April 19, 2013

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

Re: Docket No. FDA–2009–N–0458; RIN 0910–AG29: Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure

Dear Sir/Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, we are pleased to submit these comments in response to FDA’s supplemental notice of proposed rulemaking on the requirement for submission of information on pediatric subpopulations that suffer from a disease or condition that a device is intended to treat, diagnose or cure.

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 treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world. These 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 sales annually.

AdvaMed supports FDA’s proposed regulation relating to the submission of pediatric subpopulation information in PMAs, PMA supplements, PDPs and HDEs. AdvaMed would like to take this opportunity to thank FDA for developing draft guidance on providing information about pediatric uses of medical devices under § 515A of the Food and Drug Administration Amendments Act of 2007 (FDAAA) consistent with comments AdvaMed has submitted in the past on this topic. We believe the draft guidance will greatly assist companies to compile and submit readily available pediatric information as required under § 515A.
AdvaMed also wants to thank FDA for its recognition that the previous proposed rule and the companion direct final rule issued on April 1, 2010 on this topic were problematic by going beyond the statutory requirement of § 515A to require potential pediatric uses of medical devices in the amendments proposed to certain sections of Part 814. AdvaMed also thanks FDA for withdrawing the amendment proposed to § 814.2 and instead amending § 814.20(b)(13).

AdvaMed has only one specific comment and proposed amendment to § 814.39 of the proposed rule below.

**Specific Comment on 21 C.F.R. § 814.39**

*Proposed Change*

AdvaMed proposes that FDA require applicants to state whether each new PMA supplement relates to a new device and that PMA applicants provide the number of new devices approved under the PMA in the preceding year in the PMA annual report. To ease the administrative burden on FDA and applicants, we also suggest that PMA supplements filed subsequent to the initial submission of pediatric population information update this information only if there is new information readily available that results in a change in the identification of pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure, or the number of affected pediatric patients. Applicants would submit new information that does not change the pediatric subpopulation information in the PMA Annual Report (for example, new literature that reaffirms the original information).

**§ 814.39 PMA supplements.**

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(2) The supplement must include the following information:

(i) Information concerning pediatric uses as required under § 814.20(b)(13).

(ii) If information concerning the device that is the subject of the supplement was previously submitted under § 814.20(b)(13) or under this section in a previous supplement, the applicant is not required to resubmit the information, but may include the information by referring to the previous application or submission that contains the information. However, if additional information required under § 814.20(b)(13) has become readily available to the applicant since the previous submission, and that additional information changes the information required under § 814.20(b)(13), the applicant must submit that information as part of the supplement. Readily available additional information that does not change the information previously submitted may be included in the PMA annual report submitted under § 814.84(b).

(iii) Whether the supplement relates to a new device. The number of new devices approved by PMA supplement in a year shall be noted in the PMA annual report submitted under § 814.84(b) for that year.

**Rationale**

We note that 21 U.S.C. § 360e-1(a) entitled “New Devices” establishes annual reporting requirements for FDA under § 360e-1(a)(3). FDA is required to report “the number of devices approved in the year preceding the year in which the report is submitted, for which there is a
pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure.” Many, if not most PMA supplements, do not relate to a new device, but rather relate to changes to existing devices that have the potential to affect safety and effectiveness. For example, PMA supplements are required for changes in:

- Labeling (21 C.F.R. § 814.39(a)(2))
- Manufacturing facilities (21 C.F.R. § 814.39(a)(3))
- Sterilization procedures (21 C.F.R. § 814.39(a)(4))
- Packaging (21 C.F.R. § 814.39(a)(5))
- Performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device (21 C.F.R. § 814.39(a)(6))
- Expiration date (21 C.F.R. § 814.39(a)(7))

Thus, applicants may file many PMA supplements that do not relate to a new device. As a result, it may be administratively challenging for FDA to assess the number of devices approved from the number of PMA supplements filed in the preceding year. Accordingly, we propose that FDA require applicants to state whether each new PMA supplement relates to a new device, and that PMA applicants provide the number of new devices approved under the PMA in the preceding year in the PMA annual report. To ease the administrative burden on FDA and applicants, we also suggest that PMA supplements filed subsequent to the initial submission of pediatric population information update this information only if there is new information readily available that results in a change in the identification of pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure, or the number of affected pediatric patients. Applicants would submit new information that does not change the pediatric subpopulation information in the PMA Annual Report (for example, new literature that reaffirms the original information).

In closing, thank you for this opportunity to submit comments on the proposed rule on pediatric uses of devices. Please don’t hesitate to contact me if you have any questions.

Sincerely,

/s/
Tara Federici
Vice President
Technology and Regulatory Affairs