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Orphan drugs list is available from...

Orphan drugs and biologicals

Cumulative list available

A cumulative list, updated 31 December 1999, of designated orphan drugs and biologicals is now available from the FDA[1]. Copies of the list may be obtained from the Dockets Management Branch (HFA-305), FDA and the Office of Orphan Products Development (HF-35), FDA, 5600 Fishers Lane, Rockville, MD 20857, USA (tel: + 1 301 827 3666).

References

1. *Federal Register*, 2000, **65**(41), 11066.

Informed consent

Exemption for emergency research: draft guidance

Comments are required by 30 May 2000

The FDA is soliciting comments on the draft *Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: [on] Exception from [the] Informed Consent Requirements for Emergency Use*[1]. The deadline for submission of written comments to the FDA's Dockets Management Branch (HFA-305) is 30 May 2000.

Copies of the draft guidance document may be obtained from the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, FDA, 5600 Fishers Lane, Rockville, MD 20857, USA or from the Internet at http://www.fda.gov/ora/compliance. For further information, contact Bonnie M Lee, Division of Compliance Policy (HFC-230), Office of Enforcement (*see above* for address) (tel: +1 301 827 0415).

Regulatory comment

This document[1] provides Institutional Review Boards, product sponsors, and clinical investigators with guidance for implementing regulations on exemption from informed consent as described in the CFR[2]. To qualify for this exemption, the emergency research must meet several requirements:

Criteria to qualify for the exemption are given

- the human subjects need to be in life-threatening situations;
- appropriate human subjects cannot be identified in advance;
- subjects are incapable of giving their informed consent as a result of their emergency clinical situation, and are similarly incapable of refusing enrolment into the research protocol;
- other available treatments are unsatisfactory;
- the risks and potential benefits of the experimental protocol are reasonable in relation to the known risks of the underlying medical condition and the risks and benefits of existing standard therapies;
- participation in the experimental research must provide the prospect of direct clinical benefit to the patient; *and*
- obtaining informed consent is not feasible within a limited therapeutic time frame (that is, further attempts to obtain informed consent would delay therapy beyond the period within which it could reasonably provide benefit to the patient).

The guidance document discusses ways to implement this exemption while ensuring that the interests of the research population are protected as much as possible. At the centre of the issue is the vulnerability of the individual subject because of the inability to refuse participation in the research. Such vulnerability is especially acute when considering that certain specific subjects would be fully expected to refuse treatment on the basis of religious or other beliefs. Since by definition it is not feasible to obtain permission for participation in the emergency research protocol from the patient or a legal representative, it becomes particularly important that an effective dialogue be established between the research sponsors and the at-risk community. Much of this guidance document is directed at discussions of methods to involve the public prior to initiation of the protocol: community input into protocol development, public disclosures, methods for open discussion in public fora, and methods to identify potential subjects likely to refuse participation if afforded the opportunity. Also discussed is the tricky balance between public disclosure of study results while avoiding promotional suggestions of the product's effectiveness or safety.

ROBERT I ROTH

References

1. *Federal Register*, 2000, **65**(62), 16923.
2. Exception from Informed Consent Requirements for Emergency Research, 21 CFR Part 50.24.