



May 16, 2000

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Re: Docket No. 00D-1223;
Response to Request for Comments

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Sir/Madam:

Reference is made to the April 12, 2000 Federal Register notice (65 FR 19777) requesting comments on the FDA's draft guidance entitled "E11: Clinical Investigations of Medicinal Products in the Pediatric Population," prepared under the auspices of the International Conference on Harmonisation.

Warner Lambert Company offers the following 2 comments on this draft guidance. The suggested deletions are shown in strikethrough, additions are provided in italics, and our rationale for the suggested revision follows.

1. Section 2.3.2. Medicinal Products Intended to Treat Serious or Life-Threatening Diseases for Which There Are Currently No or Limited Therapeutic Options

The second sentence reads: "Pediatric study results should be part of the marketing application data base." We suggest that this be revised to read "~~Pediatric study results~~ *Data from pediatric patients participating in clinical trials* should be part of the marketing application data base."

This revision reflects that separate studies in pediatric patients are not necessarily required. Rather, with the concurrence of the FDA reviewing division, pediatric patients may be included in adult studies, especially adult safety and efficacy studies.

2. Section 2.6. Ethical Issues in Pediatric Studies

Paragraph two, the second sentence reads: "In addition, participants in clinical studies are expected to obtain some direct or indirect benefit from the clinical study except under the special circumstances discussed in ICH E6..." (the special circumstances in Section 4.8.14 in E6 refer to non-therapeutic trials). We suggest that this be revised to read "In addition, participants in clinical studies are *reasonably* expected to obtain some direct or indirect benefit from the clinical study except under the special circumstances discussed in ICH E6 (Good Clinical Practice, section 4.8.14)."

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“Expected” seems too strong and may sound like a guarantee. This wording is probably intended to encourage the use of pediatric patients rather than healthy pediatric subjects. However, even though one would have reason to think that a pediatric patient may benefit directly from the investigational agent, or at least indirectly from the clinical visits associated with the trial, this is by no means certain for all patients even after proof of concept has been established and some safety data is available. Indeed, an individual patient may (only) suffer injury, even if the whole community benefits from that patient’s experience (as noted in 2.6.4). ICH E6, Section 4.8.10(h), notes that the consent form should refer to *reasonably* expected benefits when there are intended clinical benefits in the trial. This would allow the caveat of reasonableness, and as it is part of the ICH E6 GCP guidance for therapeutic trials, we suggest that “reasonably” be added into this guidance as well.

Thank you for the opportunity to comment on this draft guidance. If you have any questions please contact me by phone at 734/622-7426.

Sincerely,



Janeth L. Turner
Director
Worldwide Regulatory Affairs

JT:kb
05-16-2000\General Correspondence

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