Guidance for Industry and FDA Staff

Pediatric Expertise for Advisory Panels

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Device Evaluation
Office of In Vitro Diagnostic Device Evaluation and Safety

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Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

The purpose of this guidance is to describe internal office procedures to ensure that an advisory panel reviewing a premarket submission or other regulatory documents includes or consults with one or more pediatric experts, when appropriate. These premarket submissions may include premarket approval applications (PMA) or premarket notification submissions (510(k)). These regulatory documents may include general or device-specific guidance documents.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/

Background

On October 26, 2002, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was signed into law. MDUFMA amended section 515(c) of the Federal, Food, Drug, and Cosmetic Act (the act), Application for Premarket Approval to read, in part: "Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts." This is one of several provisions in MDUFMA intended to promote the development of safe and effective pediatric devices and to protect this vulnerable patient population during the course of clinical trials involving such products. This guidance puts procedures in place to implement this new provision. A collateral guidance document, which we are currently developing, will address the other related provisions of MDUFMA.

Pediatric Populations

For purposes of this guidance, we are defining pediatric subpopulations as shown below.

Pediatric Subpopulation	Approximate Age Range
newborn	birth to 1 month of age
infant	1 month to 2 years of age
child	2 to 12 years of age
adolescent	12-21 years of age

Although the upper age limit used to define the pediatric population varies among experts, including adolescents up to the age of 21 is consistent with the definition found in several well-known sources.[1,2,3] The Center for Devices and Radiological Health (CDRH) believes this age range is generally appropriate for the use of medical devices in pediatric subpopulations, but recognizes that there may be cases in which the pediatric population should be defined differently, depending upon the type of device.

Circumstances Requiring Pediatric Expertise

Although MDUFMA amended the premarket approval section of the statute, CDRH will include pediatric expertise on an advisory panel, when appropriate, for all types of premarket submissions (i.e., PMA, product development protocol (PDP), 510(k), humanitarian device exemption (HDE), de novo applications, and investigational device exemption (IDE)). We will also include pediatric expertise on advisory panels when we seek panel recommendations for other documents, e.g., device-specific guidance documents, reclassification petitions. Therefore, the executive secretary of the panel, following consultation with the team leader and division management, should arrange for a pediatric expert to be consulted or included in panel deliberations for any of the above submissions or documents when:

- There are labeled indications for use that include a pediatric subpopulation or there is a reasonable likelihood that the device would be used in a pediatric subpopulation for the labeled indication;
- There are data in the study that include a pediatric subpopulation;
- There is a reasonable likelihood that the data from the study in the adult population may be used by the applicant to subsequently support a pediatric indication;
- There is a need for advisory panel input on a study design and/or protocol for use of the device in the pediatric population; or
- There is a reasonable likelihood that the advisory panel may discuss the potential use of the device in the pediatric population.

Advisory Panel Readiness

The Medical Device Advisory Committee will have a cadre of special government employees (SGEs) with pediatric expertise who have already been appointed to serve on one of its 18 advisory panels. In addition, CDRH may utilize pediatric expertise available on advisory committees of the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) The Office of the Director, Office of Device Evaluation (ODE) or Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD) will recruit individuals with pediatric expertise to serve as panel members or consultants through outreach efforts that will include contacting pediatric professional associations, current SGEs, and industry stakeholders.

Appointment of Pediatric Experts

For SGEs recruited for their pediatric expertise, as with all SGEs, the Center's Committee Management will complete the paperwork in accordance with the policies and procedures described in the Policy & Guidance Handbook for FDA Advisory Committees. (Although currently being revised, the previous version of this handbook is available from National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, 703-487-4650 (Order No. PB94-158854))

Team Leader Responsibilities

The review team leader will determine the need for pediatric expertise during panel deliberations by conferring with appropriate individuals in the review division and ODE/ OIVD management, as well as with the applicant and advisory panel members. If the team leader concludes that pediatric expertise is appropriate, (s)he will advise the executive secretary of the advisory panel that will review the premarket submission or regulatory document.

Executive Secretary Responsibilities

The executive secretary will ensure that pediatric expertise is available for the advisory panel deliberations.

Quality Control Measures

The availability of individuals with pediatric expertise will be monitored as a part of ODE's and OIVD's Performance Scorecards in the "Panel Readiness Index" measurement.

References

1. Berhman RE, Kliegman R, Arvin AM, Nelson WE. Nelson Textbook of Pediatrics, 15th Ed. Philadelphia: W.B. Saunders Company; 1996.

2. Rudolph AM, et al. Rudolph's Pediatrics, 21st Ed. New York: McGraw-Hill; 2002.

3. Avery MD, First LR. Pediatric Medicine, 2nd Ed. Baltimore: Williams & Wilkins; 1994.