data elements to identify medical devices. We believe however, that FDA has underestimated the burden of collecting, maintaining, and synchronization of the required data elements. Many of the required data elements do not currently exist in a company database, rather they are maintained in marketing, customer service, or other files not normally associated with device design or manufacturing databases. Companies will need to establish new data systems and new procedures to collect this information and to ensure its continuing accuracy. Companies will also have to develop methods to ensure that the data in the UDI database remains synchronous with the source of the data. AdvaMed recommends that data elements that merely duplicate information that already exists on the product label, such as whether the
product is sterile or contains latex, not be required under § 830.310. Furthermore, to ameliorate the burden of initial collection of data elements and establishment of new data management systems, AdvaMed recommends allowing 18 months, after the effective date designated in § 801.20, to complete submission of required data elements to the Global UDI Database.

6) Conforming Amendments
AdvaMed recommends that FDA allow a reasonable implementation period after the effective data delineated in § 801.20 for the various conforming amendments. Specifically, the addition of UDI to the Medical Device Report (§ 803) will require modifications of company software with validation necessary for changes to critical regulatory documents. The requirement for listing UDI in Periodic Reports (§ 814) required for all Class III PMA products will require development of new information systems integration capabilities. The well-established information systems for handling device and patient tracking information (§ 821) will need to be modified as will critical design files required by the Quality System Regulation (§ 820). AdvaMed recommends at least an 18 month implementation period for all conforming amendments, beginning after § 801.20 effectivity.

7) Unidentified burdens
The proposed rule fails to identify the following burdens:

A. The burden associated with proposed § 830.50, “Changes that result in a new version or model.”

The creation of new models for device changes as described in proposed § 830.50 would annually impact tens of thousands, if not hundreds of thousands of individual devices, and create one of the most burdensome ongoing requirements of the proposed rule. For each model change, the manufacturer would have to ensure that the following activities are undertaken for each new device model:

- Creation of new device labels and device label drawings
- Creation of new or revision of existing device labeling (e.g., directions for use, operator manuals, service manuals)
- Creation of new device drawings
- Creation of new device specifications (e.g., material specs, product specs, manufacturing specs, packaging material specs)
- Revision of existing Design History Files (DHF)
- Creation of new Bills of Materials (BOMs) and Device History Records (DHRs)
- Creation of new or revision of existing promotional materials
- Revision of catalogues
- Revision of product websites (internal and external)
- Creation of a new entry in the company’s enterprise management system (e.g., SAP)
- Revision of inventory management/forecasting models
- Creation of a new entry in the UDI database
- Notifications to all customers of the model change

The manufacturer would also have to ensure that the following activities are undertaken in an effort to obsolete the prior model, when inventories run out:

- Obsoleting of device labels and device label drawings
- Obsoleting or revision of existing devices labeling (e.g., directions for use, operator manuals, service manuals)
- Obsoleting of device drawings
- Obsoleting of device specifications (e.g., material specs, manufacturing specs, packaging material specs)
- Revision of existing Design History Files (DHF)
- Obsoleting of Bills of Materials (BOM)
- Obsoleting or revision of existing promotional materials
- Revision of product catalogues
- Revision of product websites (internal and external)
- Obsoleting of entry in the enterprise management system (e.g., SAP)
- Obsoleting of entry in the UDI database
- Notifications to all customers

The manufacturer will also have to manage the difficult and costly task of inventory depletion for each obsoleted model and inventory buildup for each added model.

In-patient and outpatient healthcare facilities, as well as nursing homes, surgical centers, doctors’ offices, dental offices, urgent care facilities, etc., would have to continuously understand which new models replace which old models, and update their order entry systems to remove obsoleted models and add new models. They would have to manage parallel inventories while both models coexist.

Finally, for regulatory registrations outside the US, additional, country-specific regulatory submissions would be required each time a model number changes, in each of over 15 countries.

We estimate that each model revision would require nearly 100 hours of recordkeeping and reporting across all the activities required to change a model.

We respectfully request that the burden of complying with proposed § 830.50 as currently written be added to the existing burden estimates.

B. The burden associated with proposed § 801.20(b), “Effective dates”

The burden associated with proposed § 801.20(b) does not appear to be included, since the preamble to the proposed rule makes no mention of the impact that retrospective implementation of the rule would have on products in manufacturers’ warehouses on the effective dates.
At any time, manufacturers may hold products within their distribution centers, at third party distributors, or on consignment with customers, that may have been manufactured days, months or years earlier, depending on the shelf life of the product.

Requiring that UDI requirements become effective on labels and packages of products which are in inventory on the effective date corresponding to their respective class, but were manufactured prior to the effective date, would result in the following:

a) Recall of products from consignment centers in order to implement UDI requirements
b) Rework of products in warehouses to comply with UDI requirements. Depending on the product configuration, this may entail breaking down multi-unit packaging and single-unit packaging to apply the corresponding UDIs, resulting in significant waste, cost, and delays in shipping products to customers

c) Rework of partial batches, as products in warehouses on the effective date do not usually represent full manufacturing batches/lots, because product may have already shipped out. Any rework of partial batches to conform to UDI requirements will effectively complicate future field actions as well as populate the GUDID with misleading information (partial manufacturing batch information that would not tie out to actual field action numbers). A manufacturer would then be able to rework full manufacturing batches only, and would have to dispose of or export partial batches, thus greatly increasing the possibility of US backorders and product shortages.

d) Limitations for class III devices. Class III medical devices are limited to re-work at sites that are approved in their corresponding PMAs. These products would have to be returned to a manufacturing location approved in their corresponding PMA, or supplemental applications for approval of the rework sites would have to be submitted and approved in order to allow the rework at the distribution centers.
This issue is particularly burdensome for class III products, which are required to be in compliance with the proposed rule within a year of publication of the final rule. Some elements of the proposed rule cannot be implemented ahead of publication of the final rule due to the cost of equipment and software modifications and upgrades should the final rule introduce new or different criteria than the proposed rule. One year will not be sufficient to implement all of the internal changes, to manufacture product that is compliant with the UDI requirements, and update the GUDID database by the effective date. We respectfully request that the burden of complying with proposed § 801.20(b) as currently written be added to the existing burden estimates.

We appreciate the opportunity to provide comments, and are available for further discussion should the Agency have questions.

Sincerely,

Jeffrey Secunda
Vice President, Technology and Regulatory Affairs
AdvaMed