Subpart H—Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses

314.500 Scope.
314.510 Approval based on a surrogate endpoint or on an effect on a clinical endpoint other than survival or irreversible morbidity.
314.520 Approval with restrictions to assure safe use.
314.530 Withdrawal procedures.
314.540 Postmarketing safety reporting.
314.550 Promotional materials.
314.560 Termination of requirements.

Subpart I—Approval of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

314.600 Scope.
314.610 Approval based on evidence of effectiveness from studies in animals.
314.620 Withdrawal procedures.
314.630 Postmarketing safety reporting.
314.640 Promotional materials.
314.650 Termination of requirements.


SOURCE: 50 FR 7493, Feb. 22, 1985, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 314 can be found at 69 FR 13717, Mar. 24, 2004.