NIH Comments

OPRR has reviewed the proposed FDA Federal Register notice that you sent to OPRR for clearance (#169855).

The proposed notice omits definitions of key terms. These definitions would appear to be required, if FDA is to stimulate and receive meaningful public comment on its proposal (including comment on the proposed definitions).

In OPRR's view, use of the term "permanently disabling" in the proposed rule requires definition. It may be that this term is defined elsewhere in Title 21 of the Code of Federal Regulations. If that is the case, then importation of that definition into 21 CFR 314, or reference to that definition, will suffice.

It is arguable that use of the term "lethal" in the proposed rule also requires definition. OPRR's concern about defining "lethal" actually arises from the language of this FDA notice itself. Despite the use of "lethal" in the proposed rule on page 28-29, FDA references on page 13 its tentative conclusion about "...potentially lethal..." substances. Perhaps, use of the word "potentially" on page 13 is unintended, and it should be deleted.

OPRR's substantive concern is that an overestimate of the potential for lethality or permanent disability of exposure to toxic biological, chemical, radiological, or nuclear substances, may lead to marketing of a biological product that could have and should have been put through human testing prior to use in humans. In order to delimit estimates of the potential for lethality or permanent disability of exposure to toxic biological, chemical, radiological, or nuclear substances, OPRR recommends that FDA (i) clarify its intent on "potentially lethal" versus "lethal" with inclusion of a proposed definition, as appropriate, and (ii) include a proposed definition of "permanently disabling."

OPRR appreciates the opportunity to comment.

Gary B. Ellis, Ph.D.
Director, Office for Protection from Research Risks
National Institutes of Health
301-435-5646 Phone
301-402-2071 FAX

98N-0237

C4