ECETOC Document

No 4

Non-Clinical Laboratory Studies: Amendment of Good Laboratory Practice Regulations

December 1979

ECETOC DOC-4

28.12.79.

TO THE

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

EUROPEAN CHEMICAL INDUSTRY ECOLOGY AND TOXICOLOGY CENTRE

(ECETOC)

ON

NON-CLINICAL LABORATORY STUDIES : AMENDMENT OF GOOD LABORATORY PRACTICE REGULATIONS

21 CFR, Part 58
44 Federal Register,
69666 - 69668
(Dec. 4, 1979)

Docket N° 76 N - 0400

L. Turner
Executive Secretary
ECETOC
Avenue Louise 250, B 63
B - 1050 Brussels
Belgium

DRAFT December 28, 1979

Pursuant to the instructions given in the Federal Register of 4 December, 1979 page 69666, please accept written comments from ECETOC on the Food and Drug Administration's proposed Amendment of Good Laboratory Practice Regulations which were published in the Federal Register on December 4, 1979, pages 69666 - 69668.

The European Chemical Industry Ecology and Toxicology Centre (ECETOC) is a non-profit making international association of 40 companies who operate in West Europe, and are engaged in the industrial manufacture of chemicals, and research in this field.

ECETOC was formed to :

a) procure all types of information relevant to the protection of the health of any person who may come into contact with chemicals and to reduce the ecological impact of the manufacture, processing and use of chemicals.

b) coordinate efforts by chemical manufacturers to study and attempt to resolve the ecological and toxicological problems which may result from the manufacture, processing and use of chemicals.

c) cooperate in a scientific context with government, health authorities and all other public institutions concerned with ecological and toxicological problems relating to chemicals.

Commercial questions are excluded from the objectives and concerns of the Centre.

Members of ECETOC have a vital interest in the promulgation of good practicable GLP standards. ECETOC therefore appointed a group of responsible practicing scientists from member companies to draw up a set of GLP recommendations based on their experience and ability.

Among the criteria which the group listed as necessary for effective GLP proposals* were the following :

a) They must be effective in the basic aim of ensuring the quality and integrity of test data.

b) They must be necessary and sufficient, ie. detailed enough to be unambiguous and achieve their purpose, but not so over-detailed and constrictive as to prevent the full deployment of scientific initiative, experience, expertise and judgement.

./.

* See attached monograph.

c) They must not add unnecessarily to the cost and administrative burden on those responsible for testing, and should impose the minimum of non-productive, bureaucratic work on trained personnel and management.

ECETOC COMMENTS ON FDA PROPOSAL

In the GLP proposals put forward by ECETOC we did not include a requirement to retain reserve samples of substance with carrier.

ECETOC therefore strongly supports the present FDA proposal. We believe that to revoke the requirement to retain reserve samples of test or control article-carrier mixtures will not lower the quality or integrity of test data, and we support the reasoning given by the petitioners as set out in col.2 of page 69667 of the Federal Register.

The petioners quote,from FDA's GLP regulations, a number of other provisions which in our view are necessary and sufficient to achieve the purpose of GLP without the storage of reserve samples which we consider to be over-detailed and an unnecessary cost and administrative burden.

Finally, we express our appreciation of the fact that the FDA has responded to the presentation of factual evidence from practising scientists by proposing the modification in question.