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October 2, 2003

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

Docket No. 2003D-0319

Dear Sir or Madam:

Attached are comments from Respironics, Inc. regarding the Premarket Assessment of Pediatric Medical Devices Draft Guidance issued on July 24, 2003.

Please contact me if you require additional information.

Sincerely,

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Premarket Assessment of Pediatric Medical Devices Draft Guidance Document Comments from Respironics

1. **Page 2 Section II Objectives**
Issue or Concern:
Objective 1 should be separated into 3 distinct parts
Suggestion:
Separate Objective 1 into
   - To help define pediatric population
   - To help define pediatric use for medical devices
   - To present requirements for conducting pediatric device clinical

2. **Page 3, Section III, Table 1**
Issue or Concern:
Defining an adolescent to the age of 21.

   Although the reference sources 1, 2 and 3 used in the guidance set the upper age limit of adolescents to 21, in practice the upper limit can be from 16 to 18 years of age. In fact, the guidance "E11 Clinical Investigation of Medicinal Products in the Pediatric Population" referenced on page 13 last sentence lists adolescents from "(12 to 16-18 years (dependent on the region))".

   In Section IX, page 13 Protection for Pediatric Populations in Clinical Trails, 2nd paragraph, one justification is that in 21 CFR Part 50 Section 50.3(o) defines children as "persons who have not attained legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted. For the purposes of this guidance, the terms pediatric population and children are synonymous." If this definition is applied to FDA's age table, it appears that the terms are not synonymous.
Suggestion:
Subjects or patients over the age of 18 years should represent the maximum age for consideration as a pediatric patient. Further clarification is required in defining the age range for adolescents.

3. **Page 3, Section III, Table 1**
Issue or Concern:
Pre-adolescent should be added to Table 1
Suggestion:
Amend Table 1 as follows:
   - Change child to 2 to 10 years
   - Add pre-adolescent 10 to 14
   - Change Adolescent to 14 to 18 years

4. **Page 3, Section III, last paragraph**
Issue or Concern:
   - "Babies" was not included as a pediatric subgroup in Table 1
   - The presentation of weight guidelines is not consistent

Suggestion:

- Replace "babies" with "newborns"
- List weights in kilograms and grams for both categories

5. **Page 4, Section IV**
Issue or Concern:
The list of issues to consider does not address the primary location of use of the device such as the home or a monitored hospital ward. This is a critical factor to consider in the design and testing of a medical device.
Suggestion:
Add location of use as a factor to consider.

6. **Section VII a, pg. 12 Clinical Studies**
Issue or Concern:
Data from clinical trials will have a high probability of being misinterpreted or not comprehended by a typical pediatric patient or their parent or guardian. There is no benefit in presenting this information to pediatric patients or their parent or guardians.
Suggestion:
If it is presumed that the information described in this section can be understood by the typical health care provider, then the results of clinical studies data should be required only for those prescribing or managing the care of the patient using the device.

7. **Section VII a, pg. 12 Clinical Studies**
Issue or Concern:
The statement "Labeling should present these data using whatever qualitative and quantitative analyses are most appropriate...." is somewhat vague and is certainly open to interpretation.
Suggestion:
The guidance document should be more specific in the requirements for the presentation of data. Suggest revising the sentence to state "Labeling should summarize these data using the most appropriate qualitative or quantitative analyses..." It should not be necessary to present all data relevant to clinical study, and FDA would have the opportunity to review clinical data summaries during the premarket approval process.

8. **Section VII a, pg. 12 Instructions for Use**
Issue or Concern:
Any instructions provided specifically for the pediatric patient be age appropriate with respect to written language and other visual and auditory tools. Most device labeling will be instructions for safe and effective use targeted to the caregiver.
Suggestion:
Change the last sentence to state that "FDA recommends that labeling, provided for the use of devices for the pediatric patient, be written to provide the caregiver or device user with instructions for safe and effective use. Any instructions provided specifically for the pediatric patient be age appropriate with respect to written language and other visual and auditory tools."

9. **General Comment**
We would also like to add a comment that this guidance does not mention or refer to

either "least burdensome" principles under FDAMA, or the guidance for Early Collaboration Meetings. FDA does not commit in this guidance to working with industry or sponsors to develop the least burdensome approach to determining safety and efficacy for the pediatric population; and while we acknowledge that this population may be more vulnerable, the commitment on FDA's part to work with industry or the sponsor to determine, through meetings and under the "least burdensome" principle, is the best way to approach this population.