

and address areas of concern, all the while with an eye to the goal of improving human health.

APPENDIX

WEBSITES OF INTEREST

ICH: <http://www.ich.org/>

EC: <http://pharmacos.eudra.org/>

EMA: <http://www.emea.eu.int/>

EFPIA: <http://www.efpia.org/>

MHLW: <http://www.mhlw.go.jp/english/>

JPMA: <http://www.jpma.or.jp/12english/>

FDA: <http://www.fda.gov/>

FDA CDER Guidance Documents: <http://www.fda.gov/cder/guidance/index.htm>

FDA CBER Guidance Documents: <http://www.fda.gov/cber/guidelines.htm>

FDA Redbook 2000: <http://www.cfsan.fda.gov/~redbook/red-toca.html>

Federal Register Online: http://www.access.gpo.gov/su_docs/aces/aces140.html

PhRMA: <http://www.phrma.org/>

IFPMA: <http://www.ifpma.org/>

WHO: <http://www.who.int/en/>

EFTA: <http://secretariat.efta.int/>

TPD: <http://www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/index.html>

Medicines Control Agency (MCA) of the United Kingdom Department of Health: <http://www.mca.gov.uk/>

Therapeutic Goods Administration (TGA) of the Australian Department of Health and Ageing: <http://www.health.gov.au/tga/index.htm>

REFERENCES

1. Food and Drug Administration (FDA). Single Dose Acute Toxicity Testing for Pharmaceuticals. Fed. Reg. Vol. 61. August 26, 1996:43934-43935.
2. ICH Topic S4A Document "Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)." Step 4 reached September 2, 1998.
3. ICH Topic M3 Document "Non-clinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals." Step 4 reached July 16, 1997.
4. Food and Drug Administration (FDA). Code of Federal Regulations (CFR) Parts 312 and 314. Final Rule: Investigational New Drug Applications and New Drug Applications. February 11, 1998.