

Meeting Minutes
AAP/FDA
Pediatric Exclusivity Provisions of the FDA Modernization Act
February 11, 1998

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AAP Participants:

Elaine Holland
Bob Ward (via telephone)
Ralph Kauffman (via telephone)
Gail McCarver (via telephone)

FDA Participants:

Leanne Cusumano, Regulatory Policy Staff, CDER
Rosemary Roberts, M.D., Pediatric Subcommittee, CDER
Linda Carter, Office of Review Management, CDER
Elizabeth Dickinson, Office of the Chief Counsel, FDA
Ann Witt, Office of Policy, FDA
Murray Lumpkin, M.D., Deputy Director, CDER
Cecelia Parise, Office of Generic Drugs, CDER
Khyati Roberts, Executive Operations Staff, CDER

Type of Meeting: Information gathering meeting.

Meeting Chair: Murray Lumpkin

External Participant Lead: Elaine Holland

Meeting Recorder: Khyati Roberts

Meeting Objectives and Discussion: This meeting was scheduled to discuss the pediatric exclusivity provisions of the FDA Modernization Act (FDAMA). The goal was to hear the AAP's perspective on the FDAMA. The AAP's recommendations follow FDA's questions that are highlighted in bold.

List of Marketed Drugs

- AAP recommended that the list be comprehensive. By virtue of a drug being on the list, it should be considered a priority for being studied in children.
- It was difficult for the AAP to develop a list because they do not have access to the most recently approved labeling and they do not know the drugs that are currently in development.
- FDA stated that the list will be an evolving document.

- AAP noted that if the list is restrictive then you have the potential for leaving an important drug off the list.
- FDA plans on updating the list on a regular basis.
- The AAP recommended the list include the age group(s). There is a need to list drugs by therapeutic categories.
- The AAP noted that the greatest need for information is in the under 6 age group. This group lacks good information due to lack of proper formulation, low market profitability, and ongoing metabolic changes in this age group.

Criteria that should be used to place drugs on the list

- AAP recommended that a drug be placed on the list using the following criteria: severity, morbidity, mortality of condition for which drug is intended, documented or anticipated use in children, therapeutic index (e.g., risk of adverse effects), presence or absence of equivalent drug already available and labeled for children, and number of children impacted by drug.

Pediatric Advisory Committees

- AAP recommended the formation of a pediatric advisory committee to help implement the pediatric provisions.
- FDA informed the AAP that there is an Executive Order not to create new advisory committees. An alternative may be to place a pediatrician on each existing advisory committee. When needed, these pediatricians may be called together to form a subcommittee to address specific pediatric issues.

At what stage should the study be viewed as being completed?

- AAP recommended a study be deemed complete when the data submitted is reviewed, accepted, and there is sufficient information to support a labeling change. In addition, if a new formulation is needed, the completion of the study should include the development of the formulation.
- AAP raised the need to make available unfavorable or negative data yielded from studies. AAP suggested this information might be included in the data bank component section of FDAMA.

What should the “written request,” as used in Section 111(a) and (c), contain?

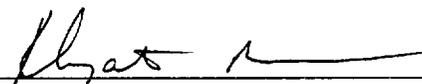
The AAP recommended that the written request FDA makes clearly define:

- scope of the studies requested
- age groups that need to be studied
- type of prior data that would be acceptable
- number of children/percentage of completion rate for each study
- type of study
- size and number of any additional studies
- time frame for completing studies
- location of trial sites
- formulation development, when needed
- scope and content of report
- analysis of published information

What are “commonly accepted scientific principles and protocols” as used in Section 111(d)(3)?

- The AAP views “commonly accepted scientific principles and protocols” as all existing GCP and GLP standards as well as current regulatory standards for studies intended to support approval of applications.

Attachments: February 2, 1998, letter from AAP to Michael A. Friedman, Lead Deputy Commissioner, FDA and March 11, 1998, letter from AAP to Murray Lumpkin, Deputy Center Director, CDER



Khyati Roberts
Meeting Recorder



Murray Lumpkin,
Chair